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EUROPEAN COMMUNITIES – MEASURES AFFECTING THE APPROVAL AND MARKETING OF BIOTECH PRODUCTS

Reports of the Panel

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Argentina – Textiles and Apparel	Panel Report, *Argentina – Measures Affecting Imports of Footwear, Textiles, Apparel and Other Items*, WT/DS56/R, adopted 22 April 1998, as modified by Appellate Body Report, WT/DS56/AB/R, DSR 1998:III, 1033
Australia – Salmon	Appellate Body Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/AB/R, adopted 6 November 1998, DSR 1998:VIII, 3327
Australia – Salmon	Panel Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/R and Corr.1, adopted 6 November 1998, as modified by the Appellate Body Report, WT/DS18/AB/R, DSR 1998:VIII, 3407
Brazil – Desiccated Coconut	Appellate Body Report, *Brazil – Measures Affecting Desiccated Coconut*, WT/DS22/AB/R, adopted 20 March 1997, DSR 1997:I, 167
Canada – Wheat Exports and Grain Imports	Appellate Body Report, *Canada – Measures Relating to Exports of Wheat and Treatment of Imported Grain*, WT/DS276/AB/R, adopted 27 September 2004
Canada – Wheat Exports and Grain Imports	Panel Report, *Canada – Measures Relating to Exports of Wheat and Treatment of Imported Grain*, WT/DS276/R, adopted 27 September 2004, as upheld by the Appellate Body Report, WT/DS276/AB/R
Chile – Alcoholic Beverages	Appellate Body Report, *Chile – Taxes on Alcoholic Beverages*, WT/DS87/AB/R, WT/DS110/AB/R, adopted 12 January 2000, DSR 2000:I, 281
Chile – Price Band System	Appellate Body Report, *Chile – Price Band System and Safeguard Measures Relating to Certain Agricultural Products*, WT/DS207/AB/R, adopted 23 October 2002, DSR 2002:VIII, 3045
Chile – Price Band System	Panel Report, *Chile – Price Band System and Safeguard Measures Relating to Certain Agricultural Products*, WT/DS207/R, adopted 23 October 2002, as modified by Appellate Body Report, WT/DS207AB/R, DSR 2002:VIII, 3127
Dominican Republic – Import and Sale of Cigarettes	Appellate Body Report, *Dominican Republic – Measures Affecting the Importation and Internal Sale of Cigarettes*, WT/DS302/AB/R, adopted 19 May 2005
Dominican Republic – Import and Sale of Cigarettes	Panel Report, *Dominican Republic – Measures Affecting the Importation and Internal Sale of Cigarettes*, WT/DS302/R, adopted 19 May 2005, as modified by Appellate Body Report, WT/DS302/AB/R
EC – Asbestos	Appellate Body Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/AB/R, adopted 5 April 2001, DSR 2001:VII, 3243
EC – Asbestos	Panel Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/R and Add.1, adopted 5 April 2001, as modified by Appellate Body Report, WT/DS135/AB/R, DSR 2001:VIII, 3305
EC – Bananas III	Appellate Body Report, *European Communities – Regime for the Importation, Sale and Distribution of Bananas*, WT/DS27/AB/R, adopted 25 September 1997, DSR 1997:II, 591
EC – Bed Linen	Appellate Body Report, *European Communities – Anti-Dumping Duties on Imports of Cotton-Type Bed Linen from India*, WT/DS141/AB/R, adopted 12 March 2001, DSR 2001:V, 2049
EC – Bed Linen	Panel Report, *European Communities – Anti-Dumping Duties on Imports of Cotton-Type Bed Linen from India*, WT/DS141/R, adopted 12 March 2001, as modified by the Appellate Body Report, WT/DS141/AB/R, DSR 2001:VI, 2077
EC – Chicken Cuts	Appellate Body Report, *European Communities – Customs Classification of Frozen Boneless Chicken Cuts*, WT/DS269/AB/R, WT/DS286/AB/R, adopted 27 September 2005
EC – Commercial Vessels	Panel Report, *European Communities – Measures Affecting Trade in Commercial Vessels*, WT/DS301/R, adopted 20 June 2005
EC – Computer Equipment	Appellate Body Report, *European Communities – Customs Classification of Certain Computer Equipment*, WT/DS62/AB/R, WT/DS67/AB/R, WT/DS68/AB/R, adopted 22 June 1998, DSR 1998:V, 1851

Short Title	Full Case Title and Citation
EC – Hormones	Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, DSR 1998:I, 135
EC – Hormones (Canada)	Panel Report, *EC Measures Concerning Meat and Meat Products (Hormones) – Complaint by Canada*, WT/DS48/R/CAN, adopted 13 February 1998, as modified by the Appellate Body Report, WT/DS26/AB/R, WT/DS48/AB/R, DSR 1998:II, 235
EC – Hormones (US)	Panel Report, *EC Measures Concerning Meat and Meat Products (Hormones) – Complaint by the United States*, WT/DS26/R/USA, adopted 13 February 1998, as modified by the Appellate Body Report, WT/DS26/AB/R, WT/DS48/AB/R, DSR 1998:III, 699
EC – Sardines	Appellate Body Report, *European Communities – Trade Description of Sardines*, WT/DS231/AB/R, adopted 23 October 2002
EC – Tariff Preferences	Appellate Body Report, *European Communities – Conditions for the Granting of Tariff Preferences to Developing Countries*, WT/DS246/AB/R, adopted 20 April 2004
Guatemala – Cement I	Appellate Body Report, *Guatemala – Anti-Dumping Investigation Regarding Portland Cement from Mexico*, WT/DS60/AB/R, adopted 25 November 1998, DSR 1998:IX, 3767
India – Autos	Panel Report, *India – Measures Affecting the Automotive Sector*, WT/DS146/R, WT/DS175/R and Corr.1, adopted 5 April 2002
India – Patents (US)	Appellate Body Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R, adopted 16 January 1998, DSR 1998:I, 9
Indonesia – Autos	Panel Report, *Indonesia – Certain Measures Affecting the Automobile Industry*, WT/DS54/R, WT/DS55/R, WT/DS59/R, WT/DS64/R and Corr.1, 2, 3, and 4, adopted 23 July 1998, DSR 1998:VI, 2201
Japan – Agricultural Products II	Appellate Body Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/AB/R, adopted 19 March 1999, DSR 1999:I, 277
Japan – Agricultural Products II	Panel Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/R, adopted 19 March 1999, as modified by the Appellate Body Report, WT/DS76/AB/R, DSR 1999:I, 315
Japan – Alcoholic Beverages II	Appellate Body Report, *Japan – Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, adopted 1 November 1996, DSR 1996:I, 97
Japan – Apples	Appellate Body Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/AB/R, adopted 10 December 2003, DSR 2003:IX, 4391
Japan – Apples	Panel Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/R, adopted 10 December 2003, as upheld by the Appellate Body Report, WT/DS245/AB/R, DSR 2003:IX, 4481
Japan – Semi-Conductors	GATT Panel Report, *Japan – Trade in Semi-Conductors*, adopted 4 May 1988, BISD 35S/116
Korea – Dairy	Appellate Body Report, *Korea – Definitive Safeguard Measure on Imports of Certain Dairy Products*, WT/DS98/AB/R, adopted 12 January 2000, DSR 2000:I, 3
Korea – Dairy	Panel Report, *Korea – Definitive Safeguard Measure on Imports of Certain Dairy Products*, WT/DS98/R and Corr.1, adopted 12 January 2000, as modified by Appellate Body Report, WT/DS98/AB/R, DSR 2000:I, 49.
Mexico – Corn Syrup	Panel Report, *Mexico – Anti-Dumping Investigation of High Fructose Corn Syrup (HFCS) from the United States*, WT/DS132/R and Corr.1, adopted 24 February 2000, DSR 2000:III, 1345
Mexico – Corn Syrup (Article 21.5 – US)	Appellate Body Report, *Mexico – Anti-Dumping Investigation of High Fructose Corn Syrup (HFCS) from the United States – Recourse to Article 21.5 of the DSU by the United States*, WT/DS132/AB/RW, adopted 21 November 2001, DSR 2001:XIII, 6675

Short Title	Full Case Title and Citation
Thailand – H-Beams	Appellate Body Report, *Thailand – Anti-Dumping Duties on Angles, Shapes and Sections of Iron or Non-Alloy Steel and H-Beams from Poland*, WT/DS122/AB/R, adopted 5 April 2001, DSR 2001:VII, 2701
US – Carbon Steel	Appellate Body Report, *United States – Countervailing Duties on Certain Corrosion-Resistant Carbon Steel Flat Products from Germany*, WT/DS213/AB/R and Corr.1, adopted 19 December 2002
US – Carbon Steel	Panel Report, *United States – Countervailing Duties on Certain Corrosion-Resistant Carbon Steel Flat Products from Germany*, WT/DS213/R and Corr.1, adopted 19 December 2002, as modified by the Appellate Body Report, WT/DS213/AB/R
US – Certain EC Products	Appellate Body Report, *United States – Import Measures on Certain Products from the European Communities*, WT/DS165/AB/R, adopted 10 January 2001, DSR 2001:I, 373
US – Certain EC Products	Panel Report, *United States – Import Measures on Certain Products from the European Communities*, WT/DS165/R and Add.1, adopted 10 January 2001, as modified by Appellate Body Report, WT/DS165/AB/R, DSR 2001:II, 413
US – Corrosion-Resistant Steel Sunset Review	Appellate Body Report, *United States – Sunset Review of Anti-Dumping Duties on Corrosion-Resistant Carbon Steel Flat Products from Japan*, WT/DS244/AB/R, adopted 9 January 2004
US – Corrosion-Resistant Steel Sunset Review	Panel Report, *United States – Sunset Review of Anti-Dumping Duties on Corrosion-Resistant Carbon Steel Flat Products from Japan*, WT/DS244/R, adopted 9 January 2004, as modified by the Appellate Body Report, WTDS244/AB/R
US – Cotton Yarn	Appellate Body Report, *United States – Transitional Safeguard Measure on Combed Cotton Yarn from Pakistan*, WT/DS192/AB/R, adopted 5 November 2001, DSR 2001:XII, 6027
US – Export Restraints	Panel Report, *United States – Measures Treating Exports Restraints as Subsidies*, WT/DS194/R and Corr.2, adopted 23 August 2001, DSR 2001:XI, 5767
US – FSC	Appellate Body Report, *United States – Tax Treatment for "Foreign Sales Corporations"*, WT/DS108/AB/R, adopted 20 March 2000, DSR 2000:III, 1619
US – FSC (Article 21.5 – EC)	Appellate Body Report, *United States – Tax Treatment for "Foreign Sales Corporations" – Recourse to Article 21.5 of the DSU by the European Communities*, WT/DS108/AB/RW, adopted 29 January 2002
US – Gambling	Appellate Body Report, *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, WT/DS285/AB/R, adopted 20 April 2005
US – Gasoline	Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, adopted 20 May 1996, DSR 1996:I, 3
US – Gasoline	Panel Report, *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/R, adopted 20 May 1996, as modified by Appellate Body Report, WT/DS2/AB/R, DSR 1996:I, 29
US – Lamb	Appellate Body Report, *United States – Safeguard Measures on Imports of Fresh, Chilled or Frozen Lamb Meat from New Zealand and Australia*, WT/DS177/AB/R, WT/DS178/AB/R, adopted 16 May 2001, DSR 2001:IX, 4051
US – Offset Act (Byrd Amendment)	Appellate Body Report, *United States – Continued Dumping and Subsidy Offset Act of 2000*, WT/DS217/AB/R, WT/DS234/AB/R, adopted 27 January 2003
US – Section 211 Appropriations Act	Appellate Body Report, *United States – Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/AB/R, adopted 1 February 2002, DSR 2002:II, 589
US – Shrimp	Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, adopted 6 November 1998, DSR 1998:VII, 2755
US – Steel Plate	Panel Report, *United States – Anti-Dumping and Countervailing Measures on Steel Plate from India*, WT/DS206/R and Corr.1, adopted 29 July 2002

Short Title	Full Case Title and Citation
US – Steel Safeguards	Panel Reports, *United States – Definitive Safeguard Measures on Imports of Certain Steel Products*, WT/DS248, WT/DS249, WT/DS251, WT/DS252, WT/DS253, WT/DS254, WT/DS258, WT/DS259, adopted 10 December 2003, as modified by Appellate Body Report, WT/DS248AB/R, WT/DS249AB/R, WT/DS251AB/R, WT/DS252AB/R, WT/DS253AB/R, WT/DS254AB/R, WT/DS258AB/R, WT/DS259AB/R, DSR 2003:VIII, 3271
US – Upland Cotton	Appellate Body Report, *United States – Subsidies on Upland Cotton*, WT/DS267/AB/R, adopted 21 March 2005
US – Wool Shirts and Blouses	Appellate Body Report, *United States – Measure Affecting Imports of Woven Wool Shirts and Blouses from India*, WT/DS33/AB/R and Corr.1, adopted 23 May 1997, DSR 1997:I, 323

LIST OF ABBREVIATIONS

ARMG	Antibiotic resistance marker genes
At.	Attachment
Bt	*Bacillus thuringiensis*
CA	Competent authority
CBD	Convention on Biological Diversity
Commission	European Commission
Council	European Council of Ministers
DNA	Deoxyribonucleic acid
DSB	Dispute Settlement Body
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes
EC	European Communities
ECJ	European Court of Justice
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GATT 1994	*General Agreement on Tariffs and Trade 1994*
GM	Genetically modified
GMHT	Genetically modified and herbicide tolerant
GMOs	Genetically modified organisms
IPPC	*International Plant Protection Convention*
ISPM	International Standard for Phytosanitary Measures
LMOs	Living modified organisms

OECD	Organisation for Economic Cooperation and Development
OIE	World Organization for Animal Health
SCF	EC Scientific Committee on Food
SCP	EC Scientific Committee on Plants
SNIF	Summary Notification Information Form
SPS	Sanitary and phytosanitary
SPS Agreement	*Agreement on the Application of Sanitary and Phytosanitary Measures*
TBT Agreement	*Agreement on Technical Barriers to Trade*
UNEP	United Nations Environmental Programme
US	United States of America
WHO	World Health Organisation

SHORT AND FULL TITLES OF PRODUCTS

Short title of product (in alphabetical order)	Full Title of Product and EC Exhibit number
COTTON	
Bt-531 cotton	*Monsanto Bt cotton (531)* *C/ES/96//02 (EC chronology 65)*
BXN cotton	*Stoneville BXN cotton (10215, 10222, 10224)* *C/ES/99/01 (EC chronology 73)*
RR-1445 cotton	*Monsanto Roundup Ready cotton (RRC1445)* *C/ES/97/01 (EC chronology 66)*
MAIZE	
Bt-11 maize (EC-69)	*Syngenta glufosinate tolerant and Bt resistant (Bt-11) maize* *C/F/96/05-10 (EC chronology 69)*
Bt-11 maize (EC-80)	*Syngenta Bt-11 maize* *C/ES/98/02 (EC chronology 80)*
Bt-11 maize (EC-163)	*Bt-11 maize* C/GB/96/M4/1 *(EC chronology 163)*
Bt-11 sweet maize (food)	*Syngenta Bt-11 sweet maize* *(EC chronology 92)*
Bt-176 maize	*Bt 176 maize (Ciba Geigy, now Syngenta Seeds)* C/F/94/11-03 *(EC chronology 158)*
Bt-1507 maize (EC-74)	*Pioneer/Dow AgroSciences Bt maize Cry1F (1507)* *C/NL/00/10 (EC chronology 74)*
Bt-1507 maize (EC-75)	*Pioneer/Dow AgroSciences Bt maize Cry1F (1507)* *C/ES/01/01(EC chronology 75)*
Bt-1507 maize (food)	*Pioneer/Dow AgroSciences Bt maize Cry1F (1507)* *(EC chronology 95)*
GA21 maize (EC-78)	*Monsanto Roundup Ready maize(GA21)* *C/ES/98/01 (EC Chronology 78)*
GA21 maize (EC-85)	*Monsanto Roundup Ready maize(GA21)* *C/GB/97/M3/2 (EC Chronology 85)*
GA21 maize (food)	*Monsanto Roundup Ready maize(GA21)* *(EC Chronology 91)*
MON809 maize	*Pioneer Bt maize (MON809)* *C/F/95/12-01/B (EC chronology 83)*
MON809 maize (food)	*Monsanto 809 maize* *C/F/95/12-01/B (EC chronology 157)*
MON810 maize	*Monsanto 810 maize* C/F/95/12-02 *(EC chronology 159)*

Short title of product (in alphabetical order)	**Full Title of Product and EC Exhibit number**
MON810 x GA21 maize	*Monsanto MaisGard & Roundup Ready (MON810 & GA21) maize (stack)* *C/ES/99/02 (EC chronology 82)*
MON810 x GA21 maize (food)	*Monsanto MaisGard & Roundup Ready (MON810 & GA21) maize (stack)* *(EC Chronology 94)*
NK603 maize	*Monsanto Roundup Ready maize (NK603)* *C/ES/00/01 (EC Chronology 76)*
NK603 maize (food)	*Monsanto Roundup Ready maize (NK603)* *(EC Chronology 96)*
T14 maize	*Agrevo maize T14 maize* C/F/96/06/12 *(EC Chronology 156)*
T25 maize	*T25 maize (AgrEvo, then Aventis Cropscience)* C/F/95/12-07 *(EC chronology 160)*
T25 x MON810 maize	*Pioneer Liberty Link and Bt (T25 and MON810) maize* *C/NL/98/08 (EC chronology 86)*
T25 x MON810 maize (food)	*Pioneer Liberty Link and Bt (T25 and MON810) maize* *(EC chronology 101)*
OILSEED RAPE	
Falcon oilseed rape	*Bayer oilseed rape (Falcon GS40/90)* *C/DE/96/05 (EC Chronology 62)*
Liberator oilseed rape	*Bayer winter oilseed rape(Liberator pHoe6/Ac)* *C/D/98/06 (EC Chronology 68)*
LL oilseed rape	*Bayer Liberty Link oilseed rape (T45 & Topas 19/2)* *C/GB/99/M5/2 (EC chronology 72)*
MS1/RF1 oilseed rape (EC-89)	*Bayer oilseed rape (MS1/RF1)* *C/F/95/01A (EC chronology 89)*
MS1/RF1 oilseed rape (EC-161)	*Bayer oilseed rape (MS1/RF1)* C/UK/94/M1/1 *(EC chronology 161)*
MS1/RF2 oilseed rape	*Bayer oilseed rape (MS1/RF2)* *C/F/95/01B (EC chronology 90)*
MS8/RF3 oilseed rape	*Bayer hybrid oilseed rape (MS8/RF3)* *C/BE/96/01 (EC Chronology 63)*
RR oilseed rape (EC-70)	*Monsanto Roundup Ready oilseed rape(GT73)* *C/NL/98/11 (EC Chronology 70)*
RR oilseed rape (EC-79)	*Monsanto Roundup Ready oilseed rape(GT73)* *C/F/9506/011 (EC Chronology 79)*

Short title of product (in alphabetical order)	**Full Title of Product and EC Exhibit number**
Topas oilseed rape	*Oilseed Rape Topas 19/2 (AgrEvo)* C/UK/95/M5/1 *(EC chronology 162)*
SOYBEANS	
High-oleic soybeans	*Pioneer/Dupont high-oleic soybeans (260-05)* *C/NL/98/09 (EC chronology 87)*
High-oleic soybeans (food)	*Pioneer/Dupont high-oleic soybeans (260-05)* *(EC chronology 99)*
LL soybeans (EC-71)	*Bayer Liberty Link soybeans (A2704-12 and A5547-127)* *C/BE/98/01 (EC chronology 71)*
LL soybeans (EC-81)	*Bayer Liberty Link soybeans (A2704-12 and A5547-127)* *C/PT/99/01 (EC chronology 81)*
LL soybeans (food)	*Bayer Liberty Link soybeans (A2704-12 and A5547-127)* *(EC chronology 93)*
MON soybeans	*Monsanto herbicide-resistant soybeans* *C/UK/94/M3/1*
OTHER	
BXN tobacco	*SEITA Tobacco tolerant to bromoxynil* *C/F/93/08-02*
RR fodder beet	*Trifolium/Monsanto/Danisco Roundup Ready fodder beet (A5/15)* *C/DK/97/01 (EC chronology 64)*
RR sugar beet	*Monsanto/Syngenta Roundup Ready sugar beet (77)* *C/BE/99/01 (EC chronology 88)*
RR sugar beet (food)	*Monsanto/Syngenta Roundup Ready sugar beet (77)* *(EC chronology 102)*
Transgenic green-hearted chicory	*Bejo-Zaden* Green hearted chicory *C/NL/96/05 (EC chronology 110)*
Transgenic green-hearted chicory (food)	*Bejo-Zaden Transgenic Green hearted chicory* *(EC chronology 98)*
Transgenic potato	*Amylogene starch potato* *C/SE/96/3501 (EC chronology 67)*
Transgenic red-hearted chicory	*Bejo Zaden red-hearted chicory (RM3-3, RM3-4, RM3-6)* *C/NL/94/25 (breeding activities)* *C/NL/94/25/A(food/feed) (EC chronology 77)*
Transgenic red-hearted chicory (food)	*Bejo Zaden red-hearted chicory (RM3-3, RM3-4, RM3-6)* *(EC chronology 97)*
Transgenic tomato	*Zeneca extended shelf life tomato (TGT7-F)* *C/ES/96/01 (EC chronology 84)*

Short title of product (in alphabetical order)	**Full Title of Product and EC Exhibit number**
Transgenic tomato (food)	*Zeneca extended shelf life tomato (TGT7-F)* *(EC chronology 100)*

I. INTRODUCTION

A. COMPLAINT OF THE UNITED STATES

1.1 On 13 May 2003, the United States requested consultations with the European Communities pursuant to Article 4 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* ("DSU"), Article 11 of the *Agreement on the Application of Sanitary and Phytosanitary Measures* ("*SPS Agreement*"), Article 19 of the *Agreement on Agriculture*, Article 14 of the *Agreement on Technical Barriers to Trade* ("*TBT Agreement*") and Article XXII of the *General Agreement on Tariffs and Trade 1994* ("GATT 1994") with regard to certain measures taken by the European Communities and its member States affecting products of biotechnology ("biotech products").[1]

1.2 On 19 June 2003, the United States and the European Communities held the requested consultations, but failed to reach a mutually satisfactory resolution of the matter.

1.3 On 7 August 2003, the United States requested the establishment of a panel to examine the matter.[2]

B. COMPLAINT OF CANADA

1.4 On 13 May 2003, Canada requested consultations with the European Communities pursuant to Article 4 of the DSU, Article XXII of the GATT 1994, Article 11 of the *SPS Agreement*, Article 19 of the *Agreement on Agriculture*, and Article 14 of the *TBT Agreement*, concerning measures affecting the approval and marketing of products that contain, consist of, or are produced from, genetically modified organisms.[3]

1.5 On 25 June 2003, Canada and the European Communities held the requested consultations, but failed to reach a mutually satisfactory resolution of the matter.

1.6 On 7 August 2003, Canada requested the establishment of a panel to examine the matter.[4]

C. COMPLAINT OF ARGENTINA

1.7 On 14 May 2003, Argentina requested consultations with the European Communities pursuant to Article 4 of the DSU, Article 11.1 of the *SPS Agreement*, Article 19 of the *Agreement on Agriculture*, Article 14.1 of the *TBT Agreement*, and Article XXII.1 of the GATT 1994 with regard to certain measures taken by the European Communities and their member States which affect products of biotechnology.[5]

1.8 On 19 June 2003, Argentina and the European Communities held the requested consultations, but failed to reach a mutually satisfactory resolution of the matter.

1.9 On 7 August 2003, Argentina requested the establishment of a panel to examine the matter.[6]

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[1] WT/DS291/1.
[2] WT/DS291/23.
[3] WT/DS292/1.
[4] WT/DS292/17.
[5] WT/DS293/1.
[6] WT/DS293/17.

D. ESTABLISHMENT AND COMPOSITION OF THE PANEL

1.10 At its meeting of 29 August 2003, the Dispute Settlement Body established a single panel pursuant to the requests of the United States in document WT/DS291/23, Canada in document WT/DS292/17 and Argentina in document WT/DS293/17, in accordance with Articles 6 and 9 of the DSU.

1.11 At that meeting, the Parties to the dispute also agreed that the Panel should have standard terms of reference. The terms of reference are, therefore, the following[7]:

> "To examine, in the light of the relevant provisions of the covered agreements cited by the United States in document WT/DS291/23, Canada in document WT/DS292/17 and Argentina in document WT/DS293/17, the matter referred to the DSB by the United States, Canada and Argentina in those documents, and to make such findings as will assist the DSB in making the recommendations or in giving the rulings provided for in those agreements."

1.12 On 23 February 2004, the United States, Canada and Argentina requested the Director-General to determine the composition of the Panel, pursuant to paragraph 7 of Article 8 of the DSU. On 4 March 2004, the Director-General composed the Panel as follows[8]:

Chairperson: Mr Christian Häberli

Members: Mr Mohan Kumar
Professor Akio Shimizu

1.13 Argentina (in respect of the United States' and Canada's complaints), Australia, Brazil, Canada (in respect of the United States' and Argentina's complaints), Chile, China, Colombia, El Salvador, Honduras, Mexico, New Zealand, Norway, Paraguay, Peru, Chinese Taipei, Thailand, Uruguay and the United States (in respect of Canada's and Argentina's complaints) have reserved their rights to participate in the Panel proceedings as Third Parties.

1.14 On 8 March 2004 the Panel received a preliminary written submission from the European Communities requesting the Panel to make an early ruling to the effect that the requests for the establishment of a panel made respectively, by the United States, Canada and Argentina fail to comply with the requirements of Article 6.2 of the DSU.

1.15 The Panel requested the United States, Canada and Argentina to provide a preliminary written submission in response to the European Communities' preliminary submission. On 24 March 2003, the Panel received preliminary written submissions from the United States, Canada and Argentina.

1.16 On 8 April 2004, the Panel issued a "Preliminary Ruling by the Panel on the Consistency of the Complaining Parties' Panel Requests with Article 6.2 of the DSU" finding that the complaining parties' requests for the establishment of a panel of 7 August 2004 (documents WT/DS291/23, WT/DS292/17 and WT/DS293/17) met the requirements of Article 6.2 of the DSU.

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[7] WT/DSB/M/155.
[8] WT/DS291/24, WT/DS292/18 and WT/DS293/18.

E. PANEL PROCEEDINGS

1.17 The Panel met with the Parties on 2-4 June 2004 for the first substantive meeting. It met with the Third Parties in a special session on 3 June 2004. The Panel in this case also sought the advice of scientific and technical experts and met with them in the presence of the Parties on 17-18 February 2005. The Panel held the second substantive meeting with the Parties on 21-22 February 2005.

1.18 On 7 February 2006, the Panel issued its interim reports to the Parties. On 17 March and 19 April 2006, the Panel received comments from the Parties on the interim reports. None of the Parties requested an interim review meeting. On 10 May 2006, the Panel issued its final reports to the Parties.

II. FACTUAL ASPECTS

2.1 This dispute concerns two distinct matters: (1) the operation and application by the European Communities of its regime for approval of biotech products; and (2) certain measures adopted and maintained by EC member States prohibiting or restricting the marketing of biotech products.

2.2 "Biotech products" in this dispute refers to plant cultivars that have been developed through recombinant deoxyribonucleic acid ("recombinant DNA") technology.

2.3 The European Communities' regime for approval of biotech products consists of two primary legal instruments: EC Directive 2001/18 (hereinafter "Directive 2001/18")[9] (and its predecessor, EC Directive 90/220 (hereinafter "Directive 90/220")[10]) governing "the deliberate release into the environment of genetically modified organisms" and EC Regulation 258/97 (hereinafter "Regulation 258/97")[11] regulating "novel foods and novel food ingredients".

2.4 The objective of the EC regime is to protect human health and the environment. To achieve these objectives, the applicable legislation requires the European Communities to conduct a case-by-case evaluation of the potential risks biotech products might pose to human health and the environment. On the basis of that evaluation, the marketing of a particular biotech product is either approved or not. The relevant legal instruments outline the administrative procedure to be conducted in the event a company seeks to obtain approval to place a biotech product on the market and the standards by which an application for approval is evaluated.

2.5 The measures maintained by EC member States are linked to the EC regime for approval of biotech products. The above-noted EC legislation – Directive 2001/18 (and its predecessor, Directive 90/220) governing "the deliberate release into the environment of genetically modified organisms" and Regulation 258/97 regulating "novel foods and novel food ingredients" – under certain conditions permits EC member States to adopt "safeguard" measures in respect of biotech products that have obtained approval for EC-wide marketing. More particularly, individual EC member States may provisionally restrict or prohibit the use and/or sale of an approved biotech product in their own territory if these member States have detailed grounds for considering, based on new or additional information or scientific knowledge, that the particular product poses a risk to human health or the environment. In cases where a member State adopts a "safeguard" measure, it must inform other EC member States and the Commission of the action it has taken and a decision on

[9] Directive 2001/18/EC, O.J. 17.4.2001 L106/1.
[10] Directive 90/220/EEC, O.J. 8.5.1990 L117/15, preamble, as amended by Directive 94/15/EC, O.J. 22.4.1994 L103, and Directive 97/35/EC, O.J. 27.6.1997 L169.
[11] Regulation (EC) No. 258/97, O.J. 14.2.1997 L043/1.

the member State "safeguard" measure must then be taken at Community level within a prescribed time period.

III. COMPLAINING PARTIES' REQUESTS FOR FINDINGS AND RECOMMENDATIONS

3.1 Below is a summary of the complaining parties' requests for findings and recommendations as set out in their requests for the establishment of a panel.

A. UNITED STATES

3.2 The United States, in its request for establishment of a panel[12], requests the Panel to find that the measures at issue are inconsistent with:

(a) Articles 2.2, 2.3, 5.1, 5.2, 5.5, 5.6, 7 and 8, and Annexes B(1), B(2), B(5), C(1)(a), C(1)(b), and C(1)(e) of the *SPS Agreement*;

(b) Articles I:1, III:4, X:1, and XI:1 of the GATT 1994;

(c) Article 4.2 of *Agreement on Agriculture*; and

(d) Articles 2.1, 2.2, 2.8, 2.9, 2.11, 2.12, 5.1.1, 5.1.2, 5.2.1, 5.2.2, 5.6 and 5.8 of the *TBT Agreement*.

3.3 The United States also requests the Panel to find that the measures at issue nullify or impair benefits accruing to the United States directly or indirectly under the cited agreements.

B. CANADA

3.4 Canada, in its request for establishment of a panel[13], requests the Panel to find that the measures at issue are inconsistent with:

(a) Articles 2.2, 2.3, 5.1, 5.2, 5.5, 5.6, 7, 8, and paragraphs 1, 2 and 5 of Annex B, and paragraphs 1(a), 1(b), 1(c), and 1(e) of Annex C of the *SPS Agreement*;

(b) Articles 2.1, 2.2, 2.8, 2.9, 2.11, 2.12, 5.1, 5.2.1, 5.2.2, 5.2.3, 5.6 and 5.8 of the *TBT Agreement*;

(c) Articles I:1, III:4, X:1 and XI:1 of the GATT 1994;

(d) Article 4.2 of the *Agreement on Agriculture*.

3.5 Canada also requests the Panel to find that that the measures at issue nullify or impair benefits accruing to Canada directly or indirectly under the cited agreements. Canada further requests the Panel to find that the measures at issue nullify and impair benefits accruing to Canada in the sense of Article XXIII:1(b) of the GATT 1994.

[12] WT/DS291/23.
[13] WT/DS292/17.

C. ARGENTINA

3.6 Argentina, in its request for establishment of a panel[14], requests the Panel to find that the measures at issue are inconsistent with:

(a) Articles 2.2, 2.3, 5.1, 5.2, 5.5, 5.6, 7, 8 and 10.1 and Annexes B(1) and (5) and C(1)(a), (b), (c), (d) and (e) of the *SPS Agreement*;

(b) Article 4.2 of the *Agreement on Agriculture*;

(c) Articles I.1, III.4, X.1, X.3(a) and XI.1 of the GATT 1994;

(d) Articles 2.1, 2.2, 2.8, 2.9, 2.11, 5.1, 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.6, 5.8 and 12 of the *TBT Agreement*.

3.7 Argentina also requests the Panel to find that the measures at issue nullify or impair the benefits accruing to Argentina under cited agreements.

IV. ARGUMENTS OF THE PARTIES

4.1 The arguments of the parties are set out in their written and oral submissions to the Panel and in their answers to questions. The parties' arguments as presented in their submissions are summarized in this Section.[15]

A. PRELIMINARY WRITTEN SUBMISSION OF THE EUROPEAN COMMUNITIES

1. Introduction

4.2 The European Communities submits that the requests for the establishment of a panel (hereinafter "Requests") made respectively by the United States[16], Canada[17] and Argentina[18] fail to comply with the requirements of Article 6.2 of the DSU.

4.3 The Requests in the present case neither identify the specific measures at issue nor do they provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly. These are two requirements provided by Article 6.2 of the DSU which form the basis for the panel's term of reference under Article 7.1 of the DSU (*US – Carbon Steel* para. 125). The purposes of these two requirements are: to define the scope of the dispute and to serve the due process objective by notifying the parties and third parties of the nature of the complainant's case (*ibidem*, para. 126).

4.4 Given the deficiencies pointed out above, neither can the Panel's jurisdiction be clearly defined, nor is the European Communities able to properly prepare its defence. Taking into consideration that these are two fundamental requirements in dispute settlement proceedings, it is of the utmost importance that the issues raised by the Requests are clarified at the earliest juncture possible. The European Communities, therefore, respectfully requests the Panel to issue a preliminary ruling on Article 6.2 in these proceedings.

[14] WT/DS293/17.

[15] The summaries of the parties' arguments below are based on the executive summaries submitted by the parties where the parties made available such summaries to the Panel.

[16] WT/DS291/23.

[17] WT/DS292/17.

[18] WT/DS293/17.

2. The Panel requests fail to identify the "specific measure at issue"

4.5 The Requests do not comply with Article 6.2 in that they fail to identify the specific measure at issue. As the Panel in *Canada – Wheat Exports and Grain Imports* has stated, a panel request "must establish the identity of the precise measures at issue."[19] The Panel has underlined the importance of the "specificity" requirement by pointing to the difference in wording between Article 6.2 and Article 4.4 of the DSU.

4.6 Whether the actual terms used in a panel request are sufficiently precise to "identify the measure at issue" under Article 6.2, according to the Appellate Body depends upon whether they satisfy the purposes of the requirements of that provision (jurisdiction and due process) and must be determined on a case by case basis.[20]

4.7 Applying these principles, the Panel, in the above case *Canada – Wheat Exports and Grain Imports*, has provided two further indications on how to assess "specificity" putting a particular emphasis on the safeguarding of due process rights.[21]

4.8 First, the panel held that, while it is not necessarily required for a request to explicitly specify measures of general application by name, date of adoption etc., "sufficient information must be provided in the request for establishment of a panel itself that effectively identifies the precise measures at issue."[22] Sufficiency of the information depends, on whether it serves the purposes of Article 6.2 (in particular due process objective) and on specific circumstances of each case (*ibidem*, para. 20).

4.9 Second, the Panel had made it clear that it considered due process to require that the complaining party fully assumed the burden of identifying the specific measures under challenge namely by bearing the risk of any lack of precision in the panel request (para. 25).

(a) The "measures" as described in the Requests

4.10 The Requests refer to a "moratorium" (United States, Canada) or "*de facto* moratorium" (Argentina) which the European Communities allegedly has applied (United States, Argentina) or maintained (Canada) since October 1998.[23] They then each list the "measures at issue", describing in ways similar to each other, two distinct measures, namely, on the one hand the suspension by the European Communities of approval of biotech products and on the other, the failure by the European Communities to consider for approval applications for the biotech products.[24]

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[19] Panel Report, *Canada – Wheat Exports and Grain Imports*, Preliminary Ruling, para. 14.

[20] *See* also Panel Report, *Canada – Wheat Exports and Grain Imports*, Preliminary Ruling, para. 17.

[21] The Panel concluded on a violation of the specificity requirement in Article 6.2. It found that the identification of the measure at issue had created "significant uncertainty" regarding the identity of the precise measure at issue thus "impairing the defendant's ability to begin preparing its defence in a meaningful way". *See*, *ibidem*, para. 28.

[22] Panel Report, *Canada – Wheat Exports and Grain Imports*, Preliminary Ruling, para. 19.

[23] The following arguments on the identification of the measure under Article 6.2 of the DSU are without prejudice to any substantive debate on the nature of measures under specific provisions of the relevant applicable agreements.

[24] WT/DS291/23, page 1; WT/DS292/17, page 1; WT/DS293/17, page 1.

(b) Speaking of two distinct measures, suspension and failure to act, without describing them, the requests fail to identify the specific measure at issue

4.11 Although it is clear that the Requests do not attack the European Communities' legislation on genetically modified products as such, but only its application, it is not clear, in what respect the latter is being challenged. All three Requests have in common that they make an explicit distinction between, on the one hand, an alleged "suspension" of the approval process and, on the other hand, an alleged "failure" to act. These are presented as separate measures. None of the Requests, however, contains any explanation or description of what the "suspension" is *as opposed to* the "failure" to proceed in the approval process.

4.12 It is, in particular, the reference to an alleged "suspension" that remains entirely in the dark. One meaning of "suspension" is "the *action* of suspending something."[25] The complaining parties may have such an "action" in mind, as might be inferred from the fact that the US request speaks of the European Communities "blocking" the approval process.[26] If this is the case, however, the action is not described anywhere. Is there supposed to be a decision or some other kind of normative or executive act, by which the European Communities has proceeded to "suspend"? If so, according to the above standards, the Requests would at least need to contain sufficient information to allow – both the Panel and the defendant – to effectively identify these acts.

4.13 "Suspension", on the other hand, according to the Oxford Dictionary may also mean "the *condition* of being suspended".[27] The word, then, would describe a state of being, a situation of "nothing happening". If that is what the complaining parties have in mind, it would seem impossible, however, to distinguish this "measure" from the alleged inaction, which is that of failing to consider/grant approvals. Listing them as two distinct measures would not make sense any longer.

4.14 From the above it can be seen that the Requests create considerable uncertainty which *de facto* shifts the burden of identifying the specific measure under challenge onto the European Communities. If it wants to properly prepare its defence, the European Communities has no choice but to second-guess what the complaining parties might have meant with "suspension" as opposed to "failure to act" taking the risk of being presented with an entirely different reading at a later stage in the proceedings. This situation is irreconcilable with the minimum standards of due process as exemplified by the WTO case law and fails to comply with the requirement in Article 6.2 to identify the specific measures at issue.

3. The Panel requests do not provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly

4.15 The Requests' lack of sufficient specificity in the identification of the measures at issue is coupled with the absence of a brief summary of the legal basis of the complaint sufficient to present the problem clearly, as required by Article 6.2 of the DSU.

4.16 According to the constant jurisprudence of the Appellate Body, this second requirement in Article 6.2 entails that the claims "must all be specified sufficiently in the request for the establishment of a panel in order to allow the defending party and any third parties to know the legal

[25] *The New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. 2, p. 3162.
[26] WT/DS291/23, page 1.
[27] Ibidem.

basis of the complaint".[28] This allows the defending party to "know what case it has to answer and what violations have been alleged so that it can begin preparing its defence" in a meaningful way, and allows it an opportunity to effectively respond to the complaint.[29] Furthermore, the panel needs to know what claims are raised by the complaining parties to exercise correctly its jurisdiction since it cannot address claims that have not been made.[30]

4.17 The significance of this requirement can be better appreciated with regard to the context of Article 6.2 of the DSU. In particular, the European Communities (following the Panel in *Canada – Wheat Exports and Grain Imports*) notes again the difference in the language between Article 4.4 and Article 6.2 of the DSU, that "must be given meaning" (para. 15). The word "indication" used in the former, means "something that indicates or suggests and thus conveys the idea of briefness and allusion. The word "summary" used by the latter however, comes from the Latin word "*summa*" and covers the idea of something "containing all the main points of a matter; dispensing with unnecessary detail. Thus, whilst it is sufficient that a request for consultations mentions the provisions invoked in order to "suggest" what the case could be about, a request for the establishment of a panel must be detailed enough to cover "all the main points of a matter".

4.18 In the present case, all three requests limit the illustration of the legal basis to long lists of provisions of the GATT 1994, the *SPS Agreement*, the *TBT Agreement* and the *Agreement on Agriculture*[31], without any link being made between the challenged measures and the facts of the case. In other words, the Requests do not make at all clear which obligations are alleged to be violated and which measures are in violation of which obligations. This has impaired the European Communities' ability to understand what the claims in the present case are and, thus, to start preparing its defence in any meaningful way.

(a) The mere listing of provisions is not sufficient in this case

4.19 It is true that the Appellate Body has recognized in *EC – Bananas III* that it may be sufficient for a complaining party "to list the provisions of the specific agreements alleged to have been violated without setting out detailed arguments as to which specific aspects of the measures at issue relate to which specific provisions of those agreements".[32] However, it has added that the question as to whether the mere listing meets the standard of Article 6.2 of the DSU must be examined on case-by-case basis, taking into account if the ability of the respondent to defend itself was prejudiced by the fact that the panel request simply lists the provisions (Appellate Body Report, *Korea – Dairy*, para. 127).

4.20 In the same case, the Appellate Body stated that in *EC – Bananas III* it did not purport that a mere listing of the provisions could always suffice to comply with Article 6.2 of the DSU without regard to the particular circumstances of the case (*ibidem*, para. 123). In particular, such a listing will not satisfy the standard of Article 6.2 if the provisions listed establish not single but multiple obligations (*ibidem*, para. 124).

[28] Appellate Body Report, *EC – Bananas III*, para. 143.
[29] Appellate Body Report, *Thailand – H-Beams*, para. 88. *See* also, more recently, Panel Report, *Canada – Wheat Exports and Grain Imports*, Preliminary Ruling, para. 29.
[30] Appellate Body Report, *EC – Hormones*, para. 156.
[31] WT/DS291/23, page 2; WT/DS292/17, page 2; WT/DS293/17, page 2.
[32] Appellate Body Report, *EC – Bananas III*, para. 141.

4.21 The Requests indicate as legal basis thirty-eight provisions, several of which contain multiple (distinct or parallel) obligations (i.e. Articles 2.2, 2.3, 5.5, 7, 8, and Annex B(5), C(1)(b), of the *SPS Agreement*; Articles 2.9, 5.2.2, 5.6 and 12 of the *TBT Agreement*).

4.22 Added to the provisions which contain a single obligation, the European Communities is faced with alleged violation of thirty-eight different provisions, which altogether contain more than sixty distinct obligations. Furthermore, several of those provisions are either mutually exclusive – such as those contained in the *SPS* and in the *TBT Agreements*[33]– or subordinated – such as those of the GATT 1994 in relation to the ones contained in the other agreements.[34] The panel requests do not explain even remotely how the claims would be articulated, for instance, whether all provisions and obligations apply simultaneously to different aspects of the measures, or whether some provisions are listed only subsidiarily. In front of such an uncoordinated array of provisions and obligations, the European Communities has not been able to understand even remotely which are the claims the complaining parties intend to pursue.

(b) No link is made between the provisions listed and the facts of the case

4.23 The fact that the complaining parties have only merely listed the provisions they allege as violated, several of which contain multiple obligations, is made worse by the fact that they have also failed to make any link whatsoever between these provisions and the facts of the case. Where a panel request covers several separate measures, as is the case in the present dispute, it should indicate which provisions may be relevant for the examination of each measure, possibly describing the substantive aspects or the effects of the measures which are allegedly in breach of those provisions. The panel requests do not provide the slightest explanation in that regard. Thus, the European Communities is completely in the dark also about which provisions would have been violated by which measures, in other words about what claims are pursued.

4.24 Even assuming, in fact, that the complaining parties intend to allege a violation of each of the thirty-eight provisions and of the over sixty obligations listed and that the measures at issue were clear – which is not the case –, in order to prepare its defence the European Communities would still have to assess each of the measures indicated against each of the obligations alleged to have been violated. This would result in the preparation of arguments of defence in case of US request for well over three thousands[35] hypotheses of different claims.

4.25 In order to facilitate the task of the Panel in assessing what is the acceptable standard of precision for requests under Article 6.2 of the DSU, the European Communities points at some recent cases[36], where the United States, Canada and Argentina were also complaining parties. In all of them both measures and claims are clearly and precisely specified.

4. Article 6.2 issues must be decided as early as possible in the proceedings

4.26 Taking into consideration the double purpose of the requirements of Article 6.2 of the DSU, that is defining jurisdiction of the panel and guaranteeing due process, it is evident in the case law that

[33] *See* Article 1.5 of the *TBT Agreement* and Article 1.4 of the *SPS Agreement*.

[34] *See* the General interpretative note to Annex 1A of the Marrakech Agreement Establishing the WTO.

[35] Forty-one applications plus nine safeguard measures applied by the member States of the European Communities equals a number of fifty measures at issue. These must then be multiplied by at least sixty obligations alleged to have been violated. The result is over three thousand!

[36] WT/DS295/2 of 22 September 2003; WT/DS277/2 of 4 April 2003; WT/DS268/2 of 4 April 2003

it is of the outmost importance that issues arising in regard of these requirements are decided as early as possible.

(a) The Panel has to be able to establish the limits of its jurisdiction

4.27 If a claim is not properly before a panel, it is established practice that the panel declines to examine it.[37] As the Appellate Body has made clear in several instances, "[t]he vesting of jurisdiction in a panel is a fundamental prerequisite for lawful panel proceedings" (Appellate Body, *Mexico – Corn Syrup*, para. 36).

4.28 Where the request for the establishment of a panel lacks precision, the panel lacks authority to proceed. It is therefore necessary that, before proceeding, it first establishes where the limits of its jurisdiction are.

4.29 If, as in the case at issue, the Panel Requests are not amended, the scope of the claims which are in front of the Panel will remain entirely unclear. Before proceeding, the Panel must know which of the three thousands hypotheses of claims are the ones actually referred to it.

(b) The European Communities has been unable to start preparing its defence in any meaningful way

4.30 Equally, safeguarding the due process rights of the defendant and possible third parties must be of central concern to the dispute settlement organs. The defendant in order to prepare its defence should know what violations have been alleged and what case it has to answer. The same holds true for member States that want to participate in the proceedings as third parties.[38]

4.31 Where a request for the establishment of a panel lacks precision, neither the defendant nor third parties can adequately prepare their arguments. A violation of this due process requirement constitutes a fundamental flaw in the proceedings, which must not proceed before the flaw has been remedied.

4.32 In the present case, the lack of specificity of the identification of the measures at issue, coupled with the mere listing of an elevated number of provisions and the absence of co-relation between the two, has so far prevented the European Communities from starting preparing its defence in any meaningful way. The European Communities still – to date – does not know the claims that the complaining parties intend to bring before the Panel. Taking into consideration the very strict deadlines, the European Communities cannot be expected to wait for the first written submission of the complaining parties to start preparing its defence in a case as sensitive and as important as the current one.

(c) The Panel must scrutinize the request to ensure its compliance with Article 6.2

4.33 Because of the fundamental nature of the above requirements in Article 6.2 of the DSU, each Panel must be satisfied that its conditions are fulfilled before assuming jurisdiction over a case. This

[37] *See*, most recently, Panel Report, *US – Carbon Steel*, paras. 8.11-8.12.
[38] Appellate Body Report, *Thailand – H-Beams*, para. 88.

should be done very carefully especially because of the DSB practice consisting of the automatic approval of the requests.[39]

4.34 Panels should deal with such issues, the Appellate Body has ruled, "even if the parties to the dispute remain silent on those issues", "if necessary, on their own motion, in order to satisfy themselves that they have authority to proceed".[40] *A fortiori* in the present case, where the European Communities as the defending party is submitting such claims to its attention, the Panel must scrutinize the Requests to ensure their compliance with Article 6.2 of the DSU.

(d) The Panel must scrutinize the request as early as possible in panel proceedings

4.35 In *EC – Bananas III*, the Appellate Body has also clarified that the claims, which are to be set out in the Panel request, must be distinguished from the subsequent arguments of the parties in support of such claims. Thus, the former must be specified sufficiently in the request of the panel and the latter cannot be used to "cure" a faulty request (para. 143).

4.36 For this reason the Panel must scrutinize the request to ensure its compliance with Article 6.2 as early as possible in panel proceedings in order to avoid causing prejudice or unfairness to any party or third party.[41] That is also why the European Communities is submitting these issues to the Panel at the earliest possible juncture in time, i.e. immediately after its composition.[42]

5. Request for preliminary ruling

4.37 For the reasons set out above, the European Communities respectfully requests that the Panel issue a preliminary ruling to the effect that the Requests do not meet the requirements of Article 6.2 of the DSU.

4.38 Since the procedural rules are designed to promote the fair, prompt and effective resolution of trade disputes[43] and in order to ensure a speedy resolution of the present dispute, the European Communities would consider it appropriate for the Panel to suggest to the complaining parties to introduce new panel requests in full compliance with Article 6.2 of the DSU to be judged by the same panel. The European Communities would like to note that such a course of action has recently been taken by a panel in another dispute.[44]

B. PRELIMINARY WRITTEN SUBMISSION OF THE UNITED STATES

1. Introduction

4.39 The European Communities offers no basis for its request for a preliminary ruling ("EC Request") that the US panel request in this dispute fails to meet the requirements of Article 6.2 of the DSU. To the contrary, as required by Article 6.2, the US panel request properly "identif[ies] the

[39] Appellate Body Report, *US – Carbon Steel*, para. 126, recalling Appellate Body Report, *EC – Bananas III*, para. 142.
[40] Appellate Body Report, *Mexico – Corn Syrup (Article 21.5 – US)*, para. 36.
[41] Appellate Body Report, *EC – Bananas III*, para. 144.
[42] Appellate Body Report, *Thailand – H Beams*, para. 95.
[43] Appellate Body Report, *US – FSC*, para. 166.
[44] Panel Report, *Canada – Wheat Exports and Grain Imports*, Preliminary Ruling, para. 65. In this case, the United States indeed introduced a new Panel request (WT/DS276/9), after which the Panel originally established continued to exercise its jurisdiction.

specific measures at issue and provide[s] a brief summary of the legal basis of the complaint sufficient to present the problem clearly."

2. The requirements of Article 6.2 of the DSU

4.40 Article 6.2 of the DSU requires, in relevant part, that a request for the establishment of a panel:

> "[I]dentify the specific measures at issue and provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly."

4.41 The EC Request contains a number of quotations from Appellate Body and panel reports, in particular from *Korea – Dairy*[45] and *EC– Bananas III*[46], that explain this provision and emphasize its role and importance in dispute settlement. It has entirely missed, however, one aspect of these reports which is critical to the issue now before this Panel: the key distinction between *claims* – which must be included in the panel request – and the *arguments* in support of those claims – which need not be included. As the Appellate Body explained in *EC – Bananas III*:

> "In our view, there is a significant difference between the *claims* identified in the request for the establishment of a panel, which establish the panel's terms of reference under Article 7 of the DSU, and the *arguments* supporting those claims, which are set out and progressively clarified in the first written submissions, the rebuttal submissions and the first and second panel meetings with the parties."[47]

4.42 Furthermore, the Appellate Body in *EC – Bananas III* made clear that a panel request may adequately state a claim if the request simply cites the pertinent provision of the WTO agreement:

> "We accept the Panel's view that it was sufficient for the complaining parties to list the provisions of the specific agreements alleged to have been violated without setting out detailed arguments as to which specific aspects of the measures at issue relate to which specific provisions of those agreements."[48]

4.43 The Appellate Body confirmed this reading in *Korea – Dairy*. In that dispute, the problem with the panel request was that it cited too broadly to Article XIX of the GATT 1994 and various articles of the *Agreement on Safeguards*, all of which contained numerous sub-articles, so that it was difficult to determine which specific obligations in those provisions were at issue. The US panel request in this dispute, by contrast, cites to specific provisions of the WTO agreements at issue, and cannot be said to suffer a similar defect.

4.44 The European Communities also fails to note that *even if* a panel request is insufficiently detailed "to present the problem clearly," the Panel is not automatically deprived of jurisdiction over the matter. Rather, the Appellate Body has found that a panel must examine, based on the "particular circumstances of the case," whether the defect has prejudiced the ability of the responding party to defend itself. As the Appellate Body explained in *Korea – Dairy:*

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[45] Appellate Body Report, *Korea – Dairy*.
[46] Appellate Body Report, *EC – Bananas III*.
[47] Appellate Body Report, *EC – Bananas III*, para. 141.
[48] *Id.*

> "In assessing whether the European Communities' request met the requirements of Article 6.2 of the DSU, we consider that, in view of the particular circumstances of this case and in line with the letter and spirit of Article 6.2, the European Communities' request should have been more detailed. However, Korea failed to demonstrate to us that the mere listing of the articles asserted to have been violated has prejudiced its ability to defend itself in the course of the Panel proceedings. Korea did assert that it had sustained prejudice, but offered no supporting particulars in its appellant's submission nor at the oral hearing. We, therefore, deny Korea's appeal relating to the consistency of the European Communities' request for the establishment of a panel with Article 6.2 of the DSU."[49]

4.45 Therefore, in evaluating claims regarding whether a panel request "presents the problem clearly," a Panel must consider the particular circumstances of the case, including whether the defending party has been prejudiced.

3. The European Communities' assertion that the US panel request does not identify the "specific measures at issue" is incorrect

4.46 The European Communities appears to have two concerns with the identification of the measures subject to this dispute. Neither of these concerns has merit.

4.47 First, the European Communities claims that, "It is, in particular, the reference [in the panel request] to an alleged 'suspension' that remains entirely in the dark."[50] Even without any context, and on the plain language of the panel request, it is difficult to see how the concept of a "suspension" of the consideration and granting of biotech approvals is at all ambiguous. But in light of well-known statements of EC officials acknowledging the existence of a *de facto* moratorium, the European Communities' claim that it is "in the dark" on the meaning of a "suspension" is not credible.

4.48 Along, these same lines, the European Communities poses the following question:

> "Is there supposed to be a decision or some other kind of normative or executive act, perhaps a moratorium legislation of the kind New Zealand had, by which the European Communities has proceeded to 'suspend'?"

Although the United States is unaware of any single executive decree or legislative act through which the moratorium has been implemented, such decree or act would be within the scope of the covered measures. Where the European Communities in this dispute denies the existence of a moratorium – a moratorium nonetheless acknowledged by its own officials – it cannot in turn try to profit from its lack of transparency by arguing that the complaining parties have not identified the moratorium with sufficient specificity.

4.49 Second, the European Communities claims that the US panel request is fatally flawed because it uses both the phrase "a suspension of consideration" and "a failure to consider". The European Communities does not explain why these two different wordings introduce any ambiguity concerning the measures subject to the request. Moreover, in the context of the panel request, the reason for using these two different wordings is quite clear.

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[49] *Id.*, para. 131.
[50] EC request, para. 22.

4.50 The first phrase – suspension of consideration – is used to describe the European Communities' across-the-board moratorium affecting all biotech products:

> "(1) as described above, the suspension by the European Communities of consideration of applications for, or granting of, approval of biotech products."

The second phrase – failure to consider – is used to describe the European Communities' conduct as it affects the specific products identified in the annexes to the panel request:

> "(2) as described above, the failure by the European Communities to consider for approval applications for the biotech products mentioned in Annexes I and II to this request."

These are simply two different wordings for the same concept -- the word "suspension" fits better with the European Communities' conduct as it affects all biotech applications, while the phrase "failure to consider" fits better with specific applications. The European Communities does not and cannot explain how these different wordings amount to a failure to identify the specific measures at issue.

4.51 For the above reasons, the European Communities has presented no reason for finding that the US panel request does not meet the requirement of Article 6.2 to identify the specific measures at issue.

4. Contrary to the European Communities' allegations, the US panel request provides a brief summary of the legal basis of the complaint sufficient to present the problem clearly

4.52 The US panel request, which lists the specific provisions of the *SPS Agreement*, *TBT Agreement*, *Agreement on Agriculture*, and GATT 1994 alleged to be violated, provides a brief summary of the legal basis of the complaint sufficient to present the problem clearly, as required by Article 6.2.

4.53 The Appellate Body has made clear on several occasions that a panel request may adequately summarize the legal basis of the complaint under Article 6.2 by simply citing the pertinent provisions of the WTO Agreement.[51] The European Communities cites *Korea – Dairy*, in which the Appellate Body stated that there may be circumstances in which a "listing of treaty articles would not satisfy the standard of Article 6.2."[52] But in that proceeding the articles cited had multiple paragraphs, many of which had their own distinct obligations: for instance, the panel request cited Article XIX of the GATT 1994, containing three sections and five paragraphs, each with at least one distinct obligation, and Article 12 of the *Agreement on Safeguards*, which spans two pages and contains 11 paragraphs.[53]

4.54 By contrast, the US panel request in this dispute lists specific provisions of the *SPS Agreement*, *TBT Agreement*, *Agreement on Agriculture*, and the GATT 1994. Where an article consisted of more than one paragraph, the US panel request specifically identified the particular paragraph number. Moreover, where a paragraph has subparagraphs, in most cases the panel request

[51] *E.g.*, Appellate Body Report, *EC – Bananas III*, para. 141; Appellate Body Report, *Korea – Dairy*, para. 124.
[52] Appellate Body Report, *Korea – Dairy*, para. 124.
[53] *Id.*

goes on to specify the specific subparagraphs.[54] Unlike in the case of *Korea – Dairy*, there are no circumstances in this dispute that would render citation to the relevant specific provision of the WTO agreement insufficient under Article 6.2.

4.55 Previous panels and the Appellate Body have been very careful to distinguish between the claims that must be made in a panel request under Article 6.2 -- *i.e.*, the brief summary of the legal *basis* for the complaint sufficient to present the problem clearly -- and the *arguments* supporting those claims. The claims must be set forth in the panel request. The arguments do not. As the Appellate Body stated in *EC – Bananas III*:

> "We accept the Panel's view that it was sufficient for the complaining parties to list the provisions of the specific agreements alleged to have been violated without setting out detailed arguments as to which specific aspects of the measures at issue relate to which specific provisions of those agreements. In our view, there is a significant difference between the *claims* identified in the request for the establishment of a panel, which establish the panel's terms of reference under Article 7 of the DSU, and the *arguments* supporting those claims, which are set out and progressively clarified in the first written submissions, the rebuttal submissions and the first and second panel meetings with the parties."[55]

4.56 In this dispute, the European Communities is not faulting the United States for failing to set out the legal *basis* for the complaint. It is faulting the United States, incorrectly, for not including its *arguments* in support of that basis.

4.57 The European Communities presents two lines of argument why in this case the US panel request must have gone beyond listing the claims, to also include the arguments in support of those claims.

4.58 First, the European Communities counts up the number of provisions listed by the United States, and proposes that this number is somehow too high to be covered by the provision actually found in the text of the DSU, namely that a panel request that specifies the claims is in compliance with Article 6.2 of the DSU.

4.59 As an initial matter, the United States notes that it does not agree with the European Communities' count of the number of obligations covered in the US panel request. For example, the European Communities argues that Article 7 of the *SPS Agreement* includes two separate obligations. The second Article 7 obligation, however, is to comply with the obligations in Annex B of the *SPS Agreement*, and the US panel request specifies the specific provisions of Annex B alleged to be violated. Accordingly, the European Communities engages in double-counting by counting both the general obligation to comply with Annex B, and also the specific provisions of Annex B listed in the US panel request.

4.60 Moreover, the simple reason that the US panel request covers a number of obligations is that the European Communities' decision to adopt, without transparency, a *de facto* moratorium on the approvals of important agricultural products understandably results in a violation of several provisions

[54] The only exceptions are Annex B(5) of the *SPS Agreement*, and Articles 2.9 and 5.6 of the *TBT Agreement*, each of which contain four subparagraphs establishing related transparency obligations. The specific subparagraphs were not identified because the United States considers the EC measures to be inconsistent with each one.

[55] Appellate Body Report, *EC – Bananas III*, para. 141.

of the WTO Agreement. Article 6.2 of the DSU does not impose an entirely different standard on a panel request on the basis that the defending party has engaged in multiple violations of the WTO Agreement.

4.61 In addition, other than pointing to the number of obligations covered by the US panel request, the European Communities does not explain how it is confused, or in any way prejudiced, by the panel request. Surely, the European Communities cannot claim, for example, that it fails to understand (and thus is unable to begin to defend itself against) the proposition that a general moratorium on the approval of biotech products might violate the obligation in Article 5.1 of the *SPS Agreement* that SPS measures must be based on risk assessments. Nor, for example, can the European Communities claim not to understand (and thus not to be able to begin to defend itself against) the proposition that a 5-year moratorium would be inconsistent with the requirement in Annex C(1)(a) of the *SPS Agreement* to undertake and complete procedures to ensure the fulfilment of SPS measures "without undue delay."

4.62 Finally, the European Communities itself acknowledges that "several of those provisions [cited in the panel requests] are either mutually exclusive – such as those contained in the *SPS Agreement* and the *TBT Agreement* – or subordinated – such as those of the GATT 1994 in relation to the ones contained in the other agreements."[56] In the consultations and at the meetings of the DSB, the United States has made clear that it considers the moratorium to be an SPS measure. The European Communities, however, has refused to even acknowledge the existence of the moratorium, much less to acknowledge that the moratorium falls within the scope of the *SPS Agreement*. It is for this reason that the complaining parties in their panel requests have been required to cite both SPS provisions and the corresponding provisions of the *TBT Agreement*. In these circumstances, it is difficult to understand how the European Communities could claim any confusion or prejudice from citing provisions of both the *SPS Agreement* and *TBT Agreement*.

4.63 Second, the European Communities suggests that the "common practice" is for panel requests to go beyond stating the claims to laying out the arguments in support of those claims. The European Communities does not, however, even begin to explain how a "practice" could alter the textual requirements of Article 6.2 of the DSU, nor does it attempt to reconcile its suggestion with the fact that the panel request in *EC – Bananas III*[57] (which the Appellate Body considered to have been consistent with Article 6.2) did not set out the complaining parties' arguments in support of their claims. Furthermore, the European Communities gives no real basis for its assertion of a "practice"; it mentions exactly three panel requests, when in fact, as of 31 October 2003, there had been **119** panels established.[58] Certainly, citation to panel requests in such a tiny fraction of cases would not be sufficient to establish a "practice" of any kind.[59]

4.64 In short, the European Communities has not presented any reasons why the US panel request, which clearly specifies the claims in this dispute, should be found inconsistent with the requirements of Article 6.2 of the DSU.

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[56] EC Request, para. 40.

[57] WT/DS27/6.

[58] *Statistical Information on Recourse to WTO Dispute Settlement Procedures (1 January 1995 – 31 October 2003): Background Note by the Secretariat*, Job(03)/225, circulated 11 December 2003, part III(A).

[59] The United States notes that the European Communities has in any event not followed any such "practice" itself; *see, e.g.*, the panel request in *US – 1916 Act*, WT/DS136/2, in which the European Communities did nothing more than provide citations to, and cursory paraphrases of, provisions of the WTO Agreement.

5. The US panel request does not prejudice the ability of the European Communities to defend itself

4.65 In *Korea – Dairy*, the Appellate Body denied Korea's Article 6.2 claim *in toto* because, although it had asserted prejudice, Korea offered no supporting particulars.[60] The European Communities does assert that it is prejudiced by the US panel request, but only in the vaguest and most conclusory manner.

4.66 The European Communities' only explanation of its alleged prejudice is that:

> "[T]he lack of specificity of the identification of the measures at issue, coupled with the mere listing of an elevated number of provisions and the absence of co-relation between the two, has so far prevented the European Communities from starting preparing its defence in any meaningful way."[61]

4.67 This argument, however, is nothing more than a restatement of its argument, refuted above, that the request is insufficiently detailed with respect to actual arguments to support the legal basis of the complaint. In light of the Appellate Body's reasoning in *Korea – Dairy*, such a mere restatement is plainly insufficient to establish prejudice. If lack of detail in the panel request automatically meant "prejudice," there would be no need for a "prejudice" analysis.

4.68 Moreover, the United States finds it hard to accept that the European Communities has not already begun to "prepare its defence in a meaningful way." To be specific, is the European Communities arguing that it has not already begun to develop explanations of why it denies the existence of a moratorium despite the statements of EC officials to the contrary; of why no new biotech products have been approved for over 5 years if there has been no moratorium; and of how such a moratorium is consistent with the substantive, procedural and transparency obligations of the *SPS Agreement*? The European Communities in its ruling request does not make such claims, and, indeed, could not credibly do so.

4.69 Accordingly, even if the European Communities had succeeded in demonstrating that the US panel request does not meet the requirements of Article 6.2 of the DSU, which it has not, the European Communities has offered nothing to suggest that it has been prejudiced.

6. The European Communities failed to raise its Article 6.2 concerns at the earliest possible opportunity

4.70 Finally, the European Communities fails to recognize that procedural objections must be raised at the earliest possible opportunity, and not for the first time in a ruling request filed after the composition of the panel.[62] In the *US – FSC* dispute, the United States requested a preliminary ruling that a claim be dismissed because of an inadequacy in the consultation request. The panel rejected that request, and the Appellate Body upheld that rejection, stating,

> "It seems to us that, by engaging in consultations on three separate occasions, and not even raising objections in the DSB meetings at which the request for establishment of a panel was on the agenda, the United States acted as if it had accepted the establishment of the panel in this dispute, as well as the consultations preceding such

[60] Appellate Body Report, *Korea – Dairy*, para. 131.
[61] EC Request, para. 50.
[62] Appellate Body Report, *US – FSC*, para. 165.

> establishment. In the circumstances, the United States cannot now, in our view, assert that the European Communities' claims ... should have been dismissed."[63]

4.71 Likewise, at no time prior to the composition of this Panel did the European Communities so much as intimate that it considered the panel request in any way deficient, waiting until after the panel was composed to offer its objection. In upholding the panel's rejection of the US request for a preliminary ruling in *US – FSC* under very similar circumstances, the Appellate Body stated, "The procedural rules of the WTO dispute settlement system are designed to promote, not the development of litigation techniques, but simply the fair, prompt and effective resolution of trade disputes."[64] This Panel should reject the European Communities' effort to avoid the fair, prompt and effective resolution of this dispute through its groundless – and untimely – objections to the US panel request.

C. PRELIMINARY WRITTEN SUBMISSION OF CANADA

1. Introduction

4.72 Canada's panel request properly "identif[ies] the specific measures at issue and provide[s] a brief summary of the legal basis of the complaint sufficient to present the problem clearly." Not only has Canada adequately identified and described the specific measures, the European Communities has no justification for professing any surprise or confusion as to the nature of these measures. The European Communities is really asking this Panel to require Canada to identify, not the specific measures, but the specific evidence that Canada intends to raise in this proceeding.

4.73 The European Communities is also asking this Panel to read into Article 6.2 a requirement that is not there and that the Appellate Body has specifically rejected, namely, that Canada is obligated to summarize specific legal arguments to be presented in its first written submission. The Appellate Body has already rejected this approach, and this Panel should do so as well. Furthermore, not only does the European Communities misrepresent the extent of the complexity of the provisions cited by Canada in its panel request, the European Communities also attempts to import from the *Anti-Dumping Agreement* a standard into Article 6.2 that is not supported by the text of that provision.

4.74 Lastly, the European Communities does not provide any evidence or rationale to support a claim that it has been prejudiced in any way by Canada's panel request. The European Communities is fully aware of the matters referenced in Canada's panel request, and has had ample time to begin to prepare a defence. If it has failed to do so, the causes of that failure cannot be found in Canada's panel request.

4.75 In sum, the EC Request is without merit. It appears to be nothing more than the kind of "litigation technique" that the Appellate Body firmly rejected in *US – FSC*.

2. Requirements of Article 6.2 of the DSU

4.76 The EC Request contains a number of quotations from Appellate Body and panel reports that explain Article 6.2 and emphasize its role and importance in dispute settlement. However, it fails to reflect one aspect which is critical to the issues before this Panel: the key distinction between the claims – which must be included in the panel request – and the arguments in support of those claims – which need not be included.

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[63] *Id.*
[64] *Id.*, para. 166.

4.77 Furthermore, with respect to the requirement for a panel request to provide a "brief summary of the legal basis of the complaint," the Appellate Body has made it clear that it may be sufficient for the purposes of Article 6.2 for a panel request to simply cite the pertinent provision of the WTO agreement. The Appellate Body has also made it clear that whether such a listing is sufficient will depend on the circumstances of each case.

4.78 Finally, the jurisprudence has established that, even where a panel request does not "present the problem clearly," the panel is not automatically deprived of jurisdiction over the matter. Rather, the panel must examine, based on the "particular circumstances of the case," whether the defect has prejudiced the ability of the responding party to defend itself.

4.79 Therefore, in evaluating claims as to whether a panel request presents the problem clearly, the Panel must consider the particular circumstances of the dispute, including whether the responding party has been prejudiced.

3. Canada's Panel request identifies the "specific measure at issue" as required by Article 6.2 of the DSU

4.80 As set out in Canada's panel request, the specific measures at issue are:

> "[T]he general suspension by the EC of its own processes for the consideration of applications for, and the granting of, approval for biotech products;
>
> the failure by the EC to consider or approve, without undue delay, applications for approval of the products identified in Annex I; and
>
> the national measures identified in Annex II prohibiting the importation, marketing or sale of the specified EC-approved biotech products."

4.81 Because the European Communities has not asserted a failure on the part of Canada to identify with sufficient precision the second and third categories of measures listed in Canada's panel request, Canada assumes that the European Communities does not dispute that these measures have been identified with sufficient precision.

(a) The moratorium is identified with sufficient precision

4.82 The reference to "the general suspension by the EC of its own processes for the consideration of applications for, and the granting of, approval for biotech products" (hereinafter "moratorium") should be read in conjunction with the second paragraph of Canada's panel request. In that paragraph, Canada states that since October 1998, the European Communities has maintained a moratorium on the approval of biotech products. It is clear that the phrase "the general suspension by the EC of its own processes for consideration of applications for, and the granting of, approval for biotech products" is a more detailed description of the "moratorium" to which Canada earlier refers. Canada clearly identifies the relevant approval legislation for biotech products in footnote 1 to Canada's panel request.

4.83 In addition, Canada's panel request sets out specific examples of applications for approval of biotech products, including a brief description of the actions taken to block their consideration or approval. The repeated failures by the European Communities to consider or approve these applications are both cited as examples of the moratorium (in the second paragraph of the panel request) and as separate measures covered by the panel request. Thus, the phrase "general suspension

by the EC of its own processes for consideration of applications for, and the granting of, approval for biotech products" when read in the light of the second paragraph of the panel request, sufficiently identifies the "specific measure at issue."

4.84 The assertion by the European Communities that it is unable to identify the precise measure at issue is difficult to understand. The existence of the moratorium has been widely recognized and discussed by EC officials since the Declaration by five EC member States at the 2194th Council Meeting of EC Environment Ministers in June 1999.

4.85 Numerous EC officials, including Commissioners Wallström and Byrne, have publicly acknowledged the existence of the moratorium. Moreover, as the European Communities is well aware, no biotech products have been approved under the relevant EC legislation since October 1998. Thus, it is disingenuous for the European Communities to claim to be unable to identify the measure at issue.

4.86 What the European Communities is really seeking in its request is pre-submission discovery of the evidence that Canada will adduce in its first written submission. However, under Article 6.2, there is no requirement that a complaining party must set out the evidence that will be adduced to support the measure or the claims made in the panel request.

4.87 Canada agrees that what can be considered a "specific measure" will depend on the circumstances of the particular case, including the characteristics of the measure in question.

4.88 Unlike measures typically at issue in WTO dispute settlement, the moratorium has neither been formally adopted nor published promptly as required by Annex B of the *SPS Agreement* and Article X:1 of the GATT 1994. Had the European Communities adopted the moratorium as a formal legal measure and complied with the transparency requirements of the *SPS Agreement* and the GATT 1994, Canada would have been in a position to identify the particulars suggested by the European Communities in paragraph 22 of its Request. It is only because of the European Communities' own lack of transparency that Canada cannot provide the information the European Communities is demanding. The European Communities should not be able to use its own lack of transparency as a shield against a WTO challenge.

4. Canada's panel request provides "a brief summary of the legal basis of the complaint sufficient to present the problem clearly" as required by Article 6.2

(a) In view of the circumstances surrounding this case, Canada's listing of the relevant provisions complies with the requirements of Article 6.2

4.89 Whether merely listing the provisions of the specific agreements alleged to have been violated is sufficient for the purposes of Article 6.2 must be decided on a case-by-case basis, taking into account all of the circumstances surrounding that case. In the circumstances of this case, the listing of the treaty provisions alleged to have been violated is sufficient to present the problem clearly.

4.90 First, from the standpoint of the so-called multiplicity of the listed obligations, the EC Request recognizes that the majority of the provisions listed by Canada contain single obligations. While some of the provisions contain more than one obligation, this fact alone does not preclude their simple listing from being sufficient to present the problem clearly.

4.91 For instance, the European Communities notes that Canada has made claims with respect to paragraph 5 of Annex B of the *SPS Agreement*, and Articles 2.9 and 5.6 of the *TBT Agreement*.

According to the European Communities these three provisions contain twelve separate obligations altogether. However, a review of these provisions makes it clear that they reflect essentially the same four obligations albeit being imposed in three different contexts. The same holds true for the five obligations the European Communities alleges are found in paragraph 1(b) of Annex C of the *SPS Agreement* and Article 5.2.2 of the *TBT Agreement*. When one considers that the *SPS Agreement* and the *TBT Agreement* are alternative agreements the true nature of the burden placed upon the European Communities to understand Canada's claims is significantly lighter than the European Communities would have the Panel believe.

4.92 Furthermore, the European Communities notes that Article 2.2 of the *SPS Agreement* contains three distinct obligations. While this may be true, the European Communities fails to mention that, according to the jurisprudence, the three obligations found in Article 2.2 are more general expressions of the obligations found in Articles 5.1, 5.2 and 5.6 of the *SPS Agreement*. Thus, claims raised with respect to these three articles are essentially the same claims as those raised with respect to Article 2.2. The same holds true for Articles 2.3 and 5.5. Surprisingly, the European Communities appears to have the impression that Canada is making a claim with respect to the obligation in Article 5.5 to cooperate in the development of guidelines with respect to the practical implementation of that article. There is nothing in the description of the measures in Canada's panel request to suggest that this is part of Canada's claim.

4.93 The European Communities also lists Articles 7 and 8 of the *SPS Agreement* as containing multiple obligations. A review of these two provisions makes it clear, however, that they simply establish general obligations on the WTO Members to meet the specific requirements of Annexes B and C. The fact that Canada's panel request specifically mentions paragraphs 1, 2 and 5 of Annex B, and paragraphs 1(a), 1(b), 1(c), and 1(e), of Annex C, makes it clear that the inclusion of Articles 7 and 8 cannot be taken to mean that Canada is claiming a general violation of Annexes B and C. If that were the case, Canada's specific references to the listed paragraphs would be redundant.

4.94 In sum, there is nothing in the DSU or the jurisprudence to suggest that listing many provisions necessarily requires any more detail than listing relatively few provisions. Also, the European Communities' complaint about being faced by multiple obligations does not stand up to closer scrutiny, or provide support for its claim that Canada's panel request does not provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly.

(b) Canada's panel request establishes an adequate link between the provisions listed and the measures at issue, consistent with Article 6.2

4.95 There is no requirement in the DSU that a panel request draw a link between the legal obligations at issue and "the facts of the case". Rather, the obligation in Article 6.2 is to identify the specific measures at issue and provide a brief summary of the legal basis. This is precisely what Canada's panel request does.

4.96 First, Canada's panel request states, after describing the measures at issue, that "[t]hese measures are inconsistent with the obligations of the EC" under four specific agreements, and specifies which provisions of those agreements are being violated. Canada has met the requirement to clearly identify the specific measures. The subsequent listing of the specific provisions being violated must be read in the overall context of the panel request. Some provisions are obviously relevant to some claims, and just as obviously irrelevant to other claims. Finally, because the *SPS* and *TBT Agreements* are mutually exclusive, it should be clear that the provisions of the *TBT Agreement* are listed in the alternative.

4.97 Second, it is inappropriate for the European Communities to challenge Canada's panel request on the basis of the alleged complexity of the three panel requests taken as a whole. Each panel request must be evaluated on its own merits in light of the requirements of Article 6.2. Canada's request is clear, specific and provides adequate information for the European Communities to understand the nature of the measures at issue and the legal basis for the complaint. The European Communities' reference to a multiplicity of provisions and legal obligations, and to 41 applications for approval of biotech products and nine EC member State national measures, misleads the Panel as to the actual scope of Canada's panel request. However, even if it were appropriate for the adequacy of the three panel requests to be judged as a whole under Article 6.2, the three panel requests all meet the standard of that provision.

4.98 Third, in examining the adequacy of Canada's panel request, the Panel should also have regard to other "attendant circumstances," such as the long history of bilateral consultations between Canada and the European Communities, and the lengthy list of questions submitted by Canada to the European Communities in advance of the WTO consultations held on 25 June 2003. When these numerous communications are taken into account, it quickly becomes clear that the European Communities has been apprised of the nature of this dispute, and of the allegations by Canada in its panel request, well before the panel was established on 29 August 2003.

4.99 Finally, the European Communities provides three recent panel requests filed by the complaining parties in other WTO disputes, and offers these as a means to "facilitate the task of the Panel in assessing what is the acceptable standard of precision for requests under Article 6.2." However, the European Communities fails to indicate that the three panel requests were all made in an anti-dumping context. The Appellate Body has pointed out that Article 6.2 and Article 17.5 of the *Anti-Dumping Agreement* are complementary, and that Article 17.5 contains "additional requirements." Specifically, the Appellate Body found that "[a] panel request made concerning a dispute brought under the *Anti-Dumping Agreement* must therefore comply with the relevant dispute settlement provisions of both that Agreement and the DSU."

4.100 To suggest that the Panel rely on these panel requests as the standard against which to judge the adequacy of Canada's panel request, is inappropriate. The three panel requests cited by the European Communities are simply irrelevant to a determination of the "acceptable standard of precision" for requests made under Article 6.2 alone.

(c) Article 6.2 does not require a complaining party to include a summary of its legal argument in its request to establish a panel

4.101 In stating that Canada's panel request "should indicate which provisions may be relevant for the examination of each measure, possibly describing the substantive aspects or the effects of the measures which are allegedly in breach of those provisions," the European Communities is actually complaining that Canada has not indicated what legal arguments it intends to pursue. According to the jurisprudence, there is no requirement to set out legal arguments in a panel request. The European Communities' arguments in this regard are clearly without merit and should be rejected.

5. Canada's panel request does not prejudice the ability of the European Communities to defend itself

4.102 Whether a responding party has suffered prejudice is a relevant consideration in determining if a panel request has met the requirements of Article 6.2. A responding party must demonstrate prejudice with "supporting particulars".

4.103 The European Communities does not offer any valid supporting particulars to justify a finding of prejudice. It appears that the European Communities is claiming prejudice on the basis that it "has been unable to start preparing its case in a meaningful way." In support of this assertion, the European Communities merely restates its arguments, refuted above, regarding the lack of specificity in the identification of the measures at issue and the multiplicity of claims being made. Such a mere restatement is plainly insufficient to establish prejudice. If lack of detail in the panel request automatically implied "prejudice," there would be no need for a separate "prejudice" analysis. Even if the European Communities could show that Canada's panel request does not meet the requirements of Article 6.2, it has offered nothing to show that it has been prejudiced.

4.104 Even if the European Communities' assertion that it "has been unable to start preparing its defence in any meaningful way" is true, which is highly doubtful, it has nothing to do with the lack of specificity in the identification of the measures at issue or the absence of a brief summary of the legal basis for the claims. Given that this panel was established in August 2003, the European Communities has had more than enough time to begin preparing its case. The consequences of its alleged failure to do so should be borne the European Communities, not by the complaining parties.

4.105 In particular, the European Communities has not provided any explanation for why it waited almost seven months since the filing of Canada's panel request to raise its concerns regarding claimed procedural deficiencies. This delay by the European Communities runs counter to the statements by the Appellate Body that responding Members must promptly bring claimed procedural deficiencies to the attention of the complaining Member, and to the DSB or the Panel, and that the procedural rules of WTO dispute settlement are designed to promote, not the development of litigation techniques, but the fair, prompt and effective resolution of trade disputes.

4.106 In light of this delay and the absence of any explanation for the delay, the European Communities' claim that it has suffered prejudice lacks credibility. Canada submits that this request is merely a litigation technique intended to undermine the fair, prompt and effective resolution of this dispute.

D. PRELIMINARY WRITTEN SUBMISSION OF ARGENTINA

1. Introduction

4.107 The European Communities claims that the request for the establishment of the panel did not present the legal basis of the complaint in a manner sufficiently clear to enable the European Communitieis to fully identify the specific measure at issue and to fully understand the legal basis of the complaint. Argentina will address these two claims on the basis of the textual obligations of Article 6.2, taking into account the general due process considerations related to the specific requirements of the article.

2. Object and purpose of Article 6.2

4.108 The main purpose of Article 6.2, as has been recognized by WTO jurisprudence, is directly related to the jurisdiction of a panel and due process considerations.[65] The process to assess the fulfilment of Article 6.2 requirement should be undertaken by a Panel on a *case by case basis*, in the light of the *attendant particular circumstances* and assessing the *prejudice* issue which remains at the heart of the due process consideration.

[65] *See* Appellate Body Report, *EC – Bananas III*, para. 142.

4.109 *Due process* requirements as previously defined by panels and the Appellate Body, are relevant for all parties in the dispute, including complaining parties. The Panel must consider the impact on the rights of Argentina and other complaining parties of an overly strict, formalistic interpretation of Article 6.2 as compared to a textual interpretation.

3. The European Communities' claim regarding partial lack of identification of the measure at issue

4.110 The European Communities' request on this point is limited to the claim of suspension of consideration of and failure to consider various applications for approval of agricultural biotech products, as presented in point (1) of the first page of Argentina's Panel request.[66] The European Communities has conceded that it has no preliminary objection related to the claims on national marketing and import bans and has put forward no argument related to Argentina's claim of undue delays in finalizing consideration of various applications for approval of agricultural biotechnology products.[67]

4.111 The need to analyse the Panel request in its entirety has been expressly recognized in the recent Panel report on *Canada – Wheat Exports and Grain Imports.* Reading the Panel request as a whole, it is apparent that the measure the European Communities claims is incompletely identified has been preceded by the fourth paragraph of Argentina's Panel request, which states:

> "This action taken by the European Communities and some of its member States adversely affects agricultural biotechnology products from Argentina"[68]

4.112 This general and introductory paragraph refers to the action undertaken by the European Communities which Argentina is challenging in these proceedings. The relevant question at this point of the analysis is:which action by the European Communities led to the measure at issue? The answer may be found easily by referring to the second paragraph of Argentina's Panel request:

> "The European Communities has applied a de facto moratorium on the approval of agricultural biotechnology products since October 1998. This de facto moratorium[69] has led to the suspension of and failure to consider various applications for approval of agricultural biotechnology products as well as to undue delays in finalizing the processing of applications for the approval of such products under Community legislation.[70]"[71]

4.113 The *de facto* moratorium is the action constituting a conduct of *suspension* of consideration or *failure* to consider. The *de facto* moratorium is an omission attributed to the European Communities

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[66] WT/DS293/17.

[67] *See* footnote 14 on EC request for preliminary ruling.

[68] WT/DS293/17, English version, paragraph fourth, page 1.

[69] WT/DS293/17, footnote 1: *"1.See Annex I"*.

[70] (footnote original) *Ibid.*, footnote 2: "EC legislation on biotech product approval includes Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001, published in Official Journal No. 106 of 17 April 2001, pages 0001-0039 (and its predecessor Council Directive 90/220/EEC of 23 April 1990, published in Official Journal No. 117 of 8 May 1990 and amended by *Directive 94/15*, published in Official Journal No. 103 of 22 April 1994, and by *Directive* 97/35, published in Official Journal No. 169 of 27 June 1997), and Regulation (EC) No. 258/1997 of the European Parliament and of the Council of 27 January 1997, published in Official Journal No. 043 of 14 February 1997."

[71] WT/DS293/17, p. 1, 2nd para.

which amounts to a breach of its obligations under WTO law.[72] According to the dictionary, *de facto* means "in fact, in reality in actual existence…whether by right or not".[73] The word *de facto* qualifies moratorium which is at the heart of this dispute. *Moratorium*, according to a textual approach, means "a postponement or deliberate suspension of some activity".[74] The action to suspend may be easily understood by reading the subject of the suspension in the same paragraph, i.e. the link to *various applications for approval of agricultural biotechnology products*. The nature and extent of the legal argument related to the suspension, as well as the specificity of the suspension in relation to specific applications, is something to be developed as part of the argument.

4.114 Equally, the failure ("omission to do"[75]) to consider *various applications for approval* is not difficult to understand. There are applications submitted for approval which are subject to the *de facto moratorium*.

4.115 The universe of the applications and the factual circumstances surrounding each of them, as well as the fact that specific applications cited by individual complaining parties may lead to different arguments during the Panel proceedings, is not a matter to be dealt with in a panel request or a request for a preliminary ruling.

4.116 It should be noted that the status of various applications is a matter discussed at length during the consultations. The European Communities cannot ignore now the kind of inquiry undertaken during the consultations, which led to the current wording in the panel request.

4.117 The European Communties further alleges that in other proceedings before the DSB, not only Argentina but the other complaining parties have been able to identify the matter at issue with a precision that, in the view of the European Communities, is absent in the case at hand. Argentina respectfully suggests that the Panel consider the following circumstances. First, Argentina is not in a position to comment on the cases cited as examples by the European Communities for the alleged deficiencies in the US and Canada panel requests. Second, Argentina notes that the three cases cited as examples were dumping cases, a subject which is governed by the specific provisions of the *Anti-Dumping Agreement* which contains rules that qualify the provisions of Article 6.2 of the DSU. Also, the very nature of the measures subject to challenge is different in each circumstance – duly enacted national provisions regulating the conduct of formal proceeding in the case of the *Anti-Dumping Agreement* on the one hand and an informal *de facto* moratorium on the application of national provisions on the other hand.

4.118 At this stage, it should be said that the alleged problem with the measure at issue is an attempt by the European Communities to request the development of a factual description of the moratorium which rightly pertains to the development of arguments and the fact-finding process. This attempt should be firmly rejected by the Panel, particularly taking into account the nature of the measure at issue. The type of measure at issue, the *de facto moratorium* leading to suspension or failure to consider applications, necessarily affects the extent and nature of information required to properly present the claim.

4.119 The request of Argentina singles out specific applications. Whether the totality of applications are at stage of suspension (i.e. have been considered and are now suffering a delay), or

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[72] *See* Appellate Body Report, *US – Corrosion-Resistant Steel Sunset Review*, para. 88.
[73] *The New Shorter Oxford English Dictionary*, 1993 Edition, page 615.
[74] *The New Shorter Oxford English Dictionary*, 1993 Edition, page 1829.
[75] *The New Shorter Oxford English Dictionary*, 1993 Edition, page 907.

alternatively were submitted but there is a failure to consider them, is an issue to be defined in the proceedings.

4. The alleged lack of brief summary of the legal basis

(a) Textual reading

4.120 The European Communities' challenge to the Argentine summary of the legal basis of the complaint, contained in document WT/DS293/17, has a wrong departure point as shown by a textual reading. The European Communities resorts to a dictionary definition of "summary" in its request for a preliminary ruling. However, it fails to take into account that Article 6.2 qualifies the word "summary" with the adjective "brief". The dictionary definition of "brief" indeed refers to something "limited…concise in expression …"[76], This is a very different standard from the concept of a summary which is close to an argument, as posited by the European Communities in its preliminary request.

(b) Identification of the legal basis

4.121 The failure to identify a specific provision of an agreement allegedly violated certainly would be a problem. However, this is not the case at hand where all relevant provisions of the different agreements have been included in the Panel request.[77]

4.122 Contrary to European Communities' allegations, a comparison between Argentina's request for a Panel and it's request for consultations shows the much more precise degree of specificity in the Panel request.[78] Document WT/DS293/17 includes some, but not all, subparagraphs of articles from different agreements that were part of the consultation process. The case-law from *Korea – Dairy*[79] quoted by the European Communities is not relevant in this case, since in *Korea – Dairy* the terms of reference included quotations of general articles without any detail on particular subparagraphs within the article, in contrast with Argentina's request for a panel. In order to clarify Argentina's position and the erroneous citation to *Korea – Dairy*, it is useful to quote the European Communities' description in that case:

> "Therefore, the EC requests that the panel consider and find that this measure is in breach of Korea's obligation under the provisions of the Agreement on Safeguards, in particular of Articles 2, 4, 5 and 12 of the said Agreement and in violation of Article XIX of GATT 1994".

4.123 This identification of the WTO legal provisions allegedly violated by Korea is strikingly different from the description provided in the current panel request. Therefore, the legal basis has been properly identified.

(c) The issue of multiple obligations

4.124 Although the EC Request addresses the issue of multiple obligations, it should be rejected for two reasons. First, the WTO precedent used in by the European Communities to support it's views is completely different from the case at hand. In the precedent, *Korea – Dairy*, multiple obligations

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[76] *The New Shorter Oxford English Dictionary*, 1993 Edition, page 282.
[77] WT/DS293/17, page 2, indents a) b) c) and d).
[78] WT/DS293/1.
[79] Section III.B EC request for preliminary ruling.

were embodied within the main articles quoted broadly by the complainant. In contrast, in the current case, Argentina has put forward the Panel's terms of reference with enough detail to identify articles and subparagraphs containing specific obligations infringed by the European Communities' *de facto moratorium*. Second, in the case at hand, the subparagraphs of specific agreements quoted by the European Communities do not contain multiple obligations, they simply set forth the necessary requirements to demonstrate an infringement of the WTO's provisions. The fulfilment of each requirement necessary to find an inconsistency is something to be developed through the arguments that the complaining parties will present to the Panel in their First Written Submission and subsequent communications.

4.125 To require the development of the rationale and argument underlying each claim is contrary to well-established and recently confirmed WTO jurisprudence, as in the case of *Canada – Wheat Exports and Grain Imports*. In other words, the European Communities' challenge is simply an attempt to impose a requirement to submit a narrative that is more proper for arguments than for a challenge of a legal basis for a claim.

5. The lack of prejudice

4.126 As established by the Panel in the *EC – Bed Linen,* prejudice has to be shown in order for an Article 6.2 claim to prevail. Argentina denies that the European Communities has suffered prejudice in this proceeding as a consequence of the Terms of Reference set out in its panel request. There is neither lack of specificity of the "measure at issue" nor inaccuracy in the identification of the WTO' obligations violated by the European Communities.

4.127 The European Communities' claim of prejudice and alleged inability to prepare its defence lacks credibility when one considers the extensive consultations in this case. Argentina provided written questions to the European Communities and consulted as required by the DSU.

4.128 Moreover, the European Communities argues that because of the obscurity of the panel request, it is unable to answer the case. This argumentation must be proved in light of the requirements of Article 6.2 of the DSU. The European Communities' complaint is merely an unsubstantiated assertion of prejudice. WTO case law demonstrates that such assertions simply do not constitute demonstrated or substantiated prejudice for the purposes of Article 6.2 of the DSU.

4.129 Finally, prior panels have rightly determined that whether there is prejudice during the panel proceedings can only be determined at the end of such proceedings. Because the European Communities requested a preliminary ruling to be granted prior to the presentation of the First Written Submissions, it must carry the burden of proving that it has suffered prejudice at this early stage of the proceedings.

E. FIRST WRITTEN SUBMISSION OF THE UNITED STATES

1. Introduction

4.130 The European Communities has adopted approval procedures for agricultural products produced with the benefit of modern biotechnology. Up to October 1998, the European Communities implemented those procedures, and approved more than ten biotech products. Consumers in the European Communities have been enjoying the benefits of these products, without any adverse health or environmental effects.

4.131 Starting in October 1998, however, the European Communities suspended its own approval procedures. In particular, the European Communities suspended consideration of applications for, or granting of, approval of biotech products under the European Communities' approval system. Particular product applications might make some progress, in fits and starts, through the European Communities' approval system, but the European Communities has failed to allow any new biotech product to move to final approval since October 1998.

4.132 The European Communities' adoption of a moratorium on product approvals was not adopted in a transparent matter. Indeed, it was not published in any official journal or otherwise memorialized. Nonetheless, the moratorium is widely-recognized, including by leading EC officials. And, it is just as effective as any amendment to the European Communities' approval legislation formally enacted into law.

4.133 The United States submits that the European Communities' adoption of the moratorium is inconsistent with the European Communities' obligations under the WTO Agreement, and in particular the *SPS Agreement*. While Members are allowed to maintain approval systems – and the United States is not objecting to the European Communities maintaining such a system for biotech products – the procedures under that system must be undertaken and completed "without undue delay." It is hard to think of a situation that involves "undue delay" more than a complete moratorium on approvals. In this case, the European Communities can present no scientific basis for a moratorium on biotech approvals. In fact, many of the products caught up in the European Communities' moratorium have been positively assessed by the European Communities' own scientific committees. In short, having established a biotech approval regime, the European Communities is obligated to apply those procedures fairly and transparently, and without undue delay.

4.134 In addition to the moratorium on the approval of new biotech products, six EC member States have adopted marketing or import bans on biotech products that previously have been approved by the European Communities. These product-specific bans, like the moratorium, are not based on science and are thus inconsistent with the European Communities' obligations under the WTO Agreement.

4.135 In challenging the European Communities' moratorium under the DSU, the United States is simply calling on the European Communities to allow its own approval procedures to run their course. The United States is confident that once the European Communities allows its scientific and regulatory procedures to reach their conclusion, it will once again approve new biotech products, benefitting EC consumers and biotech producers around the world.

2. Statement of facts

(a) Biotechnology

4.136 Modern biotechnology has a number of proven benefits for human health and the environment, including higher agricultural output, more nutritional food products, and lower utilization of agricultural chemicals, fertilizers, and water in commercial farming.

4.137 Modern biotechnology can significantly increase agricultural output by protecting plants from factors that reduce yields, such as pests, diseases, spoilage and extreme weather conditions. A report issued by seven national and international academies of science ("Multinational Science Academies Report") concluded that modern biotechnology must play a role in addressing the shortage of food in the developing world, where 800 million people currently do not have access to sufficient food and malnutrition is a contributing factor in the deaths of six million children under the age of five each year. In its Statement on Biotechnology, the Food and Agriculture Organization of the United

Nations ("FAO") said, "genetic engineering has the potential to help increase production and productivity in agriculture, forestry and fisheries. It could lead to higher yields on marginal lands in countries that today cannot grow enough food to feed their people." A Joint FAO/World Health Organization ("WHO") report of scientific experts recognized that "developing countries look on [recombinant DNA] technology as a means of addressing the need to produce sufficient quantities of nutritionally adequate and safe food for their growing populations."

4.138 Biotechnology is also helping to increase the nutritional value of foods. The multinational science academies report recognized that "[f]oods can be produced through the use of [genetic modification] technology that are more nutritious, stable in storage, and in principle health promoting – bringing benefits to consumers in both industrialized and developing nations." Further, the Pontifical Academy of Sciences stated that "the nutritional enhancement of foods, either in terms of amino acid balance or in enhancing the presence of vitamins or their precursors ... can be attained more efficiently and precisely with the use of methods that are now available involving the direct transfer of genes."

4.139 Modern biotechnology can also provide numerous environmental benefits, including, as stated by the Research Directorate-General of the European Commission, "'cleaner' agriculture." Biotech products that are resistant to insect pests require less insecticide to achieve a given level of protection than products that are not resistant to such pests. The use of biotech crops also permits farmers to employ conservation tillage techniques that reduce soil disturbance and erosion and increase carbon sequestration. In addition, modern biotechnology is producing crops that are able to absorb nitrogen and phosphorous at elevated rates, thus reducing the amount of fertilizer that needs to be applied. Scientists are also developing crops that require less water, which will not only increase productivity in areas with little water but also reduce the need for large-scale irrigation, thus protecting supplies of fresh water and reducing harm to ground and surface water quality.

4.140 The safety of biotech products has been confirmed by scientific reports issued under the auspices of renowned international institutions, such as the FAO and WHO, seven national and international academies of science, and the Organization for Economic Co-operation and Development, as well as independent scientists in the United States, Africa and Europe. In fact, the European Commission itself has endorsed the safety of biotech products, declaring that "the use of more precise technology and greater regulatory scrutiny probably make [biotech products] safer than conventional plants and foods."

4.141 The scientific findings on the safety of biotech products are confirmed by empirical evidence. For the past decade, farmers in various parts of the world have been sowing and harvesting millions of acres of transgenic corn, soybeans, rapeseed, potatoes and cotton, all of which are used, to greater or lesser degrees, in the production of food products or animal feed. The multinational science academies report concluded that "[t]o date, over 30 million hectares of transgenic crops have been grown and no human health problem associated specifically with the ingestion of transgenic crops or their products have been identified." Similarly, the French National Academy of Science noted that transgenic crops are widely cultivated, and "there has never been a health problem regarding consumers or damage to the environment."

4.142 By 2002, five and a half to six million farmers were cultivating crops derived from recombinant DNA technology on 58.7 million hectares (145 million acres) of land. Since 1996, the global land area devoted to transgenic crops has grown thirty-five-fold. Transgenic crops are cultivated in sixteen countries, which together account for more than half the world's population. Worldwide, fifty one percent of soybeans are produced from transgenic seed, as well as twenty percent of cotton, twelve percent of oilseed rape (canola) and nine percent of corn.

(b) Moratorium on approvals of biotech products

4.143 Since October 1998 – the last date of a biotech product approval -- the European Communities has failed to approve any new biotech products under its novel foods or deliberate release legislation. The United States submits that this failure to approve all pending applications is the result of a *de facto* moratorium under which the European Communities has suspended the consideration of applications for, or granting of, approval of biotech products under its pre-market approval system.

4.144 The moratorium became widely known no later than June 1999, when it was announced by Environment Ministers of five member States. In particular, at a Council Meeting of EC Environment Ministers in June 1999, Environment Ministers of Denmark, Greece, France, Italy and Luxembourg issued a Declaration stating: "in exercising the powers vested in them regarding the growing and placing on the market of genetically modified organisms… they will take steps to have any new authorizations for growing and placing on the market suspended."

4.145 The statements of Commission and member State officials confirm the existence of a moratorium. For example, as early as July 2000, European Environment Commissioner Margot Wallström publicly admitted the existence of a "moratorium," calling it "illegal and not justified." This sentiment was reiterated at a press conference in October 2001 following a meeting of the Council of Environment Ministers when Wallström reportedly "admitt[ed] that no end was in sight for the moratorium, which she said was an illegal, illogical, and otherwise arbitrary line in sand." She added that there was no other EU legislation in the same situation in which "we just simply decline to take a decision."

4.146 European Commissioner for Health and Consumer Protection, David Byrne, stated in June 2000 that the reluctance of member States to approve the placing on the market of new biotech products "has resulted in a complete standstill in the current authorizations and a *de facto* moratorium on the commercial release of GMOs." Commissioner Byrne again acknowledged the existence of the moratorium in February 2003 when he implored member States that "we must lift the moratorium."

4.147 The statements of European Commission officials acknowledge not only the existence of the moratorium but also that it is maintained without scientific or legal justification. In fact, EC Environment Commissioner Margot Wallström herself remarked after pleading unsuccessfully with the Environment Council to lift the moratorium: "We have 11 GMO seed notifications approved. ... But then there was an arbitrary line drawn before I came into office [in 2000] to stop all approval for the 13 other pending applications. But many of these 13 are simply varieties of the first 11 approved. They are essentially the same products. There is no science that says these are more or less dangerous than others." Similarly, Beate Gminder, spokeswoman for Commissioner Byrne, stated that "[t]he moratorium has no legal basis."

4.148 Commission documents also confirm the existence of the moratorium. A Commission Working Document dated November 2000 states "the current authorization procedure for commercial release of GMOs, including those that may end up in the food chain, has ground to a standstill. A Commission Press Release dated July 2001 states that the adoption of new legislative proposals "will contribute towards the lifting of the *de facto* moratorium on the commercial release of GMOs." An October 2001 internal Commission working paper states that "[t]his reluctance to go forward with authorizations of GMOs has resulted in a *de facto* moratorium on the marketing of new GMOs and impacted on product approvals under the sector-based legislation." In July 2003, a Commission fact sheet on GMO regulation stated that "[t]he revised Directive [2001/18] and the two proposals for Regulations are expected to pave the way for a resumption of GM authorizations in the European

Union," implying that authorizations had been suspended. A document issued by the General Secretariat of the Council of the European Union stated that the proposed rules on traceability and labelling of biotech products could "possibly lead to the lifting of the current moratorium." More recently, in a January 2004, Communication to the Commission, Commission officials admitted that "no authorizations have been granted since October 1998" despite the adoption of an "interim approach" to biotech product approvals allegedly adopted in July 2000.

4.149 The existence of a moratorium on approvals of biotech products is further evidenced by the failure of the European Communities to approve a single biotech product since October 1998 under Directive 2001/18 (and its predecessor Directive 90/220), as well as under Article 4 of Regulation 258/97. Currently, twenty-seven applications for placing biotech products on the market are delayed at various stages of the approval process under Directive 2001/18 (and, prior to 17 October 2002, under Directive 90/220) and Regulation 258/97.

4.150 There are eighteen biotech products with notifications pending under Directive 2001/18 that were first submitted under Directive 90/220 and then failed to advance through the approval process. Of these eighteen products, nine were stalled at the Commission level at the time Directive 90/220 expired, some having languished for as long as six years and five months. All nine of these products received favourable initial assessments from the sponsoring member State and positive opinions from the Scientific Committee for Plants, which in each case found "no evidence to indicate that the placing on the market [of the product in question] is likely to cause any adverse effects on human health and the environment." The remaining nine notifications were delayed at the member State level under Directive 90/220 and have awaited consideration for as long as four years and ten months.

4.151 Under Regulation 258/97, the requests for five products have been delayed at the Commission level for as long as five years. Each of these products received favourable assessments for their sponsoring member State and two products also received positive opinions from the Scientific Committee on Food. An additional four requests are pending with the individual member States, some of which were submitted as early as July 1998.

(c) Member States' marketing or import bans

4.152 Six EC member States – France, Germany, Austria, Italy, Luxembourg, and Greece – have invoked the so-called "safeguard" provisions in Directive 90/220 and Regulation 258/97 with respect to biotech products that have been approved for sale on the European market. Five member States enacted marketing bans (Austria, France, Germany, Italy, and Luxembourg) and one (Greece) enacted an import ban.

4.153 In particular, Austria issued three measures prohibiting the "placing on the market" of three corn biotech products: Bt-176, MON810 and T25; France issued two Orders on November 16, 1998, prohibiting the "placing on the market" of two rapeseed biotech products: MS1/RF1 and Topas 19/2; Luxembourg issued a Ministerial Order on February 7, 1997, prohibiting the "use and sale" of biotech corn Bt-176; Germany issued a Ruling 31 March 2000, "suspending the approval" and the placing on the market of Bt-176; .Italy issued a Decree on 4 August 2000, suspending the "commercialization and use" of the following corn products: Bt-11, MON810, MON809 and T25; and Greece issued a Decree 8 September 1998, prohibiting the importation of Agrevo oilseed rape (Topas 19/2).

4.154 In each case, the applicable scientific committee of the European Communities found that there was no scientific basis for the member State safeguard measure. Yet, those measures all remain in place.

3. Legal discussion

(a) General moratorium violates the *SPS Agreement*

4.155 The general moratorium is one component of the European Communities' biotech approval regime; in particular, the general moratorium is a moratorium on approvals under the novel foods and deliberate release legislation. The European Communities' biotech approval regime is unquestionably an SPS measure. Directive 2001/18 states that one of the objectives of the Directive is "to protect human health and the environment" when, among other things, "placing on the market genetically modified organisms as or in products within the Community." Similarly, its predecessor legislation, Directive 90/220, states that one of its objectives is "to protect human health and the environment" from, among other things, "placing on the market products containing, or consisting of, genetically modified organisms intended for subsequent deliberate release into the environment." Finally, Regulation 258/97 states that "[f]oods and food ingredients falling within the scope of the Regulation must not present a danger for the consumer" or be "nutritionally disadvantageous."

4.156 In addition to the purpose that is set out so clearly in the approval legislation, statements made by European Communities and member State officials reinforce that the purpose of the European Communities' approval regime, including the general moratorium, is to protect human, animal, or plant life or health from certain risks. Over the past five years, European Communities and member State officials have frequently stated that the moratorium has been imposed to protect "citizens" and "the environment." Moreover, a recent Commission "Working Document" indicated that the freeze of the current authorization procedure for biotech products has occurred in light of the fact that the "public is increasingly concerned about potential implications for *human health and the environment*."

4.157 These justifications for the European Communities' approval regime, including the general moratorium, fall within the definition of an SPS measure under the Agreement. For example, concerns that a biotech product might lead to an allergic or toxic reaction on the part of certain animals, *e.g.*, concerns that some varieties could harm beneficial organisms as well as target organisms, fall within the definition of Annex A, paragraph 1(a)—which covers measures applied to protect "animal or plant life or health" from risks arising from "disease-causing organisms." The concern that a biotech product might lead to an allergic or toxic reaction on the part of consumers, *e.g.*, concerns regarding unacceptable levels of pesticide residue in pesticide-producing plant varieties, allergic reactions based on consumption of a biotech variety that incorporates a genetic trait that can lead to such reactions, or the presence of toxins or other contaminants in foods containing biotech products, falls within the definition of Annex A, paragraph 1(b)—which covers measures applied to protect "human or animal life or health" from risks arising from "contaminants" or "toxins" in "foods, beverages or feedstuffs."

4.158 Similarly, concerns that widespread consumption of varieties containing antibiotic marker genes might lead to the development of antibiotic resistant strains of bacteria also fall under the definition of 1(b). Such concerns have been characterized as food safety issues. Thus, a measure based on these concerns is a measure designed to protect "human or animal life or health" from "disease-causing organisms" in "foods, beverages or feedstuffs." Additionally, concerns regarding the cross-contamination (or transfer) of biotech products to non-target organisms, *e.g.*, concerns that herbicide tolerance could be transferred from a biotech variety to a wild variety, fall within the scope of Annex A, paragraph 1(d)—which covers measures applied "to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests." Annex A defines "pests" to include weeds, defined in the *New Shorter Oxford English Dictionary* as "plant[s] that grow[] ... where [they are] not wanted." Thus, a measure based on this risk falls within the definition of Annex A, paragraph 1(d).

4.159 The general moratorium, as one component of the European Communities' biotech approval regime, qualifies as a "measure." Approval procedures are listed in the definition of SPS measure in Annex A as a specific example of an SPS measure. The fact that the moratorium component is not embodied in a single written document does not alter its status as a measure. Certainly, if the European Communities had acted transparently and amended its novel food and deliberate release regulations to provide for an indefinite suspension of approval procedures, the amendment would be a "law," "decree," or "regulation" and fall within the scope of an SPS "measure". The fact that the European Communities has adopted the moratorium in a nontransparent way, without official publication, in no way changes that result.

4.160 Moreover, the *SPS Agreement* includes in its definition of "measure" the terms "requirement" and "procedure", which are not necessarily in written form. For example, the *New Shorter Oxford English Dictionary* defines the term "procedure" as a "particular mode or course of action" or a "set of instructions for performing a specific task which may be invoked in the course of a program." Under the ordinary meaning of the term "procedure," a suspension by the European Communities of the consideration of applications for, or granting of, approval of biotech products is an unwritten procedure covered under the *SPS Agreement*.

4.161 In addition, the list of measures subject to the *SPS Agreement* is not exhaustive. Paragraph 1 of Annex A states, in relevant part, that "[s]anitary or phytosanitary measures *include* all relevant laws, decrees, regulations, requirements and procedures." The use of the word "include" indicates that the Agreement covers more than just the identified types of measures, and should be read to include other measures that may not fit squarely within the illustrative list.

4.162 Finally, the object and purpose of the *SPS Agreement*, and more broadly the WTO Agreement, supports a broad interpretation of what constitutes a "measure." The preamble of the Agreement provides that one object and purpose of the Agreement is to "minimize [the] negative effects [of SPS measures] on trade." If a WTO Member could avoid its SPS obligations by adopting a nontransparent, unwritten SPS measure that has a negative effect on trade, the objects and purposes of the *SPS Agreement* would not be fully realized.

4.163 The general moratorium also "affects international trade" and, thus, meets the second requirement under Article 1.1 of the *SPS Agreement*. Biotech products may not be placed on the market in the European Communities without first being approved under the required legislation. The European Communities' general moratorium has since October 1998 precluded the placing on the market of any and all biotech products in the European Communities, including imported biotech products. The general moratorium, thus, is effectively an import ban that affects any and all foreign biotech products and, thus, the "international trade" in those products.

4.164 The European Communities has failed to comply with the requirements of Article 8 and Annex C, paragraph 1(a) of the *SPS Agreement*. These provisions require that "with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, ... such procedures are undertaken and completed without undue delay ... ."

4.165 The European Communities' approval process for biotech products is subject to the requirements of Article 8 and Annex C. First, the European Communities' process is an "approval procedure" under the Agreement. Annex C defines "approval procedures," as including, *inter alia*, "procedures for sampling, testing and certification." Because biotech products must be approved before they can be placed on the market, the procedures are analogous to the types of procedures specifically articulated in Annex C, *e.g.*, procedures for certification.

4.166 Second, these procedures are imposed to "ensure" that the requirements of the European Communities' approval legislation for biotech products are met. Third, the European Communities' approval legislation is a "sanitary or phytosanitary measure" as defined in Annex A, paragraph 1 of the *SPS Agreement* because it is applied for the purpose of protecting human, animal, or plant life or health or preventing or limiting other damage within the territory of the Member from certain enumerated risks in Annex A.

4.167 The term "undue delay" is not defined in Annex C. Examination of the "ordinary meaning" of the words "in their context and in the light of [the] object and purpose" of the treaty, as required by the customary rules of treaty interpretation reflected in Article 31 of the Vienna Convention, helps provide content to the term. The ordinary meaning of "undue" is "inappropriate, unsuitable, improper; unrightful; unjustifiable. Going beyond what is warranted or natural; excessive; disproportionate." The ordinary meaning of delay is "hindrance to progress; (a period of) time lost by inaction or inability to proceed; impede the progress of, make late, hinder." Thus, the ordinary meaning of "undue delay" under paragraph 1(a) of Annex C is the "unjustifiable" and "excessive" "hindrance" in undertaking or completing an approval procedure. The ordinary meaning of "undue delay" suggests that both the reason for the delay and its duration are relevant considerations in determining whether the delay is "undue".

4.168 Although it may be difficult in particular cases to decide whether approval procedures are undertaken and completed without undue delay, the United States submits that an across-the-board suspension of approval procedures must be considered an "undue delay" under Annex C. As recognized by EC officials, there is no scientific basis for the failure to move forward under the procedures and timelines provided in the European Communities' own legislation. Moreover, many of the biotech products caught up in the European Communities' general moratorium have already been subject to positive assessments by the sponsoring member State and the European Communities' own scientific committee.

4.169 Where the European Communities' own legislation provides procedures and timelines for the approval of biotech products, an indefinite suspension of that approval procedure, without any scientific justification, must be considered "undue delay" under Annex C.

4.170 The European Communities has also violated Article 7 and Annex B, paragraph 1 of the *SPS Agreement*. Article 7 specifically states that "Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B" Annex B, paragraph 1, states that "Members shall ensure that all sanitary and phytosanitary regulations which have been adopted are *published promptly* in such a manner as to enable interested Members to become acquainted with them." As the European Communities has failed to publish, and, therefore, to "publish[] promptly," the existence of the general moratorium, the European Communities has acted inconsistently with its obligations under Article 7 and Annex B.

4.171 The general moratorium is also inconsistent with each of the related procedural obligations in Annex C(1)(b) of the *SPS Agreement*, considering each element of this provision as follows:

- "the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request": Although the European Communities' novel food and deliberate release directives contain processing periods, under the general moratorium those processing periods are not followed. Instead, the European Communities has imposed an indefinite delay. However, since the European Communities does not acknowledge the moratorium,

the standard processing period is not published, and the anticipated processing period is not communicated to the applicant.

- "when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies": Under the general moratorium, the European Communities does not promptly examine documentation and inform the applicant of all deficiencies. To the contrary, applications under the EC directives are stalled, without explanation.

- "the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary": Under the general moratorium, results of procedures are not promptly communicated to applicants so that corrective action may be taken. Instead, applications are stalled in the approval process without explanation.

- "even when the application has deficiencies the competent body proceeds as far as practicable with the procedure if the applicant so requests": Under the general moratorium, the European Communities does not proceed as far as practicable in the approval process. Instead, one again, application are stalled in the approval process.

- "and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained": Under the general moratorium, delays are not explained. To the contrary, the European Communities does not even inform applicants of the existence of the moratorium.

4.172 To the extent the European Communities' suspension of consideration of applications for, or granting of, approval of biotech products (the general moratorium) is preventing the sale or marketing of biotech products, the general moratorium violates Article 5.1 of the *SPS Agreement*. In order for a measure to be based on a risk assessment in accordance with Article 5.1, the following two criteria must be met: (1) "the study put forward as a risk assessment [must] meet the requirements of a risk assessment set forth in Article 5.1 and Annex A of the *SPS Agreement*"; and (2) "the sanitary measures ... selected [must be] *based on* this risk assessment ... ." The European Communities has not met either requirement. Each is analysed separately below.

4.173 First, the European Communities has failed to put forth either of the two types of risk assessments defined in Annex A, paragraph 4. The general moratorium was imposed to protect against risks that fall within Annex A, paragraph 1(a) (measures applied to protect animal or plant life or health from disease-causing organisms), paragraph 1(b) (measures applied to protect human or animal life or health from contaminated or toxic food or feedstuffs) and paragraph 1(d) (measures to prevent or limit damage from entry or spread of pests). The European Communities, however, did not utilize either type of risk assessment when it imposed the general moratorium. Indeed, there is no evidence in the public record that the general moratorium is based on any scientific assessment whatsoever, much less one of the two types of risk assessments defined by Annex A, paragraph 4.

4.174 Second, the general moratorium is not "based on" a risk assessment as required by Article 5.1. As the Appellate Body explained in *EC – Hormones*, Article 5.1 requires that a measure there be a "rational relationship" between the measure at issue and the risk assessment. The European Communities cannot argue that the general moratorium bears a relationship, rational or otherwise, to a risk assessment when there is no evidence that any risk assessment ever existed.

4.175 The general moratorium is also inconsistent with the European Communities' obligation under Article 2.2 of the *SPS Agreement*. Article 2.2's "sufficient scientific evidence" obligation requires that there be a "rational or objective relationship between the SPS measure and the scientific evidence. The basic obligations provided in Article 2.2 have been viewed as being specifically applied in Article 5.1. Therefore, panels and the Appellate Body have found that where a Member maintains a measure in violation of Article 5.1 – that is, where the measure is not based on a risk assessment as required under Article 5.1 and Annex A, paragraph 4 – the Member, by implication, "also act[s] inconsistently with its more general obligation in Article 2.2."

4.176 The general moratorium also violates Article 5.5 of the *SPS Agreement*, which requires that Members aim to be consistent in their application of the appropriate level of sanitary or phytosanitary protection against risks to human, animal, or plant life or health. The European Communities, however, has identified different levels of sanitary and phytosanitary protection in two different yet "comparable" situations: (i) the level of protection in respect of biotech products that exists under the general moratorium; and (ii) the level of protection in respect of products produced using biotech processing aids.

4.177 The European Communities does not regulate products produced with biotech processing aids as such. In contrast to new biotech processing aids, the European Communities has imposed a general moratorium on other new biotech products, resulting in an appropriate level of protection of zero risk.

4.178 First, these distinct levels of protection are applied in comparable situations. The same substances may be present in products produced using biotech processing aids as are present in biotech products themselves. Once present in the final product, the biotech products and products produced using biotech processing aids have the same potential adverse health risks and risks of establishment or spread of disease or pests and associated biological and economic consequences.

4.179 Second, the difference between the level of protection for biotech products and the level of protection for products produced with biotech processing aids is"arbitrary or unjustifiable." As discussed above, elements of the biotech products used in the production of the final products may be present in the final product. In such cases, the same potential risks to human health are present for new biotech processing aids and other new biotech products.

4.180 Third, the European Communities has applied the general moratorium in a manner that results in "discrimination or a disguised restriction on international trade." The European Commuities' application of the general moratorium exhibits all three "warning signals" and an "additional factor" which indicate that the measure discriminates or provides a disguised restriction on international trade.

4.181 First, as discussed above, the difference between the levels of protection for biotech products and products produced with biotech processing aids is "arbitrary or unjustifiable." Second, the degree of difference between the levels of protection is substantial – biotech products are subject to a high level of protection (*i.e.*, zero tolerance for risk, effectively banning new biotech products) whereas products produced with biotech processing aids are not subject to European Communities' regulation at all. Third, the general moratorium is not based on a risk assessment.

4.182 Finally, the "additional factor" is a disproportionate effect of the general moratorium on producers outside the European Communities as compared to producers within the European Communities. In 2001, the European Communities accounted for less than four-tenths of one percent of the worldwide land area devoted to growing biotech products. In contrast, the United States, Argentina, Canada, and China accounted for ninety-nine percent of the total land area devoted to

biotech products in 2001. For producers in these countries, the moratorium on approvals of biotech products has had a substantial negative effect.

4.183 The European Communities also has violated Article 2.3 of the *SPS Agreement*. The general obligations set out in Article 2.3 are applied more specifically under Article 5.5. As such, the Appellate Body has found that where all three elements under Article 5.5 have been fulfilled, the measures, by implication, necessarily violate the more general obligations set out in Article 2.3.

(b) Product-specific moratoria violate the *SPS Agreement*

4.184 The United States argues additionally that the product-specific moratoria are separate measures which are also inconsistent with the European Communities' obligations under the *SPS Agreement*. In particular, the United States is also challenging the European Communities' failure to consider for approval each of the twenty-seven applications for biotech products that are pending in the approval process.

4.185 Because the product-specific moratoria and the general moratorium are similar measures in that both refer to the European Communities' failure to consider biotech products for approval, the analysis of the application of the *SPS Agreement* and the violations of that Agreement are also based on similar arguments. Accordingly, arguments set forth in the section above concerning the general moratorium are incorporated by reference.

4.186 Additionally, the European Communities has put forth risk assessments for fourteen of the pending applications, which received favourable assessments from the member States to which these products were submitted and/or from the Scientific Committee on Plants or the Scientific Committee on Food. These opinions encompass both types of risk assessments referenced under Article 5.1 and paragraph 4 of Annex A as they examine: (1) the likelihood of the *establishment or spread of a pest*, and (2) the potential for adverse effects on human or animal health arising from the presence of *toxins* or *disease-causing organisms in food or feedstuffs*. All fourteen of these scientific assessments of pending applications concluded that there was no evidence that these biotech products would pose a risk to human, animal or plant life or health, or cause other damage.

4.187 Although the European Communities has put forth risk assessments for fourteen of the twenty-seven pending applications for approval of biotech products, the product-specific moratoria are not "based on" these risks assessments as required by Article 5.1. Specifically, there is no "rational relationship" between the European Communities' risk assessments and the product-specific moratoria. To the contrary, there is an irrational relationship between the opinions of the scientific committees, which found no evidence that these products pose a risk to human or animal health or the environment, and the product-specific moratoria, which, in effect, ban these products from the EC market. Because the product-specific moratoria are not "based on" the European Communities' risk assessments, the measures are inconsistent with Article 5.1 of the *SPS Agreement*.

(c) EC member State marketing or import bans violate the *SPS Agreement*

4.188 Like the moratoria (general and product-specific), the member State measures are (1) sanitary or phytosanitary measures, which (2) affect international trade. The general purpose of the member State measures can be inferred from the text of the European Communities' legislation that the member States invoked when they enacted their import or marketing bans. In particular, Article 16 of Directive 90/220 allows member States provisionally to "restrict or prohibit the use and/or sale of [an approved] product" if the "member State has justifiable reasons to consider that [the] product ... constitutes a risk to *human health or the environment.*" Similarly, Article 12 of Regulation 258/97

allows Members to "temporarily restrict or suspend the trade in and use of" an approved product if it has information that the approved product "endangers *human health or the environment.*" As each of the member States enacted their measures pursuant to Article 16 of Directive 90/220 or Article 12 of Regulation 258/97, all of the measures were enacted for the purpose of protecting human health or the environment. Second, and more importantly, the sanitary or phytosanitary purpose of the member State measures can be found in the measures themselves, as well as in the justifications offered by the member States at the time the measures were adopted.

4.189 The nine member State measures also "affect international trade," either "directly or indirectly," and, thus, meet the second requirement under Article 1.1. By blocking the sale of such products within the country that maintains the measure, the measures effectively block the importation of the products. As such, each of the measures indisputably "affects international trade."

4.190 The nine measures imposed by six member States are sanitary or phytosanitary measures which are not "based on" "risk assessment[s]" as required by Article 5.1 of the *SPS Agreement*. Although each of the six member States that have imposed bans on approved biotech products offered reasons for their measures – though unjustified according to the scientific committees – none of the member States put forth a "risk assessment" as defined in Annex A, paragraph 4. Rather, the justifications offered by the member States typically expressed concerns about adverse effects of the banned products, or biotech products in general, but did not include risk assessments of the banned products.

4.191 The only risk assessments put forth for the banned products are the positive scientific assessments rendered by member States to which the products were submitted and the European Communities' own scientific committees, as well as the European Commission Decisions approving the products. In the case of each member State ban, these favourable assessments were reaffirmed when the scientific committees considered and rejected the information provided by the member States. Thus, the member State measures do not bear a "rational relationship" to the European Communities' positive risks assessment, and are not "based on" a risk assessment, in violation of Article 5.1.

4.192 The member State measures are also inconsistent with the obligations under SPS Article 2.2, because they are not based on a risk assessment as required by Article 5.1 and Annex A, paragraph 4.

(d) Greek import ban violates Article XI

4.193 The terms of the Greek measure make it unambiguously clear that the measure is an "import ban": "We prohibit the importing into the territory of Greece of seeds of the genetically modified rape-plant line bearing reference number C/UK/95/M5/1." As an import ban, the Greek measure is a prima facie violation of Article XI:1 of the GATT 1994.

F. FIRST WRITTEN SUBMISSION OF CANADA

1. Introduction

4.194 In this dispute, Canada challenges:

(a) The general suspension by the European Communities of its own processes for the consideration of applications for, or the granting of, approval for biotech products since 1998 (referred to hereinafter as the *moratorium*);

(b) In relation to the genetically modified varieties of canola/oilseed rape identified in Annex I of Canada's Panel Request (referred to hereinafter as the *Specific Products*), the failure by the European Communities to consider or approve, without undue delay, applications for approval of such products (referred to hereinafter as the *product-specific marketing bans*); and

(c) The five national measures identified in Annex II of Canada's Panel Request prohibiting the importation, marketing or sale of, in total, six varieties of genetically modified canola/oilseed rape and maize/corn that have been approved under the European Communities' approval regime for biotech products (referred to hereinafter as *EC member State national measures*).

4.195 Biotech products cannot be marketed in the European Communities unless they have been approved. The approval process involves an assessment of the risks to human health and the environment. The *moratorium* effectively suspends the operation of key steps in this approval process, resulting in an across-the-board marketing ban on biotech products that had not received approval as of October 1998, regardless of whether these products pose risks to human health or the environment. Canada challenges the *moratorium* as a distinct measure that is inconsistent with the *SPS Agreement*.

4.196 The *moratorium* has directly affected the operation of the approval process in relation to the *Specific Products* resulting in the *product-specific marketing bans*. The *Specific Products* include the following varieties of herbicide-tolerant genetically modified canola/oilseed rape: Ms1xRf1, Ms1xRf2, Ms8xRf3 and GT73. Canada challenges the *product-specific marketing bans* as distinct measures inconsistent with the *SPS Agreement* and, in the alternative, the *TBT Agreement*. Canada also challenges the *product-specific marketing bans* as inconsistent with Article III:4 of the GATT 1994.

4.197 Finally, Canada challenges five *EC member State national measures* (enacted by France (2), Greece, Austria and Italy) banning biotech products as inconsistent with the *SPS Agreement* and, in the alternative, the *TBT Agreement*. Canada also challenges these national measures as inconsistent with Article III:4 and, in the case of Greece, Article XI:1 of the GATT 1994.

2. Scientific background

4.198 As has been recognized by the European Communities, the nature of the risks associated with biotech products is similar to the nature of the risks associated with conventionally bred plants. It is not the process through which a plant with novel traits is developed that determines the risk, but rather the characteristics of the inserted gene(s) and the host plant, the environment in which the plant is released and the use to which the plant is put. As the nature of the risks associated with biotech products varies considerably from plant variety to variety, general assertions about the risks of biotech products, as a class, cannot be made. Each biotech product needs to be evaluated on a case-by-case basis, taking into consideration the factors outlined above.

3. EC Legislation and the moratorium

(a) The approval legislation

4.199 The European Communities' approval regime for biotech products consists of two principal legal instruments: Directive 2001/18 (and its predecessor, Directive 90/220) governing "the

deliberate release into the environment of genetically modified organisms" and Regulation 258/97 regulating "novel foods and novel food ingredients".

4.200 Absent approval, biotech products covered by the European Communities' approval regime may not be placed on the market in the European Communities. The approval regime outlines, *inter alia*, the procedures with which a company must comply in order to obtain approval to place a biotech product on the market and the standards by which an application for approval is judged. In summary form, those procedures are:

- the manufacturer or importer of the product submits an application to the competent authority of the EC member State where the product is to be placed on the market for the first time;

- the competent authority conducts an initial assessment ("IA") to ensure that the product complies with the technical requirements of the relevant legislation and to determine whether the product should be placed on the market;

- the IA report is sent to the Commission and circulated to the other member States for their review and comment. If the assessment was favourable, and no EC member State or the Commission objects to the application, the competent authority consents to placing the product on the market;

- if an EC member State or the Commission objects to placing the product on the market, the Commission must adopt a decision in accordance with specific procedures laid down in the approval legislation after consultation with member State representatives;

- typically, the Commission requests an opinion of the relevant Scientific Committee. Once the scientific opinion has been received, the Commission submits a draft measure to a Regulatory Committee composed of representatives of the EC member States for its opinion;

- if the Regulatory Committee fails to render an opinion, or if it renders an opinion that conflicts with the Commission's draft measure, the Commission "shall, without delay," submit its proposal relating to the measures to be taken to the Council of Ministers;

- the Council of Ministers may, by qualified majority, adopt the proposed measure. It may also, by qualified majority, reject the proposed measure. If a qualified majority does not exist for either adoption or rejection, the Council is unable to act;

- if the Council of Ministers has not acted within three months from the date of the referral, the Commission "shall" adopt the proposed measure;

- if a product is approved for placement on the market by one of the mechanisms set out above, either the competent authority that conducted the initial assessment or the Commission must issue its consent to the placing of the product on the market.

4.201 EC legislation contains "safeguard" clauses that allow EC member States to provisionally restrict or prohibit the use or sale of an approved biotech product in its territory if that member State

has evidence that the product constitutes a risk to human health or the environment. It is under these safeguard clauses that the *EC member State national measures* have been adopted.

(b) Moratorium on approvals of biotech products

4.202 Since October 1998, the European Communities has imposed a *moratorium* on the approval of biotech products. The existence of the *moratorium* is evidenced by the European Communities' failure to approve any biotech products for nearly five years and by numerous statements from EC officials.

4.203 As a result of the weighted voting structure in the relevant Regulatory Committee, EC member States have effectively stalled the consideration or the granting of approval of biotech products. Moreover, where EC member States have been successful in blocking approval by the Commission through their voting behaviour at the Regulatory Committee stage, the Commission has failed to refer the matter to the Council to break the deadlock, even though, as noted above, it is required to do so.

4. The moratorium

(a) The moratorium violates the *SPS Agreement*

4.204 The *moratorium* meets both the form and purpose elements necessary to be considered an SPS measure under the *SPS Agreement*. In terms of form, the *moratorium* consists of concerted acts and omissions of the European Communities and its member States to stall decision-making with respect to biotech product applications at key stages of the approval process. Thus, the *moratorium* effectively renders inoperative the approval procedures under Regulation 258/97 and Directives 2001/18 and 90/220, resulting in an indefinite suspension of the placing on the market of biotech products. This indefinite suspension converts the pre-marketing approval requirement established by Regulation 258/97 and Directives 2001/18 and 90/220 into an across-the-board marketing ban on biotech products that had not been approved as of October 1998. As a ban is clearly a "measure", the *moratorium* is also a "measure" for the purposes of the *SPS Agreement*.

4.205 The purpose of the *moratorium* is to protect against risks identified in paragraph 1 of Annex A to the *SPS Agreement*. As the *moratorium* is not based on a specific legal instrument that expressly sets out the justification for this measure, the purpose of the *moratorium* must be inferred from the context. First, the declarations of the EC member States confirm that the purpose of the *moratorium* is to protect human health and environment from risks arising from biotech products. Second, it is reasonable to infer that the purpose of the *moratorium* is to protect against the same risks to human health and the environment against which the European Communities' approval legislation is intended to protect. A review of the purposes of the European Communities' approval legislation demonstrates that this legislation is designed to protect against the risks identified in paragraph 1(a) through (d) of Annex A of the *SPS Agreement*. Consequently, the *moratorium* meets the purpose element of an SPS measure.

(i) The moratorium violates Article 5.1

4.206 The European Communities has offered no risk assessment as a justification for effectively suspending the approval procedures for biotech products. Therefore, the *moratorium* is not "based on" a risk assessment as required by Article 5.1.

(ii) The moratorium violates Article 5.6

4.207 Due to the nature of the *moratorium*, it is not clear whether the *moratorium*, rather than the European Communities' approval legislation, is intended to reflect the European Communities' appropriate level of sanitary and phytosanitary protection ("level of protection"). For the purposes of its Article 5.6 argument, Canada assumes that the European Communities' level of protection is that which the European Communities has expressed in its biotech approval regime and general food safety legislation (a high level of protection). However, if Canada is mistaken on this point, and the European Communities' level of protection is that which is reflected in the *moratorium* (zero-risk level), then Canada advances, *in the alternative*, its argument with respect to Article 5.5.

4.208 The European Communities has violated Article 5.6 of the *SPS Agreement* because the *moratorium* is more trade restrictive than required to achieve the European Communities' level of protection. An alternative SPS measure is reasonably available; the alternative measure achieves the European Communities' level of protection; and the alternative measure is significantly less restrictive to trade.

4.209 First, the obvious alternative SPS measure is for the European Communities to comply with its existing approval regime for biotech products and permit biotech products to be considered for, and granted or denied, approval in accordance with the procedures established by that regime. Second, the European Communities' appropriate level of protection is reflected in the relevant EC legislation and appears to be a "high level of protection". It is reasonable to assume that the European Communities' own approval regime for biotech products would achieve the European Communities' level of protection if the European Communities and its member States allowed it to function as designed. Third, the alternative measure is significantly less restrictive to trade. If the European Communities permitted its approval regime to function as designed, biotech products would at least be considered for approval on a case-by-case basis and on the basis of scientific evidence. Consequently, biotech products would have an opportunity to be placed on the market, which is clearly "significantly less restrictive to trade" than the across-the-board marketing ban resulting from the *moratorium*.

(iii) The moratorium violates Article 2.2

4.210 As the *moratorium* is not "based on" a risk assessment contrary to Article 5.1, the *moratorium* is not based on scientific principles and is maintained without sufficient scientific evidence, contrary to Article 2.2. Similarly, as the *moratorium* is more trade-restrictive than required to achieve the European Communities' level of protection contrary to Article 5.6, it is not "applied only to the extent necessary to protect human, animal or plant life or health", contrary to Article 2.2.

(iv) The moratorium violates Article 5.5

4.211 The European Communities' level of protection appears to be a "high level of protection". However, if this assumption is not correct and the European Communities' level of protection for biotech products with pending applications is that reflected by the *moratorium*, namely a zero-risk level, the European Communities has violated Article 5.5 of the *SPS Agreement*.

4.212 The European Communities has adopted different appropriate levels of protection in several "different situations" that can be compared under Article 5.5: (i) the level of protection in respect of biotech products with pending applications that have been stalled as a result of the *moratorium* ("biotech products with pending applications"); (ii) the level of protection in respect of biotech products that were approved for commercialization prior to the imposition of the *moratorium*

("previously approved biotech products"); and, (iii) the level of protection in respect of novel non-biotech products such as those produced by conventional plant breeding techniques ("novel non-biotech products").

4.213 The European Communities has adopted different appropriate levels of protection in respect of biotech products with pending applications, previously approved biotech products and novel non-biotech products. The European Communities' level of protection in respect of biotech products with pending applications appears to be a zero-risk level. In contrast, the European Communities' level of protection in respect of previously approved biotech products and novel non-biotech products is less than zero-risk level in that such products are not subject to an across-the-board marketing ban. Moreover, biotech products with pending applications, previously approved biotech products and novel non-biotech products are in comparable situations because they share "common elements or elements sufficient to render them comparable." The types of risks to human health and the environment posed by biotech products with pending applications are the same as or similar to the types of the risks posed by the other two identified classes of products.

4.214 The differences in the European Communities' levels of protection for the situations identified above are "arbitrary or unjustifiable". The European Communities' level of protection in respect of biotech products with pending applications (zero-risk level) is higher than the level of protection in respect of previously approved biotech products (low tolerance, but not zero-risk,). The European Communities' own officials admit that there is no scientific basis for treating pending applications differently from those previously approved. Likewise, the European Communities' level of protection in respect of biotech products with pending applications is higher than its level of protection in respect of novel non-biotech products (certainly less than zero-risk level) despite the fact that biotech products and their non-biotech counterparts pose the same or similar types of risks to human health and the environment. Therefore, the difference in levels of protection is "arbitrary or unjustifiable".

4.215 The European Communities' measure embodying the differences in the levels of protection set out above, result in "discrimination or a disguised restriction on international trade." First, as discussed above, the differences between the levels of protection are "arbitrary or unjustifiable." Second, the difference between the levels of protection is substantial – for biotech products with pending applications the level of protection is the most stringent possible (zero-risk) whereas for previously approved biotech products and novel non-biotech products the level of protection is not zero risk. Third, the *moratorium* is not based on a risk assessment, contrary to Articles 5.1 and 2.2. Thus, all three warning signals are present. The difference between the levels of protection also exhibits an "additional factor". The *moratorium* disproportionately affects non-EC producers as compared to EC producers given that majority of biotech products are produced in the United States, Argentina, Canada, and China.

4.216 The presence of three warning signals and an additional factor demonstrate that the differences between the levels of protection in the comparable situations set out above, results, in the case of biotech products with pending applications, in discrimination or a disguised restriction on international trade contrary to Article 5.5.

(v) The moratorium violates Article 2.3

4.217 As the European Communities, by maintaining the *moratorium*, has acted inconsistently with Article 5.5, by implication it has also acted inconsistently with Article 2.3.

(vi) The moratorium violates Article 8 and paragraph 1(a) of Annex C

4.218 The *moratorium* has led to a systematic failure by the European Communities to undertake and complete its approval procedures for biotech products without "undue delay", contrary to the first obligation of paragraph 1(a) of Annex C. The approval procedures suspended by the *moratorium* are "approval procedures" to "check and ensure the fulfilment of sanitary or phytosanitary measures."

4.219 The ordinary meaning of "undue delay" suggests that both the reason for the delay and its duration are relevant in determining whether the delay is "undue". In the context of Annex C, the justification for a delay must be consistent with the provisions of the *SPS Agreement*, in particular, that SPS measures must be "based on scientific principles" and not "maintained without sufficient scientific evidence" as required by Article 2.2. In this case, there is no sound justification for European Communities' failure to undertake and complete the approval procedures for biotech products. Thus, the delay in undertaking and completing the approval procedures for biotech products is "unjustified".

4.220 In the case of the *moratorium*, the delay in undertaking and completing the approval procedures for biotech products is caused by a general suspension of those procedures. An unjustified general suspension of an approval procedure is on its face an "excessive" delay. In this case, the fact that the general suspension has been in place for more than 5 years compounds the excessiveness of the delay.

(vii) The European Communities has violated Article 7 and Paragraph 1 of Annex B by failing to "publish promptly" the moratorium

4.221 For the same reasons that the *moratorium* is an SPS measure, the *moratorium* is a "sanitary or phytosanitary regulation" for the purpose of paragraph 1 of Annex B. As the European Communities has failed to publish the existence of the *moratorium* at all, let alone to do so "promptly," it has acted inconsistently with Article 7 and Annex B.

5. The *product-specific marketing bans*

(a) The *product-specific marketing bans* violate the *SPS Agreement*

4.222 The moratorium and the product-specific marketing bans are closely related, though distinct, measures. The product-specific marketing bans arise as a result of the moratorium being applied to individual biotech product applications. They are also proof of the moratorium. Because the measures are closely related, the analysis of the application of the *SPS Agreement* and the violations of that Agreement with respect to the two classes of measures are based on similar arguments. Consequently, the arguments under the moratorium with respect to Articles 5.1, 5.6, 2.2, 5.5, 2.3, 8, and paragraph 1(a) of Annex C apply mutatis mutandis to the product-specific marketing bans.

(b) The p*roduct-specific marketing bans* violate Article III:4 of the GATT 1994.

4.223 The *product-specific marketing bans* violate Article III:4 by according the s*pecific products* treatment less favourable than the treatment accorded their respective "like" non-biotech counterparts, domestically-grown canola/oilseed rape.

4.224 First, the *product-specific marketing bans* are laws, regulations or requirements affecting the internal sale, offering for sale, purchase, distribution and use of the s*pecific products*. The *product-specific marketing bans* are inextricably linked to the requirement for pre-marketing approval set out

in European Communities' approval legislation. The failure of the European Communities to consider or approve, without undue delay, the s*pecific products* has affected the "internal sale, offering for sale, purchase, transportation, distribution or use" of these products because those activities require prior approval. As such, the *product-specific marketing bans* fall within the scope of "laws, regulations and requirements" as that term is used in Article III:4.

4.225 Second, the s*pecific products* are "like" their respective domestically-grown non-biotech counterparts when taking into consideration, in the light of the circumstances of this case, the four criteria used to determine "likeness".

- A comparison of the s*pecific products* with domestically-grown non-biotech canola/oilseed rape reveals that their physical differences are minor, and occur only at the genetic level. The *specific products* are otherwise physically indistinguishable from domestically-grown non-biotech canola/oilseed rape. For each *Specific Product*, the European Communities has conducted science-based risk assessments revealing that there is no evidence to suggest that the *Specific Products* are less safe than their domestic non-biotech counterparts. If a biotech product has undergone a science-based risk assessment, and the conclusions of that assessment are that the product does not pose any greater risk to human health or the environment than that product's non-biotech counterpart, there is no reason to consider that product to be different from its non-biotech counterpart in terms of the products' properties, nature and quality, particularly where physical differences between the biotech product and its non-biotech counterpart can be perceived only at the molecular level.

- The s*pecific products* and their domestic non-biotech counterparts are intended to be used interchangeably as food, feed and industrial processing materials, as the case may be.

- While Canada agrees that, in principle, consumer tastes and preferences is a relevant criterion to the determination of "likeness" under Article III:4, in this case it should be given little practical weight, if any. No reliable evidence exists regarding the consumer tastes and preferences for the s*pecific products* as compared to their domestically-grown non-biotech counterparts. In these circumstances, consumer tastes and preferences cannot be considered a reliable indicator of "likeness" given the amount of conflicting information publicly available. Finally, Canada also notes that the treatment in question arises in the course of an approval process intended to assess the safety of specific products. In that particular context – and consistent with the Appellate Body's contextual and case-by-case approach – consumer tastes and preferences should play, at most, a very limited role.

- Lastly, no differentiation is made in respect of the tariff classifications between biotech products and their non-biotech, conventionally bred, counterparts.

4.226 When taken as a whole, the factual evidence relating to each of the four criteria makes it clear that the s*pecific products* and their domestically-grown non-biotech counterparts must be considered to be "like products". Their physical properties are, in all essential aspects, virtually identical; their end uses are identical; evidence with respect to consumer tastes and preferences is inconclusive, and, in this particular context, can only be given very limited weight relative to the other criteria; and their tariff classification is identical. Based on the foregoing, the *Specific Products* are "like" their

respective non-biotech counterparts of national origin for the purpose of Article III:4 of the GATT 1994.

4.227 Third, the s*pecific products* are accorded treatment less favourable than that accorded their respective non-biotech counterparts of national origin. The *product-specific marketing bans* prohibit the importation and marketing of each respective s*pecific product*. In contrast, domestically-grown non-biotech canola/oilseed rape is sold freely on the EC market. This cannot be considered as providing "equality of competitive opportunities" to the s*pecific products*, as required by Article III:4. Accordingly, the imported s*pecific products* have been accorded treatment less favourable than "like" products of national origin in violation of Article III:4 of the GATT 1994.

(c) The p*roduct-specific marketing bans* violate the *TBT Agreement*

4.228 As demonstrated above, the *product-specific marketing bans* are SPS measures and are therefore covered by the *SPS Agreement*. If, however, the Panel finds that the *product-specific marketing bans* are not SPS measures, then Canada submits, *in the alternative*, that they are subject to the requirements of the *TBT Agreement*.

4.229 The *product-specific marketing bans* and the relevant EC legislation are "technical regulations" and "conformity assessment procedures", respectively. The *product-specific marketing bans* give rise to violations of the following TBT provisions: Articles 2.1, 2.2, 5.1.1, 5.1.2, and 5.2.1, first part.

6. The *EC member State national measures*

(a) The EC member State national measures violate the *SPS Agreement*

4.230 The *EC member State national measures* meet both the form and purpose elements necessary to be considered SPS measures. In terms of form, the *EC member State national measures* clearly fall within the scope of "laws, decrees, regulations, requirements and procedures". The two French measures and the Italian measure are in the form of "decrees". The Greek measure takes the form of a "ministerial decision" and the Austrian measure is an "ordinance", both of which can be equated with the types of measures expressly enumerated in paragraph 1 of Annex A of the *SPS Agreement*.

4.231 The purpose of the *EC member State national measures* is to protect against risks identified in paragraph 1(a) through (d) of Annex A of the *SPS Agreement*. This can be inferred from the EC legislation invoked by the member States as the basis for instituting such measures (safeguard clauses of the approval legislation), the measures themselves, and statements by government officials in relation to the passage or adoption of such measures.

(i) The EC member State national measures violate Article 5.1

4.232 The *EC member State national measures* are not "based on" a risk assessment, as required by Article 5.1 of the *SPS Agreement*. Although the four EC member States imposing the *EC member State national measures* gave reasons to the Commission when notifying their respective *national measures*, they did not file any supporting scientific evidence or analysis that meets the requirements of the definition of a risk assessment set out in the *SPS Agreement*. While the four EC member States pointed to alleged shortcomings in the risk assessments previously conducted as part of the approval process, or raised general concerns with respect to risks to human health or the environment, they did not present a comprehensive analysis of the available scientific evidence as to the risks arising from these products.

4.233 In contrast, the EC member States where the applications for the six products subject to the *national measures* were originally submitted – and the European Communities' scientific committees asked to examine the applications – produced valid risk assessments. However, these risk assessments supported the *approval* of the product applications, and, when requested by the Commission to review the EC member States' reasons for instituting bans on the approved products, the European Communities' scientific committees rejected those reasons in each case. Consequently, there is simply no rational relationship between these risk assessments and the *EC member State national measures*.

(ii) The EC member State national measures violate Article 5.6

4.234 As discussed in relation to the *moratorium*, for the purposes of its Article 5.6 argument, Canada assumes that the level of protection throughout the European Communities is that which the European Communities has expressed in its legislation. However, if Canada is mistaken on this point, and the level of protection is that which is reflected in the *EC member State national measures*, then Canada advances, *in the alternative*, its argument with respect to Article 5.5.

4.235 The *EC member State national measures* banning the importation or commercialization of the canola/oilseed rape varieties Ms1xRf1 and Topas 19/2, and the corn/maize varieties T25, Bt-11, MON809 and MON810, are more trade-restrictive than required to achieve the European Communities' appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility, contrary to Article 5.6 of the *SPS Agreement*. An alternative SPS measure is reasonably available; the alternative measure achieves the European Communities' level of protection; and the alternative measure is significantly less restrictive to trade.

4.236 First, it is reasonable to assume that the European Communities' own regulatory regime, and in particular the safeguard procedures, constitutes "another measure, reasonably available taking into account technical and economic feasibility". Second, the European Communities' level of protection, as reflected in the relevant EC legislation, appears to be a "high level of protection", not zero-level risk. It is reasonable to assume that the European Communities' own approval process, which approved the products subject to the *national measures*, was and is designed to achieve the European Communities' stated level of protection. It is also reasonable to assume that the safeguard procedures, if allowed to function as intended, would achieve the European Communities' stated level of protection. In this case, the approval process and safeguard procedures achieve the European Communities' legitimate objective because the biotech products subject to *national measures* have been marketed for several years elsewhere in the European Communities, as have other, similar biotech products that were approved prior to the *moratorium*, without any evidence arising that would tend to throw doubt on their safety. Third, it is incontrovertible that a complete ban on a product is significantly more trade-restrictive than the pre-marketing approval regime under which the products subject to the *national measures* have already been approved. Accordingly, all three elements of a violation of Article 5.6 have been met.

(iii) The EC member State national measures violate Article 2.2

4.237 As the *EC member State national measures* are not based on a risk assessment, contrary to Article 5.1, they are not based on scientific principles and are maintained without sufficient scientific evidence, contrary to Article 2.2. Similarly, as the *EC member State national measures* are more trade-restrictive than required to achieve the European Communities' level of protection, contrary to Article 5.6, they are not applied only to the extent necessary to protect human, animal or plant life or health, contrary to Article 2.2.

(iv) The EC member State national measures violate Article 5.5

4.238 The European Communities' level of protection with respect to safeguard measures appears to be a "high level of protection", but not a zero-level risk. However, if this assumption is not correct, and the level of protection for the six biotech products subject to the *EC member State national measures* is the level of protection reflected by those measures, namely a zero-level risk, then the *EC member State national measures* violate Article 5.5 of the *SPS Agreement*.

4.239 The European Communities has adopted different appropriate levels of sanitary and phytosanitary protection in several "different situations" that can be compared under Article 5.5: (i) the level of protection in respect of the six biotech products subject to the *EC member State national measures* ("biotech products subject to *national measures*"); (ii) the level of protection in respect of biotech products that have been approved for commercialization in the European Communities ("other EC-approved biotech products"); and (iii) the level of protection in respect of novel non-biotech products ("novel non-biotech products").

4.240 The European Communities has adopted different levels of protection in respect of biotech products subject to *national measures*, other EC-approved biotech products and novel non-biotech products. The European Communities' level of protection in respect of biotech products subject to *national measures* appears to be a zero-risk level. In contrast, the European Communities' level of protection in respect of other EC-approved biotech products and novel non-biotech products is less than a zero-risk level. Other biotech products that have been approved by the European Communities, including other canola/oilseed rape and corn/maize varieties, have not been banned in the four EC member States. Pre-market approval for novel non-biotech products is not required unless the product is to be used as food or food ingredients, in which case, a functioning approval process applies. Moreover, biotech products subject to *national measures*, other EC-approved biotech products and novel non-biotech products are in comparable situations because they share "common elements or elements sufficient to render them comparable." The types of risks to human health and the environment posed by biotech products subject to the national bans are the same as or similar to the types of the risks posed by the other two identified classes of products.

4.241 The differences in the European Communities' levels of protection for the situations identified above are "arbitrary or unjustifiable". The European Communities' level of protection in respect of biotech products subject to *national measures* (zero-risk level) is higher than the level of protection in respect of other EC-approved biotech products (low tolerance but not zero-risk), despite the fact that the actual level of risk present for each of these two groups of biotech products is the same. Likewise, the European Communities' level of protection in respect of biotech products subject to *national measures* (zero-risk level) is higher than its level of protection in respect of novel non-biotech products (certainly not a zero-risk level) despite the fact that these products exhibit the same risk profiles, thus giving rise to the same potential for adverse health effects or risks of the same or similar associated biological or economic consequences.

4.242 The European Communities' measures embodying the differences in the levels of protection set out above, result in "discrimination or a disguised restriction on international trade." First, the differences between the levels of protection are "arbitrary or unjustifiable." Second, the difference between the levels of protection is substantial – for biotech products subject to *national measures* the level of protection is the most stringent possible (zero-risk) while for other EC-approved biotech products and novel non-biotech products the level of protection is not zero risk. Third, the *EC member State national measures* are not based on risk assessments, contrary to Articles 5.1 and 2.2. Thus, all three warning signals are present.

4.243 There are two "additional factors" that support a finding of discrimination or a disguised restriction on international trade. First, the five *national measures* have a disproportionate impact on the producers of these biotech products located outside the EC member States' territories, as compared to producers within the EC member States. Second, not only have the EC member States failed to produce the requisite risk assessments, they have ignored both the initial risk assessments performed by the EC member States where the applications for approval were filed and the opinions submitted by the European Communities' scientific committees in support of those applications, and, later, the opinions submitted in response to the invocation of the safeguard procedures underpinning the *national measures*.

(v) The EC member State national measures violate Article 2.3

4.244 As the *EC member State national measures* are contrary to Article 5.5, they also, by implication, violate Article 2.3.

(b) The EC member State national measures violate GATT 1994

(i) Four EC member State national measures violate Article III:4

4.245 Four *EC member State national measures* (those of France, Italy and Austria; the Greek measure is addressed below in relation to Article XI:1) violate Article III:4 by according the biotech products subject to those measures treatment less favourable than the treatment accorded their respective "like" non-biotech counterparts, domestically-grown canola/oilseed rape and corn/maize.

4.246 First, the four *EC member State national measures* at issue all fall within the scope of the meaning of the phrase "laws, regulations or requirements". These measures clearly "affect" the "internal sale, offering for sale, purchase" and "use" of the biotech products in question.

4.247 Second, the biotech products in question are "like" their respective domestically-grown non-biotech counterparts when taking into consideration, in light of the circumstances of this case, the four criteria used to determine "likeness":

- A comparison of the biotech products in question with their domestically-grown non-biotech counterparts reveals that their physical differences are minor, and occur only at the genetic level. The biotech products in question are otherwise physically completely indistinguishable from the domestically-grown non-biotech varieties. The minor physical differences, in so far as they are relevant at all, cannot be considered to "influence the competitive relationship between [these] products in the marketplace", and cannot therefore detract from an overall finding of "likeness".

- The biotech products in question and their domestic non-biotech counterparts are intended to be used interchangeably as food, feed and industrial processing materials, as the case may be.

- As with the *product-specific marketing bans*, while Canada agrees that, in principle, consumer tastes and preferences is a relevant criterion and that the Panel should not ignore it, ultimately, it should be given little practical weight, if any, in determining the "likeness" of the biotech products in question as compared to their domestically-grown non-biotech counterparts. No reliable evidence exists regarding the consumer tastes and preferences for the biotech products in question as compared to their domestically-grown non-biotech counterparts. In this case, consumer tastes and

preferences cannot be considered a reliable indicator of "likeness" given the amount of conflicting information publicly available.

- Lastly, no differentiation is made in respect of the tariff classifications between the biotech products in question and their non-biotech counterparts.

4.248 When taken as a whole, the factual evidence relating to the four criteria makes it clear that the biotech products in question are "like" their domestically-grown non-biotech counterparts. Their physical properties are, in all essential aspects, virtually identical; their end uses are identical; evidence with respect to consumer tastes and preferences is inconclusive; and their tariff classification is also identical. Thus, the second element of the Article III:4 test is satisfied.

4.249 Third, the products in question are accorded treatment less favourable than that accorded their respective non-biotech counterparts of national origin. The four *EC member State national measures* have modified the conditions of competition in the relevant market to the detriment of imported products. In effect, the biotech products in question are completely prevented from competing in the French, Austrian, and Italian markets, as compared to their domestically-grown non-biotech counterparts, which enjoy unfettered access to the same markets.

(ii) Greece's import ban on Topas 19/2 violates Article XI:1

4.250 The Greek ministerial decision of 9 September 1998 imposed an import ban on the EC-approved biotech canola/oilseed rape variety Topas 19/2. The decision constitutes an "other measure" under Article XI:1 of the GATT 1994 and, is inconsistent with the requirements of that provision.

(c) The *TBT Agreement* applies to the EC member State national measures

4.251 As demonstrated above, the *EC member State national measures* are SPS measures and are therefore covered by the *SPS Agreement*. If, however, the Panel finds that the *EC member State national measures* are not SPS measures, then Canada submits, *in the alternative*, that they are subject to the requirements of the *TBT Agreement*.

4.252 The *EC member State national measures* are "technical regulations": they apply to identifiable products; lay down product characteristics; and compliance with them is mandatory. The *EC member State national measures* violate Articles 2.1, 2.2, 2.9.1, 2.9.2 and 2.9.3 of the *TBT Agreement*.

G. FIRST WRITTEN SUBMISSION OF ARGENTINA

1. Introduction

4.253 The European Communities' system for the approval of biotech agricultural products (Directive 2001/18 and its predecessor Directive 90/220) or "novel foods" (Regulation 258/97) requires that, a specific procedure must be followed before such products can be marketed for consumption in the territory of the European Communities. The complaint by Argentina is based on the following considerations: (1) Since October 1998, the European Communities has either not considered or has suspended applications for approval of all biotech agricultural products under its system of approval prior to release or marketing, and in particular applications for approval of products of interest to Argentina; (2) the European Communities has caused undue delay by failing to consider and/or not completing the processing of applications submitted with regard to various

biotech agricultural products; (3) some EC member States have banned the access to their markets for specific biotech agricultural products.

4.254 In short, the suspension of consideration of the applications, lack of approval or undue delay constitute individual manifestations of a single measure which forms the subject of this complaint – a *de facto* moratorium. Likewise, several specific products of interest to Argentina have been affected by suspension or lack of consideration or undue delay, since no decision has been made on their approval to date. This *de facto* moratorium is a measure that has the following characteristics: (a) it has never been set forth in the form of positive legislation – a regulation or directive – but has been applied and maintained as a practice in the European Communities since 1998; (b) from 1998 to the present, no new biotech agricultural product has been approved for marketing, which entails the systematic suspension of the approval procedures and the failure to consider individual applications for authorization or approval of biotech agricultural products; (c) the moratorium has affected the various applications for approval of individual biotech agricultural products, thus causing an undue delay in the completion of the processing of those applications; (d) it is not supported by scientific evidence; (e) since 1998 it has manifested itself in repeated delays and extensions of deadlines on the part of the European Communities, under the continued pretext of the approval of new legislation: amendment of Directive 90/220 by Directive 2001/18, the need to have additional legislation covering different aspects and new requirements, etc.; and (f) reveals an arbitrary and unjustified discrimination against biotech agricultural products. The *de facto* moratorium implemented by the European Communities as well as the bans adopted by some of its member States are measures inconsistent with the provisions of the *SPS Agreement*, the GATT 1994, or alternatively, the *TBT Agreement*.

2. Inconsistency with the *SPS Agreement*

(a) Inconsistency of the *de facto* moratorium with the *SPS Agreement*

(i) The de facto moratorium as a measure under the SPS Agreement

4.255 Argentina considers that the *de facto* moratorium constitutes a sanitary and phytosanitary measure within the meaning of the *SPS Agreement*. For the *SPS Agreement* to be applicable to a measure, the measure in question has to meet two requirements: (a) the measure in dispute must be a sanitary or phytosanitary measure; and (b) the measure must be able to affect international trade. In the opinion of Argentina, the *de facto* moratorium meets both requirements.

4.256 According to the first paragraph of Annex A of the *SPS Agreement*, for the *de facto* moratorium to meet the first requirement, it must satisfy two conditions: (i) it must have as its objective at least one of the objectives cited in sections (a) to (d) of paragraph 1 of Annex A; and (ii) it must also be reflected in one of the instruments cited in the first paragraph of Annex A The *de facto* moratorium meets both conditions.

4.257 In Argentina's view, the *de facto* moratorium fits the descriptions contained in paragraph 1(a) to 1(d) of Annex A. First, the European Communities itself has explicitly acknowledged that the purpose of the moratorium is to protect against risks to life and health and to protect the environment. The European Communities has also admitted that its policy with regard to biotech agricultural products relates to the protection of life and health. Second, given the fact that the *de facto* moratorium was imposed in the context of the various EC regulations, each of which has different mechanisms for evaluating the potential damage to health or the environment, it is covered by the first paragraph of Annex A.

4.258 With regard to the second condition, the European Communities' moratorium has not been introduced through one of the traditional instruments employed by WTO Members to give expression to their decisions, but has been established *de facto* by the European Communities. Nevertheless, the European Communities' own authorities have acknowledged its existence. It should also be noted that the phrase in the second part of paragraph 1 of Annex A, *"including, inter alia,"*, clearly indicates that the list that follows is not intended to be exhaustive.

4.259 With regard to the second requirement, the *de facto* moratorium has had effects on international trade. It should suffice to note that, since 1998, various biotech agricultural products have been denied access to the EC market.

(ii) The de facto moratorium is inconsistent with Article 5.1

4.260 Article 5.1 establishes the obligation on Members to conduct a risk assessment. In this particular case, the European Communities is required to conduct at least one of the two types of risk assessment mentioned in paragraph 4 of Annex A. The *de facto* moratorium was implemented by the European Communities without reference to any type of scientific evidence. Furthermore, the *de facto* moratorium has been applied even in cases in which the European Communities had received favourable scientific opinions from the pertinent scientific committees. Therefore the European Communities has violated Article 5.1, and, in accordance with WTO jurisprudence, the violation of Article 5.1 also entails a violation of Article 2.2.

(iii) The de facto moratorium is inconsistent with Article 2.2

4.261 The inconsistency of the *de facto* moratorium with Article 2.2 is partly the result of an inconsistency between the *de facto* moratorium and Article 5.1. However, Argentina claims that the *de facto* moratorium violates Article 2.2, irrespective of its analysis in the light of Article 5.1. Article 2.2 requires Members to base their sanitary or phytosanitary measures on scientific principles. The European Communities has no scientific basis for, nor scientific evidence that might support, the *de facto* moratorium. This lack of any scientific basis means that the moratorium is inconsistent with Article 2.2. Besides, the *de facto* moratorium has been maintained for more than five years (1998-2003) without sufficient scientific evidence. Article 2.2 also uses the terms "only to the extent necessary," and thus no sanitary or phytosanitary measure can be applied in such a general and comprehensive form as the European Communities has done with the *de facto* moratorium. Moreover, such a broad and general imposition on all biotech products contradicts the "case-by-case" evaluation which the European Communities itself claims has to be upheld.

(iv) The de facto moratorium cannot be justified under the exception provided for in Article 5.7

4.262 The Appellate Body in *Japan – Agricultural Products II* stated that Article 5.7 sets out four requirements which must be met in order to adopt and maintain a provisional SPS measure: (1) the measure is imposed in respect of a situation where "relevant scientific information is insufficient"; (2) the measure is adopted "on the basis of available pertinent information"; (3) the Member "seek[s] to obtain the additional information necessary for a more objective assessment of risk"; and (4) the Member "review[s] the ... measure accordingly within a reasonable period of time".

4.263 With regard to the first requirement, there is no basis in this case for using "insufficient scientific evidence" as an excuse for the *de facto* moratorium under Article 5.7. As all biotech agricultural products approved by the European Communities prior to the *de facto* moratorium had to undergo a case-by-case scientific assessment, the biotech agricultural products that have not been approved since 1998 should also have undergone an approval process that included a risk assessment.

In fact, some of these products received a favourable scientific opinion recommending their approval. With regard to the second requirement, the European Communities has not adopted this measure "provisionally" and has not based its actions on the information available because the European Communities has maintained this measure for more than five years and ignored the scientific evidence provided by its own bodies. With regard to the third requirement, at no time has the European Communities attempted to obtain additional information. On the contrary, the European Communities has only argued that it needs to impose even more requirements on applications, amend its legislation, or introduce additional legislation on another issue. With regard to the fourth requirement, the *de facto* moratorium has never been reviewed since 1998.

4.264 In conclusion, Argentina considers that the *de facto* moratorium is not based on scientific evidence, and that the European Communities cannot justify this measure under the exception provided by Article 5.7. Consequently, Argentina requests that the *de facto* moratorium be found to be inconsistent with Article 2.2.

(v) The de facto moratorium is inconsistent with Article 5.5

4.265 In respect of the first sentence of Article 5.5, the Appellate Body in *EC – Hormones* has indicated that there are three cumulative elements that must be proven to claim a violation of this rule: (i) application of different levels of protection to different situations; (ii) arbitrary and unjustifiable differences in protection; and (iii) discrimination and a disguised restriction on international trade.

4.266 With respect to the first element, this element is made up of two aspects: "different levels of protection" and "different" yet comparable situations. With respect to the concept of "different levels of protection", Argentina notes that the level of protection of the *de facto* moratorium is equivalent to a "zero risk" level. With respect to the concept of "different situations", the comparability of different situations arises from the fact that such situations share some common element or elements that make a comparison possible. The European Communities has applied different levels of protection to two "comparable" situations, that is, with respect to the approval for marketing of biotech products before and after the *de facto* moratorium and with respect to the new biotech products and new "non-biotech" products, thereby satisfying the first element of the conditions for the violation of Article 5.5.

4.267 The second element also needs to be analysed with regard to the two comparable situations. With respect to the approval for marketing of biotech products before and after the *de facto* moratorium, there is an equivalent level of risk between the products concerned. Nevertheless, through the moratorium the European Communities has imposed a level of protection so high that it has resulted in an absolute ban on imports without any scientific evidence. With respect to new biotech products and new "non-biotech" products, the latter can be freely placed on the market within the European Communities, except when intended for human or animal consumption, whereas the former are affected by the *de facto* moratorium. In Argentina's opinion, the second element required for a violation of Article 5.5 is apparent from the lack of scientific evidence in the opinions of the relevant EC committees to support these differences in levels of protection imposed by the European Communities.

4.268 To determine whether a measure meets the third element, in *Australia – Salmon* the Appellate Body considered three "warning signals" and certain "additional factors". The three "warning signals were: (a) the arbitrary and unjustifiable character of the differences in the levels of protection; (b) a rather substantial difference in the levels of protection; and (c) the inconsistency of the sanitary or phytosanitary measure with Articles 5.1 and 2.2. The *de facto* moratorium applied by the European Communities possesses the three "warning signals" indicated above and an additional factor, as explained below.

4.269 With regard to biotech products before and after the *de facto* moratorium, there is a substantial degree of difference in the level of protection accorded by the European Communities, without any justification in terms of the level of risk involved. In addition, the difference in the levels of protection applied is "arbitrary and unjustifiable." Finally, the European Communities has not based the *de facto* moratorium on a risk assessment. With regard to new biotech agricultural products and new "non-biotech" products, the degree of difference in the level of protection is considerable since it represents a low level of protection for the latter and a level that implies an import ban for the former. In addition, the difference in the level of protection is arbitrary and unjustifiable. Likewise, the *de facto* moratorium is not based on a risk analysis and has an adverse effect on new biotech agricultural products, the vast majority of which are produced outside the European Communities.

4.270 Moreover, the *de facto* moratorium contains an "additional factor", which is the disproportionate impact that the *de facto* moratorium has had on producers of biotech agricultural products outside the European Communities vis-à-vis producers within the European Communities.

(vi) The de facto moratorium is inconsistent with Article 2.3

4.271 As noted by the Appellate Body in *Australia – Salmon*, once it has been confirmed that the *de facto* moratorium infringes Article 5.5, that measure will also be inconsistent with Article 2.3.

(vii) The de facto moratorium is inconsistent with Article 7 and Annex B:1

4.272 The European Communities' measure implemented since 1998 is a *de facto* measure, which was never set forth in any regulation, or published, thus constituting a violation of Article 7 and paragraph 1 of Annex B.

(viii) The de facto moratorium is inconsistent with Article 10.1

4.273 This provision is mandatory and not simply an obligation to cooperate. The European Communities' suspension of consideration of applications, its failure to approve biotech agricultural products and the unjustifiable delays in processing constitute a restraint of trade in those products amounting to an absolute ban on access, which has had and continues to have a considerable impact on Argentina, a developing country, in breach of the provisions of Article 10.1. Argentina, like other developing countries, has special needs, in that Argentina is highly dependent on agricultural production and exports.

4.274 On the grounds set forth above, the *de facto* moratorium is inconsistent with the *SPS Agreement*, specifically with Articles 5.1, 2.2, 5.5, 2.3, 7, 10,1 and paragraph 1 of Annex B.

(b) Inconsistency of the "suspension of processing and failure to consider individual applications for approval of specific biotech agricultural products of particular interest to Argentina" with the *SPS Agreement*

(i) Suspension of the approval processes for biotech agricultural products of particular interest to Argentina

4.275 Since October 1998, the European Communities has suspended consideration of applications for approval of all biotech agricultural products under its approval system. This suspension is apparent from the fact that before the end of 1998, the European Communities had approved a considerable number of biotech agricultural products, whereas since that date the European Communities has not approved a single such product. Among the pending applications stalled at

various stages of the approval process under Directive 2001/18 (or, prior to 17 October 2002, under Directive 90/220) and Regulation 258/97, are: GA21 maize, NK – 603 maize, Bt-531 cotton, RR 1445 cotton, and A2704-12 and A5547-127 soya.

4.276 The suspension of processing and failure to consider individual applications for the approval of specific biotech agricultural products of particular interest to Argentina [hereafter "the suspension"] must be also analysed in the light of the *SPS Agreement*, in accordance with Article 1.1. Four of the enlisted biotech received positive scientific opinions by the respective EC Scientific Committees, favouring their approval. The fifth biotech product did not even get to the stage of risk assessment.

(ii) The suspension is inconsistent with Article 5.1

4.277 The following requirements must be met for a sanitary and phytosanitary measure to be consistent with Article 5.1: (i) a risk assessment must exist; and (ii) the measure must be "based" on that risk assessment. Argentina considers that the suspension is inconsistent with Article 5.1 because neither the member States nor the European Commission authorities have complied with the above-mentioned requirements.

4.278 With regard to the first requirement, the European Communities did not undertake any type of risk assessment provided by paragraph 4 of Annex A as the basis for the suspension. Therefore, there is no risk assessment within the meaning of Article 5.1. With regard to the second requirement, WTO jurisprudence has established that "based on" is appropriately taken to refer to a certain objective relationship between an SPS measure and a risk assessment. In the present case, a distinction must be made between the two hypothetical cases: (i) absence of such a relationship because no scientific assessment was conducted; and (ii) absence of such a relationship in spite of the fact that a scientific assessment was conducted. In the first case, the requirements have not been met because no risk assessment was performed (the case of soya A2704-12 and A5547-127). In the second case, the requirements have not been met because the favourable risk assessment was not taken into consideration as a basis for the suspension (as in the case of maize and cotton).

(iii) The suspension is inconsistent with Article 2.2

4.279 On the basis of the provisions of Article 2.2 and the WTO jurisprudence with regard to the relationship between Articles 2.2 and 5.1, if a sanitary measure is not based on a risk assessment as required by paragraphs 1 and 2 of Article 5, it can be assumed more generally that the measure is not based on scientific principles and that it is being imposed without sufficient scientific evidence. Therefore, Argentina maintains that the suspension does not meet the requirements of Article 2.2.

(iv) The suspension is inconsistent with Article 5.5

4.280 The scope of Article 5.5 has been addressed in previous disputes, which have confirmed that a complainant must demonstrate the existence of three distinct and cumulative elements: (a) the Member that imposed the measure at issue adopted levels of protection against risks to human, animal or plant life or health in various different situations; (b) these levels of protection exhibit arbitrary or unjustifiable differences in different situations; and (c) these differences result in discrimination or a restriction of international trade.

4.281 The first element consists of two aspects: "different levels of protection" and "different situations". The comparability of different situations derives from the fact that the situations have one or more elements in common that make comparison possible. The European Communities has established different levels of protection in two "comparable" situations, that is different levels with

respect to biotech products for products introduced before and after the moratorium, as well as different levels for new "non-biotech" products and new biotech products. The second element is also present in the measure adopted by the European Communities because, given that the levels of risk are the same in both comparable situations, it is inconsistent to apply different levels of protection as has been done by the European Communities. The third element is also present. To determine whether the third element had been present in *Australia – Salmon*, the Appellate Body took into account three "warning signals" and certain "additional factors". The suspension applied by the European Communities, as well as the moratorium has the same three "warning signals" and one additional factor with respect to both comparable situations.

4.282 For the reasons indicated above, the suspension is inconsistent with Article 5.5 of the *SPS Agreement* with regard both to the treatment of biotech products before and after 1998, and the treatment of new biotech agricultural products as compared with new "non-biotech" products.

(v) The suspension is inconsistent with Article 5.6

4.283 WTO jurisprudence indicates that to establish a violation of Article 5.6, it is necessary to determine whether there exists another sanitary or phytosanitary measure that: (1) is reasonably available taking into account technical and economic feasibility; (2) achieves the Member's appropriate level of sanitary or phytosanitary protection; and (3) is significantly less restrictive to trade than the contested sanitary or phytosanitary measure. These three elements are cumulative.

4.284 The first element is present, because the European Communities' procedures, as applied up to 1998, constitute a "measure with technical and economic feasibility" that offers an alternative to the suspension of procedures imposed later by the European Communities. With respect to the second element, the European Communities' procedures presuppose the existence of a level of protection, which prior to 1998, served as a basis for the approval of products. Argentina claims that, if the European Communities' level of protection has been changed, the procedures should also have been changed accordingly. With respect to the third element, the previous implementation of the legislation allowed the approval and consequent access to the market of biotech agricultural products of interest to Argentina, whereas the suspension from 1998 to the present has operated as a restriction on access to the EC market.

4.285 For all the reasons set forth above, Argentina maintains that the suspension implemented by the European Communities from 1998 to the present is inconsistent with Articles 5.1, 2.2, 5.5 and 5.6 of the *SPS Agreement*.

(c) Inconsistency with the *SPS Agreement* of the "undue delay" in the processing of individual applications for approval of biotech agricultural products of particular interest to Argentina

4.286 Argentina will now proceed to demonstrate the inconsistencies between the control, inspection and approval procedures of the European Communities and Article 8 and Annex C of the *SPS Agreement*.

(i) Analysis in light of the provisions of Article 8 and paragraph 1(a), 1(b), 1(c) and 1(e) of Annex C

4.287 In the case of each of the biotech agricultural products of particular interest to Argentina, the application of the European Communities' legislation has involved violations in terms of the obligations under Annex C, and in particular paragraph 1(a), 1(b), 1(c) and 1(e).

4.288 As the moratorium is a sanitary or phytosanitary measure within the meaning of paragraph 1 of Annex A the European Communities' approval procedures must comply with Article 8 and Annex C. The delay has resulted from the complete suspension of consideration of the applications, and ultimately suspension of the application of the control, evaluation and approval procedures provided for biotech agricultural products of particular interest to Argentina.

4.289 The European Communities' legislation sets deadlines for each of the required steps. It is possible to estimate an approximate length of time within which it seems "reasonable" that the procedures could be completed. The suspension of procedures has resulted in delays that can in no case be justified in light of the periods of time stipulated in the European Communities' legislation, and these delays are not based on sufficient scientific evidence.

4.290 With regard to paragraph 1(a) of Annex C, although Regulation 258/97 defines a procedure that does not differentiate in terms of implementation between biotech products and new non-biotech products, the undue delay has occurred only in connection with the former products. Another example is the treatment accorded to products of this same type before and after the *de facto* moratorium. With regard to paragraph 1(b), in some cases the authority failed to determine promptly whether the documentation was complete, and in other cases it failed to inform the applicant of the results of the procedure or of the current stage of the procedure. Paragraph 1(c) limits information requirements to what is necessary for appropriate control, inspection and approval procedures. The European Communities has violated this paragraph by delaying the examination of applications submitted or by requiring successive submissions under the terms of subsequent legislation. Paragraph 1(e) which establishes the obligation to ensure that the requirements for control, inspection and approval of individual specimens of a product are limited to what is "reasonable and necessary"; however, the detailed requirements of the European Communities do not appear to meet the criteria of reasonableness and necessity. Moreover, the European Communities' own bodies have failed to exercise their authority, which failure to act cannot be deemed reasonable or necessary. Furthermore, when the European Communities was pursuing its policy of replacing Directive 90/220 with its successor Directive 2001/18, and even when the latter Directive was in force, no consideration was given to the new applications submitted.

3. Inconsistency with GATT 1994

(a) Inconsistency with Article III:4

4.291 The suspension of the approval processes for biotech agricultural products of particular interest to Argentina is inconsistent with Article III:4 since the treatment accorded to biotech agricultural products is less favourable than that accorded to "non-biotech" agricultural products. In this regard, Argentina considers that: (a) the products are "like products" within the meaning of Article III:4; (b) the suspension is a "requirement" that affect "the sale, offering for sale, purchase, transportation, distribution or use of these products in the internal market"; and (c) "less favourable treatment" has been accorded.

(i) "Like products" within the framework of Article III:4

4.292 "Like" does not mean "identical." Likeness must be determined on a case-by-case basis, using four general criteria, in accordance with GATT/WTO case law. Therefore, Argentina has selected four criteria for examination: (i) the physical properties of the products; (ii) the extent to which the products are capable of serving the same or similar end-uses; (iii) the extent to which consumers perceive and treat the products as alternative means of performing particular functions in order to satisfy a particular want or demand; and (iv) the international classification of the products

for tariff purposes. The Appellate Body in *EC- Asbestos* found that each of the criteria should be analysed. Argentina considers that biotech and "non-biotech" agricultural products share these four criteria, as explained below.

4.293 With respect to (i), as a risk assessment has determined that there is no difference between the risks presented by the biotech agricultural products of particular interest to Argentina and those presented by their "non-biotech" counterparts, from the standpoint of their physical properties, there is no difference between these products. With respect to (ii), biotech products and their counterpart "non-biotech" products have similar end-uses. The relevant European Communities' scientific committees, in evaluating the biotech agricultural products, confirmed that their end-use could be the same as that of "non-biotech products". With respect to (iii), in the EC market, the *de facto* moratorium and the suspension have had the effect of barriers to trade and competition. These types of measures can induce or lead to errors in consumer perception of biotech products. With respect to (iv), there is no difference in tariff classification between biotech products and their "non-biotech" counterparts.

(ii) The suspension is a "requirement" affecting "the sale, offering for sale, purchase, transport, distribution and use of products on the domestic market"

4.294 The suspension is a "requirement". The GATT/WTO jurisprudence indicated that a government action that imposes no legal obligation may be considered a "requirement" under this provision. The suspension is also capable of affecting the sale, offering for sale, etc., because it affects the conditions of competition. Therefore, this second element is satisfied.

(iii) "Less favourable treatment" is accorded

4.295 As a result of the suspension, these products are not being approved even though some of them have received a favourable opinion from the relevant European Communities' scientific committees. Therefore, this third element is satisfied.

4.296 On the grounds set forth above, Argentina considers that the "suspension of processing and failure to consider individual requests for approval of specific biotech agricultural products of particular interest to Argentina" violates paragraph 4 of Art. III of the GATT 1994.

4. Inconsistency with the *TBT Agreement*

(a) Alternative application of the *TBT Agreement*

4.297 As the moratorium constitutes a sanitary or phytosanitary measure, the *SPS Agreement* is applicable. It must be emphasized that the *SPS* and *TBT Agreements* are mutually exclusive, as stipulated by Article 1.5 of the *TBT Agreement* and Article 1.4 of the *SPS Agreement*. Nevertheless, if the Panel considers that it should not analyse Argentina's claim under the *SPS Agreement*, Argentina will argue alternatively under the *TBT Agreement*.

4.298 The *TBT Agreement* applies to "technical regulations" and "conformity assessment procedures" as defined in Annex 1, paragraphs 1 and 3, respectively. In this regard, Directive 2001/18 (and its predecessor Directive 90/220) and Regulation 258/97 are "technical regulations" pursuant to Annex 1, paragraph 1; and the approval procedures of this same regulation constitute "conformity assessment procedures" pursuant to Annex 1, paragraph 3.

(b) Inconsistency with the *TBT Agreement* of the application of the European Communities' legislation in relation to the approval of biotech agricultural products of particular interest to Argentina

(i) The European Communities' legislation constitutes "technical regulations" pursuant to paragraph 1 of Annex I

4.299 The Appellate Body in *EC – Asbestos* has established the three following criteria for determining whether a document fits the definition of "technical regulation" in the *TBT Agreement*: (a) the document must apply to an identifiable product or group of products; (b) the document must lay down one or more characteristics of the product; and (c) compliance with the product characteristics must be mandatory. Directive 2001/18 (as well as its predecessor Directive 90/220) and Regulation 258/97 are technical regulations that meet these three requirements.

4.300 With regard to the first criterion, this requirement is met since the regulation in question refers to "genetically modified organisms", that is, an identifiable group of products. With regard to the second criterion, it is also met since the characteristic established by the European Communities' legislation is the absence of adverse effects on human health and the environment. The third requirement is also met, as a reading of the legislation makes clear its mandatory nature.

(ii) The procedures under the European Communities' legislation constitute conformity assessment procedures

4.301 The procedures under the European Communities' legislation constitute conformity assessment procedures as defined by point 3 and the Explanatory Note of Annex 1, because the requirements therein were established "to determine that relevant requirements in technical regulations … are fulfilled".

(iii) The application of the European Communities' legislation is inconsistent with Article 2.1

4.302 The way in which the European Communities has applied its legislation to biotech products of particular interest to Argentina is inconsistent with Article 2.1. Since Article 2.1 basically develops the same obligations as Article III.4 of the GATT 1994, we refer to the arguments made in the relevant part of this submission.

(iv) The application of the European Communities' legislation is inconsistent with Article 2.2

4.303 For the application of a technical regulation to be consistent with Article 2.2, it must comply with three requirements: (a) pursue a legitimate objective; (b) fulfil that objective; and (c) not be more trade-restrictive than is necessary to fulfil that legitimate objective, taking account of the risks non-fulfilment would create. The EC regulation is inconsistent with Article 2.2 in light of these requirements.

4.304 With respect to the first requirement, the way in which the EC regulation has been and continues to be applied is inconsistent with this provision, even though the technical regulations at issue include health among their legitimate objectives. With regard to the second requirement, the objective of protecting against the potential risks associated with the products has already been satisfied by seeking the opinion of the relevant European Communities' scientific committees. However, the European Communities has chosen to disregard this scientific evidence. With regard to the third requirement, the biotech products of particular interest to Argentina have already received a favourable scientific opinion, which implies that these products do not pose any risks that differ from

those posed by their "non-biotech" counterparts. Nonetheless, these products have not been approved, which is clearly more restrictive than necessary and creates barriers to international trade.

(v) The application of the European Communities' legislation is inconsistent with Articles 5.1.1, 5.1.2, 5.2.1, 5.2.2.

4.305 The application of the European Communities' legislation is inconsistent with Article 5.1.1 since it is applied in such a way as to ensure less favourable treatment of biotech products than of like "non-biotech" products. The application of the European Communities' legislation is also inconsistent with Article 5.1.2, since it has had the effect of imposing an absolute ban on imports of biotech products and created unnecessary obstacles to international trade. The obligation of Article 5.2.1 to complete the procedures "as expeditiously as possible" has not been fulfilled by the European Communities, because since 1998 there have been neither approvals nor processing of applications. The way in which the European Communities has applied the EC procedures since 1998 fails to meet the requirements of Article 5.2.2, since the decision to suspend or postpone the processing of applications does not fulfil such obligations as to "proceed as far as practicable with the conformity assessment"; nor have the competent EC bodies fulfilled their obligations "promptly."

(vi) Inconsistency of the application of the European Communities' legislation with Article 12

4.306 This provision is part of the "special and differential treatment" envisaged in WTO agreements. The provision is mandatory and more than a mere obligation to cooperate. The obligation applies to both the preparation and the application of technical regulations, standards and conformity assessment procedures.

4.307 The suspension constitutes a restriction on trade that has had effect of an absolute ban on access into the EC market of the biotech products of interest to Argentina. This has had and is still having a considerable impact on Argentina, a developing country. Like other developing countries, Argentina has special trade, financing and development needs, as Argentina is heavily dependent on agricultural production and exports. Argentina is also the world's second-largest producer of biotech agricultural products, and it ranks first among developing countries producers.

4.308 On the grounds set forth above, we alternatively request that the application by the European Communities of its own legislation to biotech agricultural products of particular interest to Argentina be declared inconsistent with the *TBT Agreement*, and specifically with Articles 2.1, 2.2, 5.1.1, 5.1.2, 5.2.1, 5.2.2 and 12 thereof.

5. Bans by various EC member States

4.309 The specific bans that Germany, Austria, Italy and Luxembourg have applied to the entry of biotech agricultural products are inconsistent with WTO rules. All the products concerned have been approved by the relevant EC authorities. The European Communities' legislation allows member States to provisionally restrict or prohibit the use and/or sale of a product on their territory. Several member States sought to protect themselves under this provision. However, the relevant EC bodies have considered these actions by the member States and ruled against these member States' actions.

(a) The member State bans are inconsistent with the *SPS Agreement*

(i) The EC member State bans as measures under the SPS Agreement

4.310 To constitute a sanitary or phytosanitary measure as defined by Article 1.1, the measure in question has to meet two requirements: (a) the measure in dispute must be a sanitary or phytosanitary measure, and (b) the measure must be able to affect international trade.

4.311 To be considered as such, a sanitary or phytosanitary measure must contain two elements. First, it must have as its objective at least one of the objectives cited in paragraphs 1(a) to 1(d) of Annex A, and second, it must also be reflected in one of the instruments cited in the second part of paragraph 1 of Annex A. In respect of the first element, the sanitary or phytosanitary objective of the measures applied by the member States can be inferred from the relevant EC legislation. With respect to the second element, Argentina reiterates its previous arguments with respect to the non-exhaustive nature of the instruments listed. The measures applied by the member States also affect international trade, because each and every one of them denies the affected biotech products access to the market of member State taking the action.

(ii) The member State bans are inconsistent with Article 5.1

4.312 In not having performed the risk assessment established in this provision, the member States have not fulfilled their obligations under Article 5.1 and paragraph 4 of Annex A. Furthermore, even though the relevant European Communities' scientific committees ruled against them, the EC member States have not lifted the bans and have violated Article 5.1.

(iii) The member State bans are inconsistent with Article 2.2

4.313 The inconsistency of the member State bans with Article 2 arises due to its inconsistency with Article 5. However, the bans also violate Article 2 for the following reasons. This provision implies that a rational relationship must exist between the sanitary measure and the scientific evidence. This rational relationship clearly does not exist in this case, since not only do the EC member State bans have no scientific evidence to support them but there is even scientific evidence against them. The bans furthermore conflict with the obligation in Article 2 that a measure be applied "only to the extent necessary", and this conflict cannot be justified under the exception of Article 5.7.

(iv) The member State bans are inconsistent with Article 5.5

4.314 As stated above, three elements must be demonstrated in order to establish that this provision has been violated. All three elements are present with regard to the bans imposed by the EC member States.

4.315 With regard to the first element, while all the products affected by the bans have been authorized under the procedures of the European Communities and the member States concerned participated in the approval process, these member States are maintaining their bans. They claim that their measures are justified because they have a level of protection <u>different</u> from that used by the European Communities for <u>the same products</u>. However, as these products have the same level of risk, the member States are applying different levels of protection in comparable situations.

4.316 With regard to the second element, given that the levels of risk are the same, it is inconsistent to apply different levels of protection. Yet this is what some EC member States have done with

respect to biotech agricultural products approved under EC procedures and those banned under national regulations.

4.317 An inspection of the actual text of the regulations concerned shows that there is an explicit restriction on international trade, the third element of an Article 5.5 violation. The member State bans display the three "warning signals" and one additional factor. With regard to the "warning signals", the difference between the levels of protection applied by the EC member States is "arbitrary and unjustifiable." Furthermore, there is a considerable and unjustified degree of difference between the level of protection applied to authorized biotech products and the banned products. Finally, the member States did not base these bans on a risk assessment. With regard to the "additional factor", the effect of the bans imposed on the biotechnology-producing countries is significant and adverse. Similarly, the bans are not based on a risk assessment and have an adverse effect on biotech products, the vast majority of which originate outside the European Communities.

(v) The member State bans are inconsistent with Article 2.3

4.318 Pursuant to the WTO's jurisprudence, Argentina maintains that as the member State bans have been shown to be inconsistent with Article 5.5, they also violate Article 2.3.

(vi) The member State bans are inconsistent with Article 5.6

4.319 We reiterate our previous assertions with respect to the three requirements under this article. These three requirements are present, and thus the bans at the level of the EC member States violate Article 5.6.

4.320 With regard to the first element, the member States in question could have imposed alternative measures to the extreme of an absolute ban. With regard to the second element, an appropriate level of protection was established by the European Communities' own regulations as they functioned until 1998. If a member State considered it necessary to redefine the appropriate level of protection, it could invoke the "special safeguard", but always subject to a final scientific opinion that would justify the different level of protection. With regard to the third element, any measure other than a ban would have had a less restrictive effect. The "special safeguard" itself, given its provisional nature, has a less restrictive effect.

4.321 On the grounds set forth above, Argentina maintains that the bans established by the member States are inconsistent with Articles 5.1, 2.2, 5.5, 2.3 and 5.6 of the *SPS Agreement*.

(b) The member State bans are inconsistent with the GATT 1994

(i) Inconsistency with Article III:4

4.322 The bans of some EC member States infringe Article III:4 because the above-mentioned three requirements identified by the Appellate Body for establishing a violation of Article III:4 are met. With regard to the first element, we reiterate our previous arguments relating to the suspension. With regard to the second element, the member State bans have clearly been implemented through positive legislation: "regulations," "ministerial orders," [and] "decrees" and relate explicitly to restrictions on the entry of biotech agricultural products into the respective markets. With regard to the third element, the bans constitute an absolute ban on imports of those products, whereas like "non-biotech" products and other biotech products are not subject to restrictions in the internal markets of these member States.

(c) Inconsistency of the EC member State bans with the *TBT Agreement*

4.323 It must be emphasized that the *SPS* and *TBT Agreements* are mutually exclusive, as stated above. However, if the Panel concludes that it should not analyse the matter under the *SPS Agreement*, Argentina argues in the alternative that the EC member State bans are inconsistent with the *TBT Agreement*.

(i) The European Communities' legislation for approval of biotech agricultural products constitutes "technical regulations" pursuant to paragraph 1 of Annex 1

4.324 As explained above, the Appellate Body has established three criteria for determining whether a document fits the definition of a "technical regulation" in the context of the *TBT Agreement*. The member State bans are technical regulations that satisfy the three requirements. The first criterion is met since the bans at issue refer explicitly to specific biotech agricultural products. With regard to the second criterion, the Appellate Body in *EC – Sardines* ruled that the product characteristics may be imposed in positive or negative form. In the bans at issue, the EC member States have opted for a negative description. The third criterion is also satisfied, as a reading of the regulations establishing the member State bans clearly indicates their mandatory nature.

(ii) The bans applied by some EC member States to specific biotech agricultural products of particular interest to Argentina are inconsistent with Article 2.1

4.325 Since Article 2.1 basically develops the same obligations concerning treatment as in Article III:4 of the GATT 1994, we refer to our arguments in the relevant part of this submission.

(iii) The application of the European Communities' legislation is inconsistent with Article 2.2

4.326 For the application of a technical regulation to be consistent with Article 2.2, it must comply with three requirements: (a) pursue a legitimate objective; (b) fulfil that objective; and (c) not be more trade-restrictive than is necessary to fulfil that legitimate objective, taking account of the risks non-fulfilment would create. The EC member States bans are inconsistent with Article 2.2, because they fail to meet all of these three requirements. With regard to the first requirement, the member State bans are inconsistent because, even though the legitimate objectives of technical regulations include health, this does not authorize the EC member States to ignore the existing risk assessments of specific biotech products in order to achieve potentially legitimate objectives. With regard to the second requirement, although the objective of protecting against the potential risks associated with these products has already been met by seeking the opinion of the relevant European Communities' scientific committees, the member States did not take this scientific evidence into account, nor did they produce any evidence that might have refuted those opinions. With respect to the third requirement, although the biotech products of particular interest to Argentina had already received a favourable scientific opinion and thus the legitimate objective was satisfied, these products have been the subject of a ban on imports that is clearly more restrictive than necessary, thus creating barriers to international trade.

(iv) The bans imposed byEC member States on specific biotech agricultural products of particular interest to Argentina are inconsistent with Article 2.9 of the TBT Agreement

4.327 Article 2.9 applies whenever two conditions are present: (a) whenever there is no relevant international standard; and (b) whenever the technical regulation may have a significant effect on other Members' trade. Both conditions are present in the case of the member State bans in question. No relevant international standard exists. The bans are having a significant effect on other Members'

trade, because they are preventing the products from entering the markets of the EC member States that established the bans.

4.328 With respect to Article 2.9.1, Argentina has received no notice in any publication at any stage. Therefore, Article 2.9.1 has clearly been violated. The EC member State bans are also inconsistent with Article 2.9.2 because no notification has been made to the WTO Secretariat. Nor was there compliance with the requirement in Article 2.9.4, because Members were not allowed reasonable period of time to make comments in writing. None of the EC member States that established bans on products of particular interest to Argentina has alleged any of the circumstances mentioned in Article 2.10 that allow Members to avoid their obligations under Article 2.9.

4.329 Thus, should the Panel consider that it is not required to analyse the question under the *SPS Agreement*, Argentina maintains that the identified EC member States, by instituting bans on specific biotech agricultural products, have violated Articles 2.1, 2.2, 2.9.1, 2.9.2 and 2.9.4 of the *TBT Agreement*.

H. FIRST WRITTEN SUBMISSION OF THE EUROPEAN COMMUNITIES

1. Introduction

4.330 Argentina, Canada and United States have initiated these proceedings to challenge what they allege to be a general "moratorium" in the European Communities concerning the approval of genetically modified organisms (GMO) and products derived therefrom, the alleged failure to approve a number of specific applications for the placing on the market of certain GMOs, and certain temporary measures adopted by six EC member States concerning GMOs that have already been authorized in the European Communities.

4.331 The European Communities wish to underline from the very beginning that it has not adopted any general position either in favour or against any of the products subject to these proceedings. In accordance with its regulatory framework, the European Communities assesses each individual GMO on its own merits, in order to evaluate the potential benefits and risks of these novel products. The European Communities does certainly not seek to impose its prudent approach on other countries, who are free to form their own views on the balance of benefits and risks. Similarly, the present WTO challenge should not be used as a means for the complaining parties to impose their approach on the European Communities or indeed any other countries, especially at a time where countries around the world are still trying to clarify their respective positions on this complex issue. The European Communities can only regret that the complaining parties have chosen to start a dispute settlement procedure based on flawed premises, rather than to promote international co-operation as a means to build a sound international framework for addressing the GMO issue.

4.332 In their submissions, the complaining parties seek to evade or ignore the whole socio-political, legal, factual and scientific complexity of the case. The complaining parties wilfully ignore the social controversies that led to the revision of the European Communities' regulatory framework in the period 1998-2001 (a framework that is not challenged). They also ignore the scientific and regulatory debates at the international level that have taken place over the past years, including the process that led to the conclusion of the Cartagena Protocol on Biosafety. The Protocol is based on the understanding that the inherent characteristics of GMOs require them to be subject to rigorous scrutiny so as to ensure that they do not cause harm to the environment or human health, or cause socio-economic disruptions. Moreover, the complaining parties avoid to discuss the specific steps taken in the authorization procedures for GMOs in connection with each individual product, and they instead blur the picture referring to the existence of a "moratorium". Finally, the complaining parties

try to artificially compress this complex dispute into the SPS framework, ignoring the fact that the aims of the European Communities' policies on GMOs go beyond the protection against the specific risks covered by the *SPS Agreement*. The European Communities submits that the Panel will need to analyse all the aspects of the case in their full complexity before the true simplicity of the dispute can be properly recognized.

4.333 Finally, the European Communities would like to remark that it has chosen to respond to the main claims of the three complaining parties through a single first written submission. The submission is not designed to respond to each and every argument of the complaining parties but rather to address the most serious of the distortions inherent in the complaining parties' presentation of the facts and to highlight the fundamental legal errors on which their cases are constructed. The European Communities will provide a full refutation in subsequent procedural steps, when the complaining parties will hopefully clarify the substance of their challenge and their claims. For the avoidance of doubt, the European Communities should not be considered to have accepted any factual or legal submissions by the complaining parties which are not specifically addressed in its submission. Nor should the fact that the European Communities responds to the submissions of the complaining parties globally be taken as an acceptance that anyone of them may make or develop claims that it has not itself made or developed in its panel request and first written submission.

4.334 The European Communities' overall approach in its first written submission can be summarized as follows:

- the GMOs which are the subject of these proceedings each have characteristics which are recognized by the international Community to pose potential threats to human health and the environment, and they cannot be treated as "like" or "equivalent to" their non-GMO counterparts;

- in addressing the potential risks for each of these GMOs the Community regulatory framework has operated on a case-by-case basis, and there has been no formal (*de jure*) or informal (*de facto*) moratorium in respect of the authorization process or any part of it;

- the approach of the European Communities to the identification, assessment and prevention of risks to human health and the environment from each of these GMOs has been fully consistent with evolving and applicable international standards, and any finding to the contrary would seriously undermine the effectiveness of those standards, which are premised on the application of a prudent and precautionary approach;

- it is of fundamental importance that the nature of the action or alleged inaction of the European Communities in respect of each of the GMOs be correctly understood. The WTO agreements contain different provisions relating to different kinds of measures and it is not admissible to re-designate them artificially to allow for the application of provisions that the complaining parties find more convenient but which are not in reality applicable;

- in particular, in respect of each of the GMOs the steps which have been taken to protect the environment and to conserve biodiversity are reasonable and legitimate, are not necessarily sanitary or phytosanitary in character, and fall in whole or in part outside the scope of the *SPS Agreement*;

- to the extent that any steps taken to protect against risks to human, animal or plant life or health in respect of each of the GMOs could be said to be subject to the *SPS Agreement*, there has been no undue delay or breach of any part of that Agreement on the part of the European Communities or any member States, and in any event such steps are provisionally justified on the basis of the insufficiency of scientific evidence;

- all steps taken by the European Communities and its member States in respect of each of the GMOs are consistent with the *TBT Agreement* and the GATT 1994, and in any event are justified in accordance with Article XX of the GATT 1994.

2. Factual part

(a) Scientific background

4.335 A genetically modified organism (GMO) is an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. Contrary to conventional methods of altering genetic material, genetic modification allows for the crossing of natural species barriers, or for the transfer of single or few genes instead of whole genomes.

4.336 Techniques of genetic modification include the use of the bacteria as the delivery mechanism, micro-injection and high velocity ballistic delivery. All techniques have in common that they are actually not able to control where the foreign gene will be inserted and whether that insertion will be stable.

4.337 Development of GMOs began in 1970 and has since then has rapidly evolved in what could be called generational steps. First generation GMOs are mainly crops with either herbicide-tolerant traits or insecticidal properties or the combination of both (so-called stacked genes). More recent generations, most of which are not yet being commercialised include nutritionally enhanced crops and crops that are used for industrial or medical purposes (so-called phytofarming). The European Communities recognizes the potential benefits of the new technology, and subscribes to the approach taken in the preamble to the Biosafety Protocol, which states that "modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health".

4.338 Research so far has identified a number of potential harmful effects resulting either from the very process of genetic modification itself (wrong or unstable insertion) or from the successfully modified end product. Potential harmful effects on human health include toxicity, allergenicity, horizontal gene transfer and antibiotic resistance. Potential harmful effects on the environment, in addition to the above (to the extent they can affect animal or plant life or health) include non-target effects, invasiveness and development of resistance, unintended effects arising through GMO related management practices, and effects on biodiversity. These effects depend on the nature of the specific GMO in question and on the intended use. Where GMOs have been released into the environment, such harmful effects might be irreversible. The need for a pre-marketing case by case assessment, thus, is obvious. In addition, research has only started to identify these issues and long term effects are largely unknown.

(b) International and comparative regulatory arrangements

4.339 In light of these risks, governments around the world, since the first commercialisation of GMOs in the early nineties, have started to address the question of how to regulate GMOs. Regulatory approaches range from complete bans to "laissez faire." Most, however, consist in setting up an approval system specific to GMOs, based on a case-by-case detailed risk assessment. Often such systems are based on a precautionary approach, and decisions are sometimes made dependent on considerations other than scientific factors, such as, for instance, socio-economic considerations. Furthermore, approval may be subject to post-market surveillance requirements. Given the constant evolution of the science on GMOs, regulatory approaches are under constant review in many countries.

4.340 With a view to seeking international consensus governments have also addressed the issue in various international fora. Most importantly, after long and difficult negotiations, they have adopted the Cartagena Protocol on Biosafety in 2000 (103 signatories including Canada and Argentina). The Protocol addresses the safe transfer, handling and use of living modified organisms that may have adverse effect on biodiversity. It establishes an Advance Informed Agreement (AIA) for imports of living modified organisms (LMOs) intended for deliberate release into the environment, incorporates the precautionary principle and details information and documentation requirements.

4.341 In addition, work on specific issues related to GMOs is ongoing in specialized agencies and other international bodies or organisations such as Codex Alimentarius, FAO, WHO, UN, OECD, ASEAN and the African Union. The guidance documents established by these fora, in particular, recognize the need for a case-by-case decision on individual GMOs based on a scientific risk assessment and on risk management considerations.

4.342 Against this background the European Communities submits that it is not plausible to argue that GM products are – or should be treated as – equivalent to non-GM products.

(c) The European Communities' regulatory framework

4.343 The evolution of the European Communities' own legislative framework on GMOs has to be seen against this background. Legislation on the release into the environment of GMOs has been put in place as early as 1990 with the adoption of Directive 90/220, with sector specific legislation, and most specifically, Regulation 258/97 on Novel Foods (including GM foods), following later. The above described developments in scientific research and in international regulatory standards have soon made it necessary for the European Communities to review its legislation. The review process which started in 1998 has led to the replacement of Directive 90/220 through Directive 2001/18 and to the adoption, most recently of further legislation concerning specifically GM food and feed and traceability and labelling.

4.344 Directive 90/220 (and its successor Directive 2001/18) as well as Regulation 258/97, which are the legislative acts relevant to the issues raised in this case, establish approval procedures for the release into the environment of GMOs and for the marketing of GM food. Approval granted on the basis of these acts is valid throughout the European Union. The procedures provide for case-by-case decisions based on scientific risk assessments. Essentially, the assessment takes place at two levels and in two stages: Once an application is lodged in a EC member State, its authorities ('the lead competent authority') make an initial assessment. If it is positive, the dossier is sent up to the Community level from where it is circulated to all other member States. If all agree with the initial assessment, the lead member State grants final consent. If objections are raised, and no agreement can be found, a decision has to be taken at Community level. The Commission consults a scientific

committee (nowadays, the European Food Safety Authority) before presenting a proposal for a decision to a so-called Regulatory Committee consisting of member States representatives. If the proposal does not get a qualified majority in this Committee, the Commission presents a proposal to the Council of Ministers for adoption (or rejection) by qualified majority. If the Council does not act within three months the Commission adopts the decision. While approval is valid throughout the European Union, the legislation provides for the possibility for member States to adopt safeguard measures prohibiting the release/marketing in their own territory.

4.345 As mentioned above, the rapid developments in science as well as in the international regulatory debate, made it necessary for the European Communities to substantially revise its legislation. Directive 90/220, in particular, lacked harmonised standards for the risk assessment and provisions on post-market monitoring and traceability. The proposal for a revised Directive, which the Commission presented in 1998, went through the legislative procedure of co-decision by the European Parliament and the Council, an elaborate process of negotiation between the two bodies, which resulted in the adoption of Directive 2001/18 in the year 2001. The Directive entered into force in October 2002. It provided that pending applications were to be re-submitted in an up-dated form replying to the new requirements by January 2003.

4.346 To the extent that the applicants for authorizations under Directives 90/220 and 2001/18 and Regulation 258/97 are dissatisfied with any act or failure to act of the national authority of a member State or of a Community institution they are free to bring proceedings for administrative or judicial review of such acts. In respect of the 43 products which are the subject of these WTO proceedings the European Communities is aware of proceedings brought in respect of national measures (safeguard provisions) only in the case of Italy. No applications have been made to the European Court of Justice challenging any actions or alleged failure to act of the Community institutions in respect of any of the products.

(d) Individual product applications

4.347 A detailed examination of each of the product applications listed by the complaining parties shows that, contrary to the complaining parties' claims, there has never been a "general suspension" and the individual applications have not been stalled at any moment. As the detailed chronologies and exhibits submitted by the European Communities prove, no single pattern can be identified and each single product has merited and merits an analysis on its own. The evaluation processes have continued through the past years, with the EC authorities at national and European Communities' level trying to take account of the changing legislative and regulatory framework as well as the evolving scientific debate in treating the pending applications.

4.348 Each application has thus its own individual history, with assessments being conducted and concerns being raised, in a process that involved exchanges between competent authorities and between the authorities and the applicant companies. It should be noted that many applications had to be re-submitted under Directive 2001/18 by January 2003 (which is not challenged by the complaining parties) for a fuller assessment. Also, many of the applications listed by the complaining parties have been withdrawn or not re-submitted, usually for purely commercial reasons. It is worth mentioning that in some cases the applicants did not want to be associated with the GM products anymore.

4.349 All pending applications have in the past been subject to requests for additional information of varying kinds. Often requests were related to insufficient data in the dossier to allow for a proper risk assessment as required by the existing legislation. In quite a few cases, however, some requests in the past were also related to requirements which were not yet foreseen in the legislation existing at

the time, and, in particular, to monitoring and traceability issues. Such requests were made in anticipation of the new legislation to be adopted and were based on voluntary commitments on the applicant's side (so-called "interim approach").

4.350 On the applicants' side, in many cases, considerable delays have been taken in replying to requests for additional information. These delays may also have to be seen against the background of the permanent structural changes on the production side of the market. Mergers, acquisitions, transfers of production rights have taken place, changing often the protagonist of the application. This caused sometimes substantial time delays in pursue of the procedure.

4.351 Since the entry into force of Directive 2001/18, the individual applications are now being processed smoothly and are moving through the different instances of the procedures as described above. In some cases, requests for additional information have been put to the applicants related to insufficient data (as required by the legislation) in the application dossier.

3. Legal arguments

(a) Preliminary issues

4.352 The European Communities has considerable difficulties with the complaining parties' identification and characterization of the challenged measures and with their arguments on the applicable law.

4.353 As regards the identification of the measures, all three complaining parties are alleging the existence of a "general moratorium" affecting all GMOs, as well as the existence of a separate measure consisting in "suspensions" affecting certain specific GMOs. Aside from the fact that the complaining parties fail to explain how the European Communities would be applying simultaneously those two separate measures, they try unsuccessfully to identify an instrument or other text in which such a "moratorium" is brought into effect. In reality, the European Communities does not impose nor does it intend to impose any "moratorium" on GMOs, let alone a ban. As the complaining parties' case concerns the conduct of approval procedures (i.e. the delay in completing such procedures), the relevant WTO rules should be those obligations that concern procedures rather than those that deal with the adoption of substantive measures. Once the acts complained of are correctly characterised as delay, it is clear that they cannot amount to a ban. The fact that GMOs cannot be marketed until approved is an intrinsic feature of the European Communities' GMO legislation, which is not challenged in these proceedings, and it has to be clearly distinguished from allegations about delays in the assessment procedures.

4.354 As regards the applicable law, the European Communities does not agree that the *SPS Agreement* is the only relevant agreement for the purposes of this dispute. The scope of the *SPS Agreement* is limited to measures adopted to prevent an exhaustive list of narrowly defined risks. To the extent that a domestic measure is aimed at the protection against other risks, or that it pursues other different objectives, the *SPS Agreement* is not applicable.

4.355 The issues arising out of the existence of GMOs go far beyond the risks envisaged and regulated by the *SPS Agreement*. A rigorous interpretation of the definitions in Annex A.1 of the *SPS Agreement* unequivocally shows that measures addressing issues such as antibiotic resistance or changes in the ecological balance are not among the measures that the *SPS Agreement* intends to discipline. Since the European Communities, through its actions, aims at the fulfilment of objectives that go beyond the specific situations that determine the applicability of the *SPS Agreement*, such

Agreement does not provide a sufficient legal framework for the examination of the European Communities' behaviour.

4.356 The above conclusion does not imply that the *SPS Agreement* is irrelevant for the present dispute, nor it means that the European Communities' behaviour cannot be scrutinised under any WTO rule. The European Communities is of the view that the *SPS Agreement* is relevant in relation to some of the issues that are examined by EC authorities in the course of GMO approval procedures (including safeguard mechanisms). However, the *SPS Agreement* cannot exclude the applicability of other WTO rules to different, non-SPS, aspects of the challenged measures. GATT 1994 and, where relevant, the *TBT Agreement*, can be used to examine those other aspects of the European Communities' behaviour. In that regard, it should be noted that the effect of Article 1.5 of the *TBT Agreement* is to exclude the cumulative application of the *TBT* and the *SPS Agreements* to measures that squarely fit in the definitions of Annex A.1 of the *SPS Agreement*. Article 1.5 certainly does not imply, in the case of a composite measure that is only *partly* pursuing SPS aims, that the *TBT Agreement* is entirely irrelevant and that a narrow examination of one single element of the measure under the *SPS Agreement* can lead to a conclusion on the WTO-consistency of the measure as a whole. Clearly, any measure or part of any measure adopted for reasons that fall outside the scope of the *SPS Agreement* cannot be inconsistent with that agreement.

4.357 The European Communities therefore claims that the measures subject to these proceedings must be revised separately under more than one WTO agreement, according to their nature and aims, before reaching a conclusion on their overall consistency with WTO obligations. Furthermore, the European Communities claims that the general exceptions contained in Articles XX and XXI of the GATT 1994 also apply to the *TBT Agreement*.

4.358 Finally, as a general remark, the European Communities would like to stress the importance of international regulatory acts in the field, in particular the Cartagena Biosafety Protocol. According to the Appellate Body, the rules of customary law "call for an examination of the ordinary meaning of the words of a treaty, read in their context, and in the light of the object and purpose of the treaty involved". The Biosafety Protocol can assist the Panel in the process of interpreting WTO rules, in accordance with the Appellate Body findings in *US – Shrimp*.

(b) The product-specific delays

(i) The measure

4.359 At the outset, the European Communities would underline that nineteen of the applications listed by the complaining parties have been withdrawn or abandoned. The European Communities submits that the Panel should consider the claims concerning those applications as inadmissible. Findings on those specific applications cannot serve any useful purpose, as required by Article 3 of the DSU, since the European Communities cannot take any action with regard to those product applications.

(ii) SPS Agreement

4.360 The European Communities submits that among the various provisions which the complaining parties allege to have been violated under the *SPS Agreement* only Article 8 together with Annex C can be applied to the facts of the case, to the extent that the European Communities' approval procedures address risks coming under point 1 of Annex A of the *SPS Agreement*. The alleged failure to deal with certain product applications is not an SPS measure, the nature of the latter (as defined in Annex A point 1) requiring the existence of an act, however formal or informal. The

alleged failure to reach a final decision on certain product applications, therefore, can only be challenged as the *application* of an SPS measure, but not as an SPS measure itself.

4.361 Only Article 8 and Annex C address issues of *application* of an SPS measure (with the latter being the approval system as established by the European Communities' GMO legislation). All other violations alleged by the complaining parties relate to an SPS measure *as such.* Given that the alleged failure to act does not constitute an SPS measure, the provisions invoked by the complaining parties are not applicable.

4.362 There is no violation of Article 8 and the various provisions of Annex C cited by the complaining parties, and, in particular, there have not been any "undue delays" within the meaning of Annex C point 1 (a).

4.363 The concept of "undue delays" is to be interpreted in accordance with the general rules of international law on treaty interpretation and can be understood to be referring to a period of time lost by inaction or inability to proceed which is unjustifiable. It is clear also that the meaning of the words "undue delay" cannot be inferred from the domestic legislation of WTO Members. It is not the purpose of the *SPS Agreement* to transform any departure from national legislation to the level of a breach of international law. Argentina's and the United States' argument, therefore, that "undue delay" can be inferred from the alleged fact that procedural delays set out in the European Communities' legislation have not been respected, must be dismissed.

4.364 On the basis of the facts outlined above it is clear that the approval process for individual applications in question, has not been "generally suspended" (as the complaining parties allege) at any time since 1998. Where delays have occurred in individual instances due to requests for additional information such delays (to the extent they are, at all attributable to the European Communities) have been justified by the nature of these requests.

4.365 On a level of principle, the European Communities submits that it is legitimate to request additional information necessary for the completion of a risk assessment and/or compliance with certain standards of risk management or risk communication as they have been established by a regulator and as they apply to the given product in question. That principle applies generally to any product that goes through an approval or inspection procedure designed to ensure that this product is safe. It applies *a fortiori* when the product in issue is based on a new technology which is generally untried and untested and which is recognized by the international Community to have characteristics which inherently require prudence and caution.

4.366 Such requests do not become "illegitimate" if and because they are not expressly set out in the legislation applicable at the time of the application nor do they become "illegitimate" where they are put in the form of a legislative requirement to re-submit an up-dated dossier (a requirement that has not been challenged by the complaining parties in their panel requests).

(iii) GATT 1994 – Article III:4

4.367 Canada and Argentina have invoked Article III:4 of the GATT 1994 in relation to the alleged product specific delays. The European Communities disagrees that its conduct with regard to specific product applications constitutes a breach of said article. First of all, the measures challenged by Canada and Argentina are alleged delays in dealing with specific requests for approval. These measures are not in themselves "laws, regulations or requirements". Second, a violation of Article III can only occur if it can be shown that imported products are treated less favourably than domestic like products. The European Communities has not taken more time to authorize the importation of the

GMOs at issue than to authorize their domestic cultivation or processing. Therefore, there is no difference in treatment. Third, conventional, non-GM products are not subject to the same approval procedure, and the international community has recognized that GM products require their own, distinct authorization procedure. As a result, the only "like" products for comparison can be GM products and not their non-biotech counterparts.

(c) The "general suspension"

(i) The measure

4.368 The complaining parties seem to argue is that in the European Communities there exists an alleged practice of suspending the consideration of applications and approvals, in the form of a repeated pattern of systematic behaviour. Such a practice is not based on any document even informal or non binding in nature.

(ii) There is no general suspension

4.369 The European Communities has shown through extensive factual evidence that there is no general suspension and there has never been one any at any point in time. There is no consistent practice in respect of all the applications as a whole. Each has been taken on its own merits.

4.370 The "evidence" put forward by the complaining parties regarding the absence of final approvals in the past 5 years is incorrect, inconclusive and inconsistent. It is incorrect, because (as is uncontested) GM products have been authorized to be put on the market during this time. It is inconclusive, because the absence of an approval does not mean that an approval process has been suspended. It is inconsistent, because the United States only refers to a limited number of products (instead of all) and only to an alleged situation in the past (and not to the present). Canada, on its part, cannot reconcile its presentation of processes being "stalled" with the plain fact that dossiers are moving through the different instances.

4.371 The "evidence" of various "statements" from different sources presented by the complaining parties is mostly irrelevant and otherwise inconclusive. On the basis of WTO jurisprudence on statements as evidence, only official statements of the European Communities could at all be relevant. Those statements of the European Commission which come closest to being "official statements," do not announce nor confirm a suspension of the approval processes.

4.372 In any event, even assuming that on the basis of that "evidence", and in spite of the actual facts, it could be said that there was in the past a systematic suspension of the approval process, such a pattern or practice would not as such constitute a challengeable measure under the *WTO Agreement*.

(d) The EC member State safeguard measures

(i) SPS Agreement

4.373 As regards the measures taken by the EC member States, which affect GMOs already authorized in the European Communities, these are provisional measures pending a full assessment at European Communities' level, which will eventually lead either to a modification of the Community-wide authorization or a termination of the national safeguard measures. The safeguard measures are therefore provisionally and temporary in their character. This is confirmed by the measures themselves, by the explicit terms of the legal provisions on which they are based (Article 16 of

Directive 2001/18 and Article 12 of Regulation 258/97) and finally by the European Court of Justice (case C-236/01).

4.374 Consequently, these measures should be reviewed under Article 5.7 of the *SPS Agreement* to the extent that they are falling under the *SPS Agreement*. Indeed, Article 5.7 is specifically designed to discipline a subset of SPS measures, namely temporary measures, to the exclusion of other SPS provisions wrongly invoked by the complaining parties such as Article 5.1.

4.375 Far from being an exception, Article 5.7 is the relevant provision to examine temporary measures. All three complaining parties have failed to assert in their panel requests that any of the measures adopted by the member States are inconsistent with Article 5.7 of the *SPS Agreement*. Therefore, their claims on the safeguard measures must be dismissed. Moreover, there is no burden of proof on the European Communities concerning the four conditions in Article 5.7. In any event, the European Communities contends that the four conditions are met: first, the scientific evidence was insufficient; second, the member States based their measures on available pertinent information; third, member States and the European Communities are engaged in an ongoing process by which they are seeking to obtain the additional information necessary for a more objective assessment of the risk; and fourth, the measures are subject to a review within a reasonable period of time.

4.376 As said before, Article 5.7 of the *SPS Agreement* contains specific rules regarding provisional measures, and it is by reference to these rules, not the rules in Article 5.1, that the member State measures must be assessed. However, should Article 5.1 be considered relevant, the European Communities stresses the importance of the terms "appropriate to the circumstances" that qualify the obligation to base measures on a risk assessment. Those terms logically imply a certain degree of flexibility, especially in cases where scientific knowledge is still developing and the potential risks being assessed are important. Furthermore, SPS measure must be "based on" (not "conform to") a risk assessment, and a given risk assessment may reasonably support more than one possible SPS measure. As a matter of fact, there is no obligation for WTO Members to follow mainstream scientific opinions.

4.377 The complaining parties' claims under Articles 5.6 and 5.5 of the *SPS Agreement* must also be rejected. As regards the former Article, the complaining parties' arguments are based only on the basis of a wrong assumption about the appropriate level of protection that is being sought. Furthermore, it is self-evident that the necessity of the measure would have to be judged by reference to the insufficiency of scientific evidence, and the reasonable period of time necessary. As regards Article 5.5, its application is effectively excluded by Article 5.7 of the *SPS Agreement* and, in any event, the European Communities has not behaved in an arbitrary manner or made unjustifiable distinctions. The differences in treatment alleged by the complaining parties are between entirely *different* GMOs or between GMOs and conventional products and are not arbitrary or unjustified.

4.378 Finally, since the complaining parties' claims under Articles 2.2 and 2.3 of the *SPS Agreement* are in fact derived from their claims under Articles 5.6 and 5.5, they must equally be dismissed.

(ii) The GATT 1994

4.379 Argentina and Canada allege that the member States measures violate Article III:4 of the GATT 1994. The European Communities rejects such claims as unfounded. The prohibitions established by the member States, which are no more than temporary territorial exceptions to the original EC authorizations, cannot but apply in the same way to GMOs which are domestically produced or processed within the Community territory and to those that are imported. A "treatment less favourable" for imported than for domestic products is thus intrinsically impossible in this case.

Furthermore, as mentioned above, the European Communities considers that in the context of marketing approval legislation, the "like" product has to be a product which is similarly subject to the approval procedure. Choosing a category of like product which is outside the approval procedure amounts to attacking the ratio of the distinction operated by the legislation, which is not being challenged in these proceedings. Moreover, the European Communities also contests that the "like products" comparison can be carried out on the basis of such broad categories and generic terms such as "respective domestically-grown non-biotech counterparts" and "imported biotech products and 'non-biotech' domestic products", without any proof being provided on the specific properties, nature, quality, end-uses, consumers' tastes and habits of each specific product at stake.

4.380 Canada also contends that the Greek measure is in breach of Article XI:1 of the GATT 1994. It is however clear that the nature and aim of the Greek measures does not differ from those of the other national measures called into question by Canada. Indeed, the aim pursued by Greece is the temporary restriction of the introduction or use of a given GMO within its territory, no matter the origin of the product.

(iii) The TBT Agreement

4.381 Finally, no TBT violation can be found in relation to the challenged member States measures.

4.382 The European Communities considers that the member State measures are not technical regulations within the meaning of the *TBT Agreement*. The definition of "technical regulation" in the Agreement refers essentially to a *normative* type of measures, that is, one that lays down in relatively abstract terms certain rules, with which products must comply. However, each member States measure is in fact an *individual administrative act* relating to *a* specific product from a specific applicant or manufacturer. Each of those measures amounts to a simple ban on a product *in its natural state*, and they do not therefore contain "product characteristics" in the general and abstract sense in which that term is used in Annex 1, point 1 of the *TBT Agreement.*

4.383 In any event, neither Article 2.1 nor Article 2.2 of the *TBT Agreement* would provide support to the complaining parties' case. On the one hand, even if non-GM products could be considered to be "like" a GM products (*quod non*), Article 2.1 of the *TBT Agreement* can only apply to differences in treatment between products that are, by their nature, susceptible of being covered by the technical regulation in question. On the other hand, the assertion that the member States measures do not contribute to achieving their objectives is unsubstantiated and it fails to take into account the review of the relevant EC legislation and the parallel review of the EC authorizations concerning the products affected by the member States measures.

(e) The special and differential treatment claims

4.384 The European Communities does not accept that there is violation of the "special and differential treatment" obligations in Article 10.1 of the *SPS Agreement* and Article 12 of the *TBT Agreement*. Argentina deduces those violations merely from the alleged breach of other provisions of the agreements, which the European Communities contests. Furthermore, trade statistics show that imports from developing countries that have widely adopted GM agriculture have not decreased.

(f) Article XX of the GATT 1994

4.385 Last but not least, the European Communities submits that if the Panel found any of the challenged measures to be inconsistent with any of the provisions invoked by the complaining parties,

those measures should be found to be justified under Article XX of the GATT 1994 because (1) they come under one of the particular exceptions of paragraphs (b), (d) or (g) and (2) they do not constitute an arbitrary or unjustifiable discrimination between countries where the same conditions prevail or disguised restrictions on international trade.

4. Conclusion

4.386 In conclusion, the European Communities requests the Panel to reject the complaining parties' claims and to find that:

- The delays in the examination of the applications which are the subject of these proceedings are not in violation of the *SPS Agreement*, the *TBT Agreement* or the GATT 1994;
- There is no general suspension of the process of authorizing GMOs and GM products;
- The EC member States national measures are not in violation of the *SPS Agreement*, the *TBT Agreement* or the GATT 1994.

I. FIRST ORAL STATEMENT OF THE UNITED STATES

1. General comments on European Communities' first written submission

4.387 First, much of the European Communities' submission addresses issues that have little, if any, connection to the legal questions in dispute in this proceeding. The European Communities' submission stresses the European Communities' view that biotechnology involves complexity. However, the European Communities does not claim, and indeed could not claim, that any of the scientific issues discussed in its background section justified either a general moratorium or the product-specific moratoria. Instead, the European Communities claims that there was no moratorium at all. To make this claim, the European Communities asks us to believe that the European Communities' own highest officials misunderstand the European Communities' approval system, and that the failure to approve any biotech products between October 1998 and August 2003 was mere coincidence.

4.388 Moreover, if the European Communities has scientific questions about biotechnology, those questions can be and should be addressed within the context of the European Communities' own approval system, and in a manner consistent with its WTO obligations. Indeed, this is just how the European Communities approached scientific and technical issues for the biotech products that the European Communities approved prior to October 1998.

4.389 Similarly, the European Communities does not claim, and could not claim, that any proceedings in other international fora absolve the European Communities from complying with its WTO obligations regarding biotech products. Most notably, the European Communities discusses the Biosafety Protocol at length. The European Communities itself, however, acknowledges that the Protocol explicitly provides that parties may <u>not</u> disregard their existing international obligations in their implementation of the Biosafety Protocol. Furthermore, the Biosafety Protocol foresees a functioning regulatory system in each Party country; it does not provide an excuse for refusing to make prompt, transparent decisions.

4.390 The second general comment regarding the European Communities' submission concerns its arguments on the applicability of the *SPS Agreement*. In this discussion, the European Communities

argues at length, and in the hypothetical, that the European Communities might adopt measures that are not covered within the scope of the *SPS Agreement*. But, once again, the European Communities does not link its discussion to the legal issues in this dispute. The pertinent question is whether the measures that the European Communities has actually adopted, and that are covered in this dispute's terms of reference, are within the scope of the *SPS Agreement*. And, the European Communities' measures in this case are plainly included within the scope of the *SPS Agreement*.

4.391 The third general comment is that the European Communities has attempted to de-emphasize the general moratorium. The United States wishes to reemphasize, as made clear in its opening submission, that the general moratorium is at the core of this dispute. The United States brought this dispute because the European Communities at the highest levels announced a general moratorium on biotech approvals, and followed through on those pronouncements by failing to approve any biotech products for over 5 years.

2. General moratorium violates the *SPS Agreement*

4.392 The European Communities' discussion of the general moratorium is remarkable in that it is concerned solely with whether or not the general moratorium qualifies as a "measure" under the *SPS Agreement*. Should the Panel find, as the complaining parties all submit, that the general moratorium is indeed a measure under the *SPS Agreement*, the European Communities has <u>not</u> contested that the general moratorium: results in "undue delay" in breach of Article 8 and Annex C; is inconsistent with its obligations under Article 7 and Annex B to publish measures promptly; is inconsistent with its obligations under Article 8 and Annex C(1)(B) to keep applicants informed of the progress of applications; is not based on a risk assessment as required under Article 5.1; and results in arbitrary or unjustifiable distinctions in the levels of protection in breach of Article 5.5.

4.393 The evidence that the general moratorium exists is overwhelming. To summarize the facts in the first written submission of the United States: Up to October 1998, the European Communities had approved at least ten biotech products. But between October 1998 and August 2003, the European Communities failed to approve a single biotech product under its novel foods or deliberate release legislation, even though many of those products had been favourably assessed by the European Communities' own scientific committees.

4.394 The moratorium became widely known no later than June 1999, when it was announced by Environment Ministers of five member States. In particular, at a Council Meeting of EC Environment Ministers in June 1999, Environment Ministers of Denmark, Greece, France, Italy and Luxembourg issued a Declaration stating: "in exercising the powers vested in them regarding the growing and placing on the market of genetically modified organisms… they will take steps to have any new authorizations for growing and placing on the market <u>suspended</u>."

4.395 The statements of Commission and member State officials confirm the existence of a moratorium. For example, the European Communities' official representative to the SPS Committee acknowledged the existence of the moratorium. At the meeting of the SPS Committee held on 31 October-1 November 2001, the summary of the meeting notes the following European Communities' response: "The recent meeting of the European Environmental Council had started a very important discussion on proposals presented by the Commission to *restart* the authorization procedure." The EC representative's statement that there were proposals to *restart* biotech authorization procedures is plainly an acknowledgment that those procedures had been suspended.

4.396 Commission documents also confirm the existence of the moratorium. Most recently, in an official Background document to the Agriculture and Fisheries Council of Ministers held on 26 April

2004, the following statement appears: "The adoption of a decision to authorize Bt-11 would bring an end to the current *moratorium* on genetically modified food and feed in Europe."

4.397 The European Communities first written submission in fact goes quite a long way toward conceding the existence of the moratorium. In describing the reasons for adopting a modified directive, the European Communities' submission states: These issues [meaning issues relating to alleged scientific uncertainty] affected some of the pending applications as **a number of member States made it clear that they were not in a position to vote in favour of granting market authorizations** for individual products without these issues being addressed first." This statement is quite close to a confirmation of the basic point that the complaining parties are making in this dispute: namely, that at a certain point in time, certain member States decided that they simply were not going to vote for new product approvals. Under the European Communities' rules of qualified majority voting, a minority of member States can block European Communities' action. Blocks by qualified majority in the regulatory committee may be overridden by a simple majority vote in the Commission. But, as the record here shows, the European Communities has decided not to submit final decisions for a majority vote by the Commission. In addition, if one of those "number of member States" that are unwilling to grant market authorizations were the original recipient of the application, then that single member State may block a Deliberate Release application all by itself.

4.398 Turning to the European Communities' arguments as to why there was no general moratorium, the European Communities first argues that it cannot be "legally affected" by "casual statements of any of its numerous representatives". But the complaining parties are not relying on "casual statements of numerous representatives"; the statements cited by complaining parties are statements made by the European Communities' highest officials, by its member States, and by its official bodies. Moreover, the European Communities itself concedes, as it must, that such statements can be considered as evidence of the existence of a measure.

4.399 The European Communities' second response is to submit application histories for each of the products covered by the moratorium. This information, however, is entirely consistent with the European Communities' imposition of a general moratorium. First, the information submitted by the European Communities confirms that there were in fact no approvals of biotech products between October 1998 and the establishment of the Panel's terms of reference in August 2003.

4.400 Second, we would like to point out a few applications in which even the European Communities' own exhibits show quite clearly how the moratorium operates. The European Communities' submission writes that the two oilseed rape products were approved for cultivation, import, and marketing under the 90/220 Directive at "Community level." However, the European Communities' submission entirely fails to note that under Directive 90/220, the "Community level" approval is <u>not</u> effective unless and until the member State that initially received the application takes a final step of placing the product on the market. In this case, that member State, which was France, never allowed the product to be placed on the market. Thus, these products in fact were <u>never</u> approved for cultivation, import, and marketing in the European Communities.

4.401 We would also like to refer to the example of Bt Cotton. Spain, the member State that initially received the application, forwarded it with a positive opinion to the European Communities in November 1997. The EC Scientific Committee on Plants made a favourable assessment in July 1998. However, in February 1999, the regulatory committee did not approve the application by a qualified majority vote. Under the European Communities' own rules, an application that fails to achieve a qualified majority of votes in the regulatory committee <u>must</u> be submitted to the EC Council for an additional vote, and such submission must be made, to quote Article 21 of the EC Directive, "without delay." But the European Communities' own chronology states that the next action is nearly three

months later, in May 1999. And the action taken is not, as required under EC legislation, the submission of the application to the EC Council. Instead, the chronology states: "Launching of Inter-Service Consultation on draft Council Decision." To our knowledge, this term, and this step, are not provided for under the European Communities' regulations. The chronology is then blank until July of 2001. We would submit that "Inter-Service Consultation" is just another word for the moratorium.

4.402 Finally, we would like to address the application under the Novel Foods regulation for Bt-11 sweet corn. This product received a favourable opinion from the European Communities' Scientific Committee on Food over two years ago, in April 2002. The European Communities' submission states that the Commission was finally ready on 19 May of this year to accept a proposal allowing the use of Bt-11 sweet corn for food use. The United States would like to make very clear that the measure that we are requesting that the Panel examine is the measure in existence at the time when the Panel and its terms of reference were established, which is the measure in effect as of 29 August 2003. Also, the United States would not view an approval of Bt-11 as a lifting of the European Communities' moratorium or as an indication that the EU will begin to meet its WTO obligations by making decisions on all other pending applications without undue delay. But any issues relating to whether or not steps taken by the European Communities after August 2003 have brought the European Communities into compliance with its WTO obligations are not before the Panel.

4.403 We would also note that the Bt-11 approval, should it occur, is entirely consistent with, and in fact supports, the existence of the general moratorium. As noted above, both the European Commission and the Council have stated that the entry into force of the European Communities' new traceability and labelling rules for biotech products might finally allow for the lifting of the moratorium. Those new rules went into effect on 19 April 2004. The fact that the Commission then approved Bt-11 just one month later is, at least in our view, certainly no mere coincidence. To the contrary, this timing indicates that, as the European Communities itself has acknowledged everywhere but in its First Written Submission, the European Communities' approval system was held up not by any problems with particular applications, but by events outside the scope of its approval legislation. Moreover, the EC Council itself acknowledges the existence of the "moratorium" – it uses this very word – in a statement concerning the scheduled Bt-11 approval.

4.404 As discussed in the first written Submission of the United States, the European Communities' approval regime, including that part of the regime modified by the general moratorium, is plainly a "sanitary or phytosanitary" measure. However, in light of the European Communities' hypothetical discussion of the types of risks covered by its Deliberate Release legislation, the United States would like to make the following points. The European Communities notes that its Deliberate Release directive repeatedly uses the word "environment". The idea, however, that all environmental issues are outside the scope of the *SPS Agreement* is plainly wrong. Article 5.2 of the Agreement explicitly requires the consideration of relevant ecological and environmental conditions in an assessment of SPS risks. In addition, the definition in the *SPS Agreement* of an SPS measure includes "Any measure applied to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests." The agreement explicitly provides that animal includes "wild fauna", and that "plant" includes "forests and wild flora." Certainly, the protection of wild fauna, forests, and wild flora are elements of environmental protection.

4.405 The European Communities' last defence is to argue that even if the European Communities, as a matter of fact, adopted a general moratorium on approvals of biotech products, such a moratorium is legally precluded from qualifying as a "measure" under the *SPS Agreement*. The European Communities' argument is based on two panel reports that considered the status under the *Anti-Dumping* and *Subsidies Agreements* of investigating authorities' so-called "practices". But, the conclusions in those reports are not applicable to the determination of whether an actual moratorium

on approvals (as opposed to a "practice") is a measure. Unlike the complaining parties in those disputes, the complaining parties here are not saying that a pattern of decisions itself *constitutes* a measure. Instead, the co-complaining parties have pointed to an unbroken pattern of decisions (or rather, to an unbroken pattern of lack of decision) as the inevitable *result* of the moratorium, which is itself an independent measure.

3. Product-specific moratoria violate the *SPS Agreement*

4.406 Turning to the European Communities' product-specific moratoria, whether one views them as separate measures or simply as undue delay in the approval process of these individual products, the European Communities once again asserts that no such measures ever existed and that no application faced any undue delays. The primary basis for the European Communities' denial of the product-specific moratoria is the vague statement that "what has happened in many of these applications is that, at different stages of the procedure, requests for additional information have been put to applicants." Nonetheless, contrary to the European Communities' assertions, its own exhibits show that applications stalled in its approval system without justification.

4.407 Earlier in this statement, we noted the examples of how Bt Cotton and two oilseed rape products had stalled in the approval process. We would also like to point out the example of Roundup Ready Cotton. Spain, the member State that initially received the application, forwarded it with a positive opinion to the European Communities in November 1997. The European Communities' Scientific Committee on Plants made a favourable assessment in July 1998. In February 1999, the Roundup Ready cotton application, like Bt cotton, did not receive a qualified majority vote in the regulatory committee. Like for Bt cotton, the next step in the European Communities' chronology is the "Launching of Inter-Service Consultation on draft Council Decision" in May 1999. There is no further entry in the chronology until January 2003, which is more than 2½ years later. Again, this is another example of a major delay that was not caused, as the European Communities' claims, by a pending request to the applicant for additional information.

4.408 These chronologies also highlight how the product-specific moratoria are inconsistent with the related procedural obligations in Annex C(1)(b) of the SPS *Agreement*. In the Bt Cotton, Roundup Ready Cotton, and oilseed rape applications, the applicant is not informed in a precise and complete manner of all deficiencies, or of the results of the approval procedure. To the contrary, when the regulatory committee fails to approve an application by a qualified majority vote, or when the EC Commission enters into "Inter-Service Consultations" rather than sending an application on to the Council, the applicant is given no explanation, and thus no opportunity to correct any deficiencies. The same is true when, as for the oilseed rape products, the member State that originally received the application fails to take the final step of placing a product on the market.

4. Member State measures violate the *SPS Agreement*

4.409 Like the moratoria (general and product-specific), the member State measures are SPS measures which affect international trade. Each of the six member States have imposed bans on approved biotech products, but none of the member States put forth a "risk assessment" as defined in Annex A, paragraph 4. These measures are thus not "based on" "risk assessment[s]" as required by Article 5.1 of the *SPS Agreement*.

4.410 In fact, the only risk assessments put forth for the banned products are the positive scientific assessments rendered by member States to which the products were submitted, and then by the European Communities' own scientific committees. In the case of each member State ban, these favourable assessments were reaffirmed when the scientific committees considered and rejected the

information provided by the member States. Thus, the member State measures do not bear a "rational relationship" to the European Communities' positive risks assessment, and are not "based on" a risk assessment, in violation of Article 5.1.

4.411 The European Communities puts forth a number of defences of the member State measures – each is without merit. First, the European Communities makes the vague and cryptic argument that "It results from that analysis [of Sections II.A.4, III.B.3 and II.D.4 of its submission] that each of the member State measures was adopted for some reasons that fall within the scope of the *SPS Agreement*, and some reasons that do not fall within the *SPS Agreement*." The United States is not able to discern from this assertion what reasons the European Communities is referring to that it considers outside the scope of the *SPS Agreement*. But no matter. The important point is that the European Communities does not dispute, and in fact agrees, that each of the member States measures was adopted for "some reasons" that fall within the scope of the *SPS Agreement*.

4.412 Second, the European Communities argues that each of the measures fall within the scope of Article 5.7 of the *SPS Agreement*. But the European Communities does not specify how Article 5.7 might apply. Its only argument is that under the terms of the EC legislation, the member State measures are labeled as provisional. The mere label of a measure, however, is most certainly not sufficient to bring it within the scope of Article 5.7.

4.413 To the contrary, as the Appellate Body has found, a measure must meet four requirements to fall within the scope of Article 5.7. Each of the member State measures, however, fails to meet any of these four requirements. First, the measures were not imposed because scientific information is "insufficient." To the contrary, the European Communities and its scientific committees found sufficient information to evaluate and render positive assessment for each of the banned products. Second, the measures were not based on "available pertinent information." To the contrary, as the European Commission stated in a memo, the member State measures "have been examined by the Scientific Committee on Plants, which in all cases deemed that the information submitted by the Members States did not justify their bans." Third, there is no evidence that the member States have sought to "obtain additional information" concerning the banned products in order to make a "more objective assessment of the risk." In this regard, we note that all the member State measures were adopted in the period 1997 to 2000, in other words more than four years ago. Finally, by failing to seek and obtain additional information, the member States have also failed to review the measure in light of such information "within a reasonable period of time".

4.414 Third, the European Communities argues that even if the member State measures fall outside the scope of Article 5.7, that the measures are nonetheless consistent with Article 5.1 because they are based on a risk assessment. The European Communities' only support for this position, however, is the conclusory statement that the "member States may have drawn their own conclusions from the relevant risk assessments." The only "relevant risk assessments" of which the United States is aware, however, are those by the EC scientific committees providing positive assessments of the banned products. The European Communities has failed to identify any other "relevant risk assessments", nor to explain how the member State marketing or import bans could be based on such assessments. In short, the European Communities' argument that the member State measures are consistent with Article 5.1 is without merit.

J. FIRST ORAL STATEMENT OF CANADA

1. Introduction

4.415 Until October 1998, the European Communities had a functioning approvals process for agricultural products produced from modern biotechnology. Since then, it has maintained a moratorium on the approval of new biotech products. The moratorium has been maintained in the face of uncontroverted opinions of the European Communities' own scientists that (i) there is sufficient evidence to reach conclusions about the safety of these products, and (ii) that there is no evidence to show that these products pose a risk to human health or the environment. In addition, several EC member States are maintaining national bans on biotech products that had been approved by the European Communities prior to the institution of the moratorium.

4.416 The European Communities' principal defence is that the moratorium does not exist. As for its member State national measures, the European Communities' principal defence is that Canada should have challenged these under Article 5.7 of the *SPS Agreement*. None of these arguments have any merit.

2. Issues relating to the moratorium

4.417 In this section, Canada will demonstrate the following three propositions: the European Communities maintains a moratorium on the approval of biotech products; the moratorium is a challengeable measure; and, the moratorium is a SPS measure for the purposes of the *SPS Agreement*.

(a) The European Communities maintains a moratorium

4.418 Since 1998, with one, very recent, exception, the European Communities has failed to approve a single application for biotech products although there are over 30 applications in the approval pipeline. Many of these applications have received not one, but two, favourable risk assessments by the European Communities' own scientific bodies.

(i) The moratorium is in effect

4.419 The European Communities gives effect to the moratorium through concerted acts and omissions that stall applications at key decision-making stages in the approval process. This converts the pre-marketing approval requirement into an across-the-board marketing ban on new biotech products.

4.420 The key stages at which the blockage occurs are highlighted by the following acts and omissions:

- EC member State competent authorities have failed to ensure that the approval procedures are completed without undue delay;
- Certain EC member States routinely object to favourable assessments by the competent authority of another member State;
- Where an application is supported by favourable risk assessments, the Commission has failed in all but four cases to submit a draft measure approving a biotech application to the Regulatory Committee;

- EC member States routinely block the adoption of a favourable opinion by the Regulatory Committee, regardless of the scientific merits of the application;

- Where there has been an impasse at the Regulatory Committee, the Commission has failed to refer the matter to the Council of Ministers; and finally,

- When the Commission has approved a product, the responsible member State has failed to issue the consent letter necessary to be able to market the product.

(ii) The European Communities denies the ample evidence of the moratorium

4.421 The European Communities denies that the moratorium exists. It says that the lack of decisions is a coincidence, caused by a series of unrelated delays in individual applications for biotech products arising from the insufficiency of scientific evidence, the on-going changes in the European Communities' regulatory regime, and requests for information. This is at odds with the facts and the opinions of the European Communities' own scientists, and with how the European Communities' own officials and documents have characterized the situation. The European Communities also says that Canada cannot point to any law or other formal act on the part of the European Communities that supports the existence of a moratorium.

4.422 Canada has six points in response. **First**, the June 1999 declaration undermines the "coincidence" argument. **Second**, the Commission's own officials have described the situation as a moratorium; EC documents continue to refer to a moratorium. **Third**, although it is true that there is no law or other formal act that Canada can point to, the European Communities cannot use its own lack of transparency as a shield in this dispute. **Fourth**, the moratorium does not arise from the failure to approve a particular application; it is the general suspension of the approval process, resulting in the failure to consider for approval all applications. The European Communities' attempt to treat delays in individual applications as isolated events ignores the surrounding circumstances. **Fifth**, the simplified procedure under Regulation 258/97 does not constitute an approval process; it does not require the Commission to take a decision, and other member States cannot block or stall this process. **Lastly**, Canada does not argue that the moratorium involves a complete shutdown of the approval process; rather it is at the critical decision-making junctures, or key stages, of the approval process where applications have been blocked.

(b) The moratorium is a "measure"

4.423 Whether one calls the moratorium a "requirement", "administrative guidance" or "practice" is immaterial. It is still a measure. A measure may be any act of a Member, whether or not legally binding, and it can include even non-binding administrative guidance by a government. In this case, the moratorium converts the pre-marketing approval requirement of the legislation into an across-the-board marketing ban on new biotech products just as effectively as an amendment to the approval legislation.

4.424 The list of measures in Annex A is not exhaustive. This is supported by the use of the word "include" in Paragraph 1. There is no doubt that the underlying approval legislation is a measure. It is stands to reason that the moratorium, should also be interpreted as a measure. To interpret "measure" narrowly would allow WTO Members to circumvent their obligations by neglecting or refusing to adopt transparent, formal, legally binding laws, regulations or procedures; this would undermine the object and purpose of the *SPS Agreement*.

4.425 The European Communities uses two panel reports to argue that "a practice not laid down in any document whether formal or informal in character" is not a measure. Neither case supports the European Communities' sweeping proposition.

(c) The moratorium is an "SPS measure"

4.426 The moratorium is not based on a legal instrument; therefore its purpose must be inferred from the context. The 1999 declaration confirms that the purpose of the moratorium is to protect human health and the environment from risks arising from biotech products. This suggests that the general suspension of the European Communities' approval procedures is based on concerns that those procedures could not adequately assess those risks. Thus, the purpose of the moratorium can be reasonably inferred from the underlying legislation.

4.427 The European Communities has admitted that the purpose of its approval procedures is, at least in part, to protect against risks to human health and the environment that fall within the *SPS Agreement*. It stands to reason that the purpose of the moratorium is the same. Thus, the moratorium was instituted, at least in part, to protect against risks identified in Annex A of the *SPS Agreement;* therefore, it is an SPS measure.

(d) The scope and application of the *SPS Agreement*

4.428 Canada has five points to make with respect to the European Communities' arguments about the scope and application of the *SPS Agreement*. **First**, the European Communities argues that the "*SPS Agreement* was not intended to address the prevention of risks to the environment." The European Communities highlights biodiversity, suggesting that measures taken to protect biodiversity somehow fall outside of the scope of the *SPS Agreement*. The European Communities concedes, however, that one of the risks posed by biotech products is that they may "choke or stunt" other plants. In other words, biotech products may become a pest or a weed. This is both a concern for biodiversity and a risk identified under the *SPS Agreement*. Thus, the suggestion that risks to biodiversity *per se* are not covered by the *SPS Agreement* should be rejected.

4.429 **Second**, the European Communities asserts that the *SPS Agreement* was not drafted with products like GMOs in mind. The *SPS Agreement* is not applied to products, *per se*, but to measures intended to protect against certain identified risks. Moreover, when the *WTO Agreement* was signed, Directive 90/220 had been in existence for several years and the European Communities had by then approved for commercial release several products.

4.430 **Third**, the European Communities insinuates that measures regulating GMOs should be dealt "outside" the *WTO Agreement* because GMOs have their own "special agreement", the Biosafety Protocol. Again, this argument is totally without merit. To the contrary, the Biosafety Protocol has no material bearing on the issues in dispute before this Panel.

4.431 **Fourth**, the European Communities states that there is "no precise match" between the European Communities' approval legislation and the objectives and scope of the *SPS Agreement*. The implication of this is that a SPS measure, in this case an approval procedure, is no longer subject to the obligations of the *SPS Agreement* if it involves the consideration of non-SPS risks or other issues. The panel should reject this argument. The obligations of the *SPS Agreement* do not cease to apply to SPS measures merely because those measures are also applied to protect against non-SPS risks.

4.432 **Lastly**, the European Communities asserts that, with reference to Codex Standard 193, "toxin" as used in the *SPS Agreement* should be limited only to naturally occurring toxicants that are

not intentionally added to food. Codex Standard 193 does not purport to provide a comprehensive definition of "toxin". It simply sets outs the types of toxins included in the scope of that Standard. The limited definition of "toxin" in the Standard in no way limits the term as it is used in the *SPS Agreement*.

3. The product-specific marketing bans

4.433 The European Communities claims that the complaint is really about "undue delay", and denies there has been undue delay. It attributes any delay to "requests for additional information". However, the European Communities makes bald assertions unsupported by specifics and carefully avoids any discussion of the scientific opinions rendered by its own scientists.

4.434 The European Communities fails to respond to Canada's claims under Articles 2.2, 2.3, 5.1, 5.5 and 5.6 of the *SPS Agreement*. The European Communities bases this failure on the contention that "alleged behaviour cannot be an SPS measure itself as well as the application of another SPS measure." There is no basis in the *SPS Agreement* for this contention. In fact, there are many instances where an act can be both an SPS measure and an application of another SPS measure.

4. EC member State national measures

4.435 In this section, Canada responds to arguments made by the European Communities in its written submission, relating to the *EC member State national measures*.

(a) Article 5.7

4.436 The European Communities states that the "safeguard" measures are provisional measures, taken pending a full assessment at the Community level. According to the European Communities, this "full assessment" will lead to either a change in the Community-wide authorization or a termination of the national safeguard measures and that "this will now be done in light of the changes in Community legislation". It is not clear what this means.

4.437 The European Communities argues that, because these measures are "provisional", they must be assessed against Article 5.7, and that, because the complaining parties have not alleged violations of this provision in relation to these measures, they have failed to demonstrate that the measures do not fall exclusively under Article 5.7; thus, there is no burden on the European Communities to respond to the complaining parties' claims that the measures are inconsistent with the remaining SPS provisions. This argument is without merit.

4.438 The language in Article 5.7 does not exclude the applicability of all other SPS provisions simply on the basis that the measures in question are provisional. The starting point for an analysis of an SPS measure is Article 2. It establishes basic rights and obligations of the Members with respect to their SPS measures. Such measures must be based on scientific principles and must not be maintained without sufficient scientific evidence. Whether the measures are provisional or not is beside the point.

4.439 In any event, the provisional nature of a given measure does not exclude the remaining provisions of the *SPS Agreement* from applying to it unless those other provisions indicate that they do not apply to provisional measures. For example, Article 2.2 is not expressed in terms that limit its application to "permanent" measures. A Member is free to challenge a provisional measure under Article 2.2 as being maintained without sufficient scientific evidence. The Member must demonstrate that the measure in question is not adequately supported by scientific evidence. Nowhere does the

jurisprudence indicate that the Member must also demonstrate that the measure does not fall within the scope of Article 5.7.

4.440 At the same time, Article 2.2 recognizes that there may be circumstances where measures have to be taken in the face of insufficient scientific evidence. In such circumstances, it is open to the Member defending such a measure to invoke Article 5.7. The panel in *Japan – Apples* recognized this. The key language in Article 5.7 is not the word "provisional", but the words "[I]n cases where relevant scientific evidence is insufficient …". It is not the provisional nature of the measure that matters; it is the insufficiency of the scientific evidence. Thus, it is not enough for the European Communities to claim that the measure is provisional in order to exempt it from scrutiny under Article 2.2.

4.441 The European Communities claims that certain statements by the Appellate Body in *Japan – Apples* support its argument with respect to the objective scope of application of Article 5.7, and the proper allocation of the burden of proof. However, the statements to which the European Communities refers do not explicitly address this matter.

4.442 Furthermore, the European Communities refers to the application of provisional measures in the *Anti-Dumping Agreement* and the *Subsidies Agreement* as support for its interpretation of Article 5.7. However, these provisions do not concern themselves with the allocation of the burden of proof, and are therefore irrelevant to the European Communities' argument concerning the proper scope to be given to Article 5.7. In short, they have no bearing whatsoever on the issues before this Panel.

4.443 The European Communities appears to base its arguments with respect to Article 5.7 solely in relation to what it terms the "threshold" argument. It claims that it is for Canada to demonstrate inconsistency with Article 5.7, and that Canada has failed to discharge this burden. The European Communities is mistaken on this point. There is no burden on Canada until the European Communities invokes Article 5.7 and makes out a *prima facie* case for its application.

4.444 Even if the European Communities were correct that the departure point for an analysis of these measures is Article 5.7, these measures do not meet the requirements of that provision. Even a cursory review of the measures and the factual and scientific circumstances surrounding their adoption and maintenance reveals that they fail to satisfy even one of the four required elements under Article 5.7.

4.445 Under the **first** element, based on the opinions adopted by the European Communities' own scientific experts, there is no indication that there was insufficient scientific evidence to allow them to come to unambiguous conclusions. Equally importantly, those conclusions were uniformly favourable as regards the safety of the products in question. Under the **second** element, a measure that bans the commercialization or marketing of a product that has repeatedly been found to be safe by the competent scientific authorities cannot be said to be based on the "available pertinent information". The **third** element becomes irrelevant as a criterion, given the sufficiency of the scientific evidence available from the European Communities' own sources. In any event, the European Communities has failed to demonstrate that the member States sought to obtain any additional information to support their measures, even in the face of the opinions of the European Communities' scientific experts that the information initially provided did not alter the original favourable risk assessments. Finally, under the **fourth** element, to Canada's knowledge, no review has taken place at all, let alone "within a reasonable period of time".

4.446 Because the *EC member State national measures* do not satisfy any of the four required elements, they cannot fall within the scope of Article 5.7.

(b) Article 5.1

4.447 The European Communities claims that even if Article 5.1 applies, the use of the words "appropriate to the circumstances" … gives the WTO Members "a certain degree of flexibility in meeting the requirements of Article 5.1". Canada agrees that, in principle, Article 5.1 offers "a certain flexibility", but it is not of the kind identified by the European Communities. The European Communities claims that the "circumstances" in the present case are that "relevant scientific evidence was or is insufficient". Canada has already responded to this argument.

4.448 Article 5.1 sets out a clear standard. A risk assessment must meet that standard and the measures must be "based on" that risk assessment. If the scientific evidence is insufficient, it is for the WTO Member concerned to make its case under Article 5.7. In this case, the risk assessments of the competent authorities of the sponsoring EC member States, and the scientific opinions rendered by the relevant scientific committees conclude that these products are safe. These risk assessments and scientific opinions do not indicate that the available scientific evidence was insufficient to support those conclusions.

4.449 The European Communities does present arguments for why it considers that the *EC member State national measures* are consistent with Article 5.1. While it states that the measures are based on risk assessments, it does not identify those risk assessments. The only risk assessments that Canada is aware of are the European Communities' own risk assessments, which found no evidence that the products in question are unsafe. These do not bear a rational relationship to a ban. Even if Canada accepted the European Communities' contention that the same risk assessment, as a matter of WTO law, might 'sufficiently warrant – that is to say, reasonably support' – more than one possible SPS measure, depending, *inter alia*, on the specific legislator", the European Communities does not make it clear to which legislators or to which circumstances it is referring. In any event, publicly available risk assessments, which uniformly concluded that there was no evidence of a risk to human health or the environment, cannot be said to "reasonably support" a complete ban on such products.

(c) Article 5.6

4.450 The European Communities' arguments with respect to Article 5.6 are difficult to follow. It is true that Canada bases its arguments with respect to Article 5.6 on an assumption as to the European Communities' appropriate level of protection. The European Communities' legislation seems to indicate that the level of protection sought by the European Communities with respect to biotech products is a high level of protection, but not zero risk. Canada asks the European Communities to state clearly whether its appropriate level of protection is the level of protection that is set out in the relevant EC legislation, or the level of protection – that is, zero risk – implied by the *EC member State national measures*. In any event, the European Communities has not refuted Canada's arguments under Article 5.6 and it remains open to the Panel to conclude that the *EC member State national measures* are inconsistent with that provision.

(d) Article 5.5

4.451 The European Communities makes a number of assertions and statements in its written submission, none of which refute the *prima facie* case that Canada has made.

4.452 Canada agrees with the European Communities that there is no inconsistency in the absence of arbitrary or unjustifiable distinctions. However, the European Communities has failed to address, much less refute, the arbitrary or unjustifiable distinctions that Canada has demonstrated exist with respect to the appropriate levels of protection applied by the European Communities to the comparable situations outlined in Canada's written submission.

4.453 When the European Communities' own experts unambiguously find that there is no evidence to show that these products are unsafe, and the member States nevertheless ban the products and maintain those bans in the face of further scientific advice that such bans are groundless, this cannot be characterized as anything other than a complete disregard or determination to ignore such opinions and advice. When this is done on a selective basis that bears no relationship to the actual risks involved, the conclusion is inescapable that the resulting measures give rise to a violation of Article 5.5.

K. FIRST ORAL STATEMENT OF ARGENTINA

1. Introduction

4.454 This case concerns inconsistencies with WTO obligations, arising from: (i) the *de facto* moratorium which the European Communities has maintained from 1998 to the present; (ii) the "suspension of processing and failure to consider individual applications for specific products of particular interest to Argentina"; (iii) the "undue delay"; and (iv) the bans imposed by some EC member States to the detriment of specific biotech agricultural products of particular interest to Argentina. Argentina maintains that the foregoing measures infringe the *SPS Agreement*.

4.455 Article 3.2 of the DSU does not authorize any broad reliance on rules of public international law beyond the *Covered Agreements* which would modify the rights and obligations of Members. Specifically, Argentina is of the view that it would not be proper for the Panel to look for additional endorsement from other rules of international law, such as the Cartagena Protocol, in interpreting the scope of the obligations included within the *Covered Agreements*.

2. The *de facto* moratorium is not based on scientific evidence and therefore infringes the *SPS Agreement*

(a) The measure at issue in these proceedings

4.456 The "de-facto" moratorium violates the *SPS Agreement*. Argentina disagrees with the assertion of the European Communities that the complaining parties have chosen to turn to the WTO dispute settlement procedures rather than to promote international cooperation.

4.457 Argentina claims that the *de facto* moratorium constitutes *per se* a breach of WTO obligations. This claim is separate from the claim concerning the "suspension of consideration and failure to process specific applications for products of particular interest to Argentina", and from the claim regarding "undue delay".

4.458 The European Communities has expressly acknowledged the existence of a *de facto* moratorium, as indicated in the abundant documentary evidence supporting this affirmation. Furthermore, the European Communities has not responded to the evidence that Argentina has produced to show the existence of the moratorium.

4.459 The European Communities does not faithfully report the actual duration of the *de facto* moratorium, but attempts to reduce it to the period from 1998 to 2001. This contradicts the European Communities' own statements which confirm what Argentina indicated in its submission (1998 to the present), on the basis of the need for further legislative changes.

4.460 The European Communities starts from the premise that the complaining parties have been "unable to identify an instrument or other text" by which the moratorium was established, and that the complaining parties' claims "are all in reality complaints about delay". This is because the complaining parties are addressing "omissions", which, in the European Communities' opinion, would not be challengeable under the WTO. We note that an "omission" is actionable under WTO rules. The European Communities' intent in so arguing is to divert the Panel's attention to what it calls issues "of procedure". The European Communities is thus attempting to evade the substantive issues: the *de facto* moratorium and the lack of scientific evidence supporting the restriction.

4.461 One of the elements that demonstrate both the existence of the *de facto* moratorium and the period during which it has been applied comprises statements by EC officials having competence in the matter at issue. Argentina nevertheless wishes to point out that the statements do not constitute the moratorium itself or the instrument embodying it, but are provided as facts demonstrating the existence of a *de facto* moratorium.

4.462 With regard to the European Communities' argument that the *de facto* moratorium could not be identified in any instrument, Argentina in its submission specifically explains the specific characteristics of the *de facto* moratorium measure. Furthermore, the fact remains that no biotech agricultural products have been approved since 1998. The European Communities concedes that it applied a moratorium on the approval of new products at least until its legislative process was completed.

4.463 Argentina notes that the European Communities has not based the *de facto* moratorium on any scientific evidence. On the contrary, the existing scientific evidence supports the position contrary to the *de facto* moratorium, since it recommends approval of the biotech agricultural products at issue.

4.464 Within the broader framework of the *de facto* moratorium, a persistent pattern of conduct by the European Communities can be observed. Through actions and, essentially, through omissions, a *de facto* moratorium has taken shape that is visible in the various stages of the procedures under EC regulations: (i) Undue delay in completing the procedures; (ii) lack of action by the Commission in presenting the draft measure to the Regulatory Committee for approval of products that have received a favourable opinion from the scientific committees; (iii)systematic opposition by member States to approval when a draft is submitted, with no scientific grounds for opposing the Commission's draft; and (iv) failure by the European Communities to refer a proposal to the Council of Ministers when the Regulatory Committee issues no opinion. Although in the foregoing combination of actions and omissions within the European Communities' regulatory system some movement of applications through the various regulatory stages is visible, in the opinion of Argentina the movement is circular in nature and never results in approval.

4.465 Argentina requests the Panel, on the basis of the evidence submitted, to consider the existence of the *de facto* moratorium as having been demonstrated above.

(b) Application of *SPS Agreement* to the *de facto* moratorium

4.466 We will now address the purpose of the *de facto* moratorium. The purpose of the European Communities' regulations for the approval of biotech products is *to determine*, by means of case-by-case assessment, the presence or absence of "additives", "contaminants" or "toxins" in foods, beverages or feedstuffs and the risks to human life and health resulting from their presence. Such regulations constitute a sanitary and phytosanitary measure within the meaning of the *SPS Agreement*.

4.467 The risk arising from the mass consumption of varieties containing marker genes falls within the definition given in paragraph 1(b) of Annex A of the *SPS Agreement*. The risk arising from the cross-contamination of biotech products with other, undesired organisms falls within the scope of paragraph 1(d) of Annex A of the *SPS Agreement* and of paragraph 1(c). Paragraph 1 of Annex A defines "pests", which include "weeds".

(c) Conclusions with respect to the *de facto* moratorium

4.468 To sum up, Argentina considers that the European Communities is in obvious breach of the rules of the *SPS Agreement*. Furthermore, the European Communities has itself admitted the existence of the *de facto* moratorium, even when its own scientific committees have ruled in favour of the approval of various biotech agricultural products. For this reason, Argentina respectfully requests the Panel first to find the *de facto* moratorium inconsistent with Article 5.1, and then with Article 2.2 of the *SPS Agreement*.

4.469 Argentina notes that, should the Panel find in respect of this claim that there is breach of Articles 5.1 and 2.2 of the *SPS Agreement*, it need not rule as to the inconsistency of the *de facto* moratorium with the other Articles of the *SPS Agreement* cited, without prejudice to Argentina's reaffirming, in the light of the Panel's finding, the other arguments concerning the Articles of the *SPS Agreement* violated by the European Communities that it adduced in its first written submission.

3. The "suspension and failure to consider" is not based on scientific evidence and therefore violates WTO obligations

4.470 Article 1.5 of the *TBT Agreement* indicates that its provisions are not applicable to the sanitary and phytosanitary measures defined in Annex A of the *SPS Agreement*. Article 1.4 of the *SPS Agreement* reaffirms the rights of the Members under the *TBT Agreement* in respect of <u>those measures not within the scope</u> of the *SPS Agreement*. Therefore, a measure may be examined – under one or other of the two Agreements – only when both are in play. The contrary would be a departure from the textual basis, which treats them as mutually exclusive.

4.471 Argentina considers that, in this case, the <u>object</u> of life and health protection places the measure within the scope of the *SPS Agreement*, regardless of the <u>form</u> the measure takes. This also rules out the applicability of *TBT Agreement* which requires the existence of at least one document embodying a "technical regulation" or setting forth a procedure for conformity assessment. The "suspension of processing and failure to consider" are not set forth in a document. This in itself rules out application of the *TBT Agreement* as a Covered Agreement against which the measures at issue are assessed for consistency.

4.472 As to the biotech agricultural products considered individually, Argentina notes, for example, that the "suspension of processing" affected four of them, which had reached the stage of receiving favourable scientific opinions.

4.473 With regard to Cotton Bt-531, the application was filed in 1996 under Directive 90/220. It obtained a favourable opinion from the competent body's biosafety committee in 1997. In 1998, the Scientific Committee on Plants issued a positive opinion. In 1999, the Regulatory Committee failed to obtain a qualified majority and so did not issue an opinion. According to Directive 90/220, the Commission should have referred a proposal to the Council without delay. The Commission never made such a referral. The application was suspended until it had to be refiled under Directive 2001/18. Although the product has had a favourable scientific opinion since 1998, as at June 2004 its marketing has not been authorized.

4.474 With regard to Cotton RRC-1445, the application was filed in 1997 under Directive 90/220. In 1998 the Scientific Committee on Plants issued a positive opinion. In 1999, the Regulatory Committee failed to obtain a qualified majority and so did not issue an opinion. According to Directive 90/220, the Commission should have referred a proposal to the Council without delay. The Commission never made such a referral. The application was suspended until it had to be refiled under Directive 2001/18. Although the product has had a favourable scientific opinion since 1998, as at June 2004, its marketing has not been authorized.

4.475 With regard to Maize NK-603, the application was filed under Directive 90/220 in 2000 and was refiled under Directive 2001/18 in 2003. The new European Food Safety Authority (EFSA) issued a favourable opinion. The European Communities indicates that the requisite majority was not obtained in the Regulatory Committee and consequently, the Commission sent a draft proposal to the Council. Argentina trusts that after the favourable scientific opinion Maize NK-603 will be approved this June as indicated by the European Communities. Unfortunately, notwithstanding the favourable opinion of the EFSA, processing the same product under Regulation 258/97 offers no alternative since there are no plans in the Council to address the application in question.

4.476 With regard to Maize GA-21, the application under Directive 90/220 dates back to 1998 and obtained a favourable opinion from the Scientific Committee in 2000. In 2003 the application for approval of this product was withdrawn. Argentina mentions this because the product is one of interest which, for nearly three years did not obtain authorization despite favourable scientific evidence. Under Regulation 258/97 the application was filed in 1998 and obtained a favourable opinion in 2002. Despite the favourable opinion, no authorization has been obtained, placing this product in the category of those which, despite scientific analysis, never obtained authorization.

4.477 The European Communities has not refuted the scientific evidence of its own committees, which recommended the approval of the products in question, clearly depriving of scientific backing the measures affecting the approval procedures of at least four of these products. Therefore, Argentina's first claim is to a finding of inconsistency of the "suspension of processing and failure to consider" with the *SPS Agreement*, specifically with Article 5.1. This would automatically imply inconsistency with Article 2.2 of the *SPS Agreement*.

4.478 Furthermore, should the "suspension of processing and failure to consider" be found to be inconsistent with Articles 5.1 and 2.2 of the *SPS Agreement*, Argentina considers that the Panel need not address the inconsistency of the other legal provisions cited in respect of these measures, without prejudice to Argentina's reaffirming, in the light of the Panel's assessment, the other arguments related to provisions violated by the European Communities that it adduced in its first written submission.

4. The "undue delay"

4.479 In Argentina's view, "undue delay" implies a violation of the provisions of Article 8 and Annex C of the *SPS Agreement*.

4.480 Both Directive 2001/18 and Regulation 258/97 set time limits for each stage in the control, assessment and approval of new biotech agricultural products. It is possible to estimate an approximate average length of time within which the procedures can reasonably be completed. The procedures established in EC regulations should not, on average, exceed 240 days.

4.481 The European Communities has simply failed to explain why new biotech agricultural products receive less favourable treatment under the same regulatory system – i.e. Regulation 258/97- than new "non-biotech" products. For new biotech agricultural products, the same procedures are applied in a way that results in an "undue delay", while new "non-biotech" products subject to the same regulations are not delayed at all and have been approved.

5. The state bans are not based on scientific evidence and therefore violate the *SPS Agreement*

4.482 First, with regard to the European Communities' argument concerning Article 5.7 of the *SPS Agreement,* Argentina reserves the right to develop this point at a later stage of the proceedings.

4.483 With regard to the measures applied by Germany, Austria, Italy and Luxembourg against certain biotech agricultural products, all of the affected products had the prior approval of the European Communities, based on scientific opinions issued by the European Communities' own committees.

4.484 Furthermore, some of these countries have resorted to safeguard procedures in an attempt to justify their measures. This has resulted in new scientific opinions from EC committees, which have specifically refuted the grounds for the EC member State measures.

4.485 Consequently, our first claim is again to a finding of inconsistency with Article 5.1 of the *SPS Agreement.* Furthermore, that violation implies inconsistency with Article 2.2 of the *SPS Agreement,* according to WTO jurisprudence.

4.486 Notwithstanding the foregoing, in the interests of procedural economy a finding of inconsistency of the state bans with Articles 5.1 and 2.2 of the SPS will obviate the need for a further finding that the bans by some EC member States violate the other legal provisions cited, without prejudice to Argentina's reaffirming, in the light of the Panel's assessment, the other arguments concerning provisions violated by the European Communities that it adduced in its first written submission.

6. Article XX of the GATT 1994

4.487 Nowhere in their submissions have the complaining parties indicated the possibility that the European Communities' conduct and breaches were justified under Article XX of the GATT 1994. In this regard, the European Communities has the burden of proof, which cannot be deemed to be discharged by a mere assertion. The European Communities has not put forward a single argument justifying the first test needed to invoke a provisional exception under one of the subparagraphs of Article XX of the GATT 1994, nor has it made any case whatsoever regarding the "chapeau". Argentina requests that the Panel reject this attempt by the European Communities to mount a defence based on an exception under Article XX of the GATT 1994.

7. Special and differential treatment

(a) In the framework of the *SPS Agreement*

4.488 Argentina does not agree with the European Communities as to the scope and interpretation of the special and differential treatment for developing countries as set forth in Article 10.1 of the *SPS Agreement*.

4.489 In the opinion of Argentina, the European Communities has failed to respond and to demonstrate that it took into account and engaged in positive actions of the kind envisaged in Article 10.1 of the *SPS Agreement*, in deciding on and applying the *de facto* moratorium to, suspending consideration of, not approving or unduly delaying approval of the biotech products of particular interest to Argentina. The ban on all access for biotech agricultural products of particular interest to Argentina arising from the European Communities' failure to consider, suspension, non-approval or undue delay in the approval of those products has, as argued, affected and continues to affect Argentina.

4.490 In this regard, the European Communities is wrong in asserting that the claim is consequential. To construe Article 10.1 of the *SPS Agreement* as containing only a consequential obligation is to devoid the provision on special and differential treatment of substance.

(b) In the framework of the *TBT Agreement*

4.491 Argentina has already made its alternative claims regarding the *TBT Agreement* in its first written submission, and will not bring them up here other than to make the following comments relating to Article 12 of the *TBT Agreement*.

4.492 The European Communities has limited its response to the argument that Argentina infers violation of Article 12.3 in the event of a finding of breach of Article 5.2.1; and since the European Communities does not accept the existence of any violation, it concludes that there is no violation of this obligation. Argentina points out that the arguments concerning the obligations laid down in Article 12.3 are much more extensive and are based on a detailed analysis of the logic of Article 12 as a whole.

4.493 Argentina also emphasizes that the European Communities has ignored the special trade, financial and development needs of developing countries. The European Communities has not responded to this argument.

4.494 Furthermore, Argentina puts forward arguments about the absolute ban on imports, whose main effect of the ban has been to prevent the access of biotech agricultural products of particular interest to Argentina not approved prior to 1998. The European Communities has failed to take into account the special needs of a developing country, in this case Argentina. The European Communities has not responded to this argument.

4.495 The European Communities submits that imports of biotech agricultural products from developing countries have not declined and, on the contrary, have increased since 1995/96 in the case of Argentina and Brazil.

4.496 Argentina considers it necessary to clarify certain aspects of this claim. First, Argentina has made no reference to any increase or decrease in imports. The GATT/WTO system protects not volumes of trade but competitive expectations. Secondly, while the European Communities' claim

mentions in particular "commodities likely to contain GMOs", what Argentina is referring to is an absolute ban on imports in respect to biotech agricultural products of particular interest to Argentina which have not been considered, or approved and have been subjected to suspension or undue delays since 1998. Thirdly, Argentina disagrees with the European Communities as to the period during which the increase has occurred "since 1995/1996" in the European Communities' submission. Argentina argued that the absolute ban on imports into the European Communities of biotech agricultural products of particular interest to Argentina started in 1998.

(c) Conclusions regarding special and differential treatment for developing countries

4.497 Argentina is of the view that, through the arguments in its first written submission the European Communities has not refuted Argentina's argument in that it has not addressed the special needs of developing countries, in this case, Argentina, by according the mandatory treatment envisaged in Article 10.1 of the *SPS Agreement*. Furthermore, the European Communities has not argued that in applying EC legislation to biotech agricultural products of particular interest to Argentina, it has observed the special needs of Argentina as a developing country, as the relevant provisions of Article 12 of the *TBT Agreement* require. Lastly, Argentina wishes to note that the special and differential treatment obligations set forth in the Agreements are not supplementary or lesser obligations.

8. Conclusion

4.498 Argentina reiterates the claims of inconsistency it put forward in its first written submission, and requests that they be analysed with a view to procedural economy as proposed earlier in this Oral Statement, so that a prompt settlement of this dispute can be reached in accordance with the provisions of the DSU.

L. FIRST ORAL STATEMENT OF THE EUROPEAN COMMUNITIES

1. Introduction

4.499 The European Communities would like to express its thanks to all three panellists for having accepted to serve on this Panel and to assist in the resolution of this difficult dispute. The complex and controversial issues before the Panel are not only about science and societal values – they also raise some very difficult issues of legal interpretation.

4.500 Despite the complaining parties' occasional attempts to suggest the contrary, this dispute is not about protectionism, nor is it about discrimination. This is, in the view of the European Communities, a case about regulators' choices of the appropriate level of protection of public health and the environment in the face of scientific complexity and uncertainty and in respect of which there is great public interest. It is a case essentially about time. The time allowed to a prudent government to set up and apply a process for effective risk assessment of products which are novel for its territory and ecosystems, and that have the potential of causing irreversible harm to public health and the environment. In these matters there cannot be a "one size fits all" kind of solution and the Panel should resist the temptation to use simplistic approaches, as suggested by the complaining parties.

2. GMOs are still in their infancy

4.501 For more than a decade, the world has witnessed extraordinary advances in the field of genetic modification. We have found ourselves are at a crossroads with many paths open in front of

us, as new opportunities are created by tremendous technological advances while, at the same time, the need is felt to harness technological progress in a context of still limited scientific knowledge.

4.502 Over that period, the international Community has been busy considering what may be the appropriate roads to take to exploit the full potential of new biotechnologies while minimising any risks to human health and the environment. The international Community has agreed that special rules are needed to address GMOs, since GMOs are inherently of a character which requires particular scrutiny, and that, in the face of scientific uncertainty, states' actions should be based on precaution. That conclusion is notably enshrined in the Convention on Biological Diversity and the Cartagena Protocol on Biosafety.

3. GMOs are characterised by scientific complexity

4.503 As early as the end of the 1970s, the need was identified to address the potential risks of genetically modified organisms for human health and the environment differently compared to non-GM organisms, because of the extraordinary new potential of genetic engineering. The new technology has brought to us the ability to theoretically introduce within any living organism, as quickly as it takes to go from one generation to the next, any trait from any other organism, and more importantly, totally new properties to that organism, as yet inexistent in nature.

4.504 The science necessary to assess the risks of these new combinations, and in particular any long term, indirect, or delayed effects, has had and is having a hard time to catch up with the rapid development of new GM products. The science traditionally used in risk assessment can hardly apprehend all the properties of highly complex individual organisms, the interaction between organisms, and the full picture of the ecosystems or the agroecosystems that might be affected, taking also into account that the consequences of the introduction of GMOs into the open environment can be highly variable between different ecosystems.

4.505 Furthermore, GMOs are living organisms, and they are able to reproduce autonomously. Any measure bringing a GMO into the environment has therefore a character of irreversibility. Another element to be considered is that the experience we have today of GMOs is still very limited both in time and in quality, as the acquisition of this technology has happened at a pace which is unprecedented in the history of agriculture. However, only an extremely limited number of inserted genes are widely used in agriculture and very few systematic studies exist or have been planned on this limited set of GMOs. As a consequence, many questions remain as yet unanswered.

4.506 The debate on the uses of modern biotechnology and its potential impact on public health, sustainability and biodiversity should be seen against this growing awareness of the fragility of human conditions and natural systems. On all of this, the complaining parties are silent.

4. GMOs raise the need for targeted regulatory approaches

4.507 In the face of the fast evolution of science, the European Communities, as well as many other governments, have chosen to act prudently, setting up effective processes for risk assessment to be performed before any of these new products is accepted for production, importation or commercialisation. In a context of growing awareness over possible effects of agriculture on health and the environment, countries that had developed early-on a regulatory framework for GMOs had to revise it in recent years and to adapt it to take account of new scientific and economic issues. Both Canada and the United Sates are examples of countries which are in the process of developing more stringent regulatory frameworks.

4.508 Scientific evolution is not, however, the only factor to take into account. As the joint EU/US Biotechnology Consultative Forum concluded in December 2000,

> "judgements about risk cannot be reduced to scientific assessment alone. There are legitimate concerns for which science, at least natural science, cannot provide answers. Such concerns may cover issues of distribution of power and influence, risks of concentration of knowledge and expertise to a few very large corporations, relations between different social groups and classes, between ethics and social values, between large corporations and small companies, between small-scale subsistence farmers and family farmers and the agroindustrial complex, between developed and developing countries. As is true of all technologies with the potential for far-reaching benefits, the societal consequences are far reaching as well".

4.509 The move towards a strong regulatory process has not been limited to the national dimension. The international Community has been working through the last two decades in order to develop a proper framework to address the specificities of GMOs, and by now, international consensus exists on a number of issues related to GMOs, such as the need for a tailor-made regulatory regime for GMOs, including pre-marketing authorization; the right of each country to make its own decisions on each and every GMO on the basis of its legitimate policy goals; the right to adopt a precautionary approach when dealing with GMOs; the need for labelling and post-marketing surveillance.

5. The regulatory choices of the European Communities are those of a prudent, responsible government

4.510 Against this background, the European Communities believes that its actions have been and are those of a prudent government. Over the years, far from having "stalled the process", as is being alleged, the European Communities has worked diligently to design and put in place a regulatory environment for GMOs which takes into account health and environmental concerns while allowing their production, importation and marketing.

4.511 In parallel, and as demonstrated by the forty-nine detailed chronologies that the European Communities has submitted in its first written submission, the European Communities has continued the assessment of each individual application on a case-by-case basis, anticipating, to the extent possible, the application of the standards of review of the upcoming legislation to pending applications. This has always been done in a constant and continued dialogue between the various levels of the EC administration and the applicants.

6. The case of Bt 11 Maize

4.512 Bt 11 Maize – the product that was granted a market authorization two weeks ago – is a perfect illustration of the fact that the approval process, far from being stalled, has been steadily proceeding over the past years.

4.513 Bt11 maize was notified in 2000 and moved up to the Community level quite quickly. The European Commission asked its scientific committee for advice on this dossier in December 2002 and, as soon as the applicant provided the necessary data (this took him more than two years), the Committee issued its opinion. In line with the new legislation that was being prepared, the applicant, on a voluntary basis, agreed to provide the necessary materials to develop validation and detection methods, but it took more than a year to obtain the necessary material from the applicant. The detection and validation method was then rapidly finalized and the decision-making process launched immediately. The proposal for the decision has made its way through the decision-making procedures

exactly as provided for in the legislation and, thus, the decision was adopted by the Commission two weeks ago.

4.514 This marketing authorization has not happened overnight because of a sudden change in the European Communities' policy on GMOs. It is simply the result of a normal process of assessment. How else can you prove the absence of a moratorium if not through demonstrating that the approval process moves on and results in decisions?

7. Legal issues

(a) Preliminary legal remarks

4.515 First, the European Communities is struck by the fact that all the complaining parties, who have the burden of proof, are requesting the Panel NOT to have recourse to scientific and technical advice. It is interesting to note that it is only the defendant who is open to a clarification of the facts in this case on the basis of expert advice. It is definitely not the case that there are no scientific facts in dispute. For instance, the European Communities does contest that the risks involved in GMOs are no different from those presented by conventional products. Most importantly, the views of the European Communities' scientific committees, now regrouped under the European Food Safety Authority, have no formal overriding effect on the opinions of the corresponding national committees, and they are only part of the evidence that EC authorities may use as a risk assessment within the meaning of the *SPS Agreement*.

4.516 Second, as explained in the European Communities' first written submission, it is simply not tenable to examine the facts of this dispute in the light of the *SPS Agreement* only. The complaining parties' approach is too simplistic.

4.517 In fact, both these features of the way in which the complaining parties are conducting their case are illustrative of one fact. That the complaining parties want to avoid that the Panel enters into any detailed factual or legal analysis of the European Communities' actions, which they intentionally misrepresent. They want this Panel to rule on certain issues of general concern for all WTO Members, but in a biased way and in the light of only limited information. It is the defendant that is prepared to confront these complexities fairly and squarely and seek to resolve them, in order to show the true simplicity of the case: there is no moratorium and no suspension to rule on. There is only a series of prudent actions in response to concerns shared by responsible governments around the world.

(b) The correct approach to interpretation

4.518 A correct interpretation of the balance of rights and obligations contained in the WTO agreements has to ensure a close and careful reading of the text of the individual agreement in question, and a reading of the relevant WTO provisions in accordance with other international law instruments and the Appellate Body's findings on the need to take into account the "contemporary concerns of the community of nations about the protection and conservation of the environment[80]". Thus, the provisions at stake in this case will have to be interpreted not in clinical isolation from, but rather in the light of, the other existing instruments of international law referred to in the European Communities' first written submission.

[80] Appellate Body Report, *US – Shrimp*, para. 129.

(c) The *SPS Agreement* alone cannot dispose of all the issues linked to GMOs

4.519 The scope of the *SPS Agreement* is identified in the text of Annex A, point 1, as relating exclusively to measures to protect animal or plant life or health within the territory of the Member from precise risks such as "the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms"; "additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs"; or "diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests". The text of this provision was carefully negotiated, is very clearly phrased and has to be strictly interpreted and applied. In particular, contrary to the complaining parties' approach, it cannot be read as applying to all products and all risks in all circumstances. Following such an approach amounts to reducing the whole of point 1 of Annex A to inutility.

4.520 The Panel will thus have to assess under the *SPS Agreement* only those measures adopted for reasons that fall within the scope of that Agreement. A same measure can pursue multiple objectives which fall within the scope of different WTO agreements. This possibility is not only inherent in the text of the agreements but it is also recognized, as noted above, by the current practice of other Members of the WTO, as is evident from the notifications of draft measures to the SPS and TBT Committees.

(d) The issue of delay

4.521 The European Communities does not contest that the WTO agreements apply to delays, or more generally to omissions or failures to act, and it has shown its readiness to answer to the Panel for each and every instance of such alleged delays under the WTO agreements. However, it is obvious that only WTO provisions that address such failures to act within a given timeframe can be relevant. The *SPS Agreement* contains such obligations in its Article 8 and Annex C. Other provisions listed by the complaining parties do not address delays but the very opposite, namely actions or acts. They address the development and content of SPS measures, not their application.

(e) Article 5.7 *SPS Agreement*

4.522 The European Communities considers that to the extent that the national safeguard measures come under the *SPS Agreement* they are regulated by Article 5.7 of the *SPS Agreement*. and not by the other provisions of the agreement invoked by the complaining parties. The burden of proving that the conditions of Article 5.7 are met is on the complaining parties, as the United States has formally acknowledged at the meeting of the DSB held on 10 December 2003. Thus, the European Communities sees the relationship between Article 5.7 and the rest of the agreement in the same way as the Appellate Body saw the relationship between Articles 3.3 and 3.1 of the *SPS Agreement* – as an autonomous right.[81]

(f) The precautionary principle is a general principle of international law

4.523 Article 5.7 of the *SPS Agreement* is of course one expression of the precautionary principle – Article 3.3 is another. This principle has by now become a fully-fledged and general principle of international law. This is another reason why Article 5.7 is an autonomous right, an autonomous right that is also recognized in the Biosafety Protocol.

[81] Appellate Body Report, *EC – Hormones*, paras. 169-172.

4.524 The precautionary principle was first recognized in the World Charter for Nature, adopted by the UN General Assembly in 1982. The 1992 Rio Declaration codified an application of this principle in its Principle 15. Since then, the United Nations Framework Convention on Climate Change and the Convention of Biological Diversity both refer to the precautionary principle. More recently, and in the specific field of GMOs, the Biosafety Protocol has confirmed the key function of the precautionary principle in the decision to restrict or prohibit imports of GMOs in the face of scientific uncertainty.

8. Conclusion

4.525 In conclusion, the Panel has been called upon to decide what the reasonable attitude of a prudent government should be faced with scientific complexity and uncertainty of a kind and on a scale unique and unprecedented in the history of trade in agricultural products. It is an important and delicate task and it will have consequences far beyond this case. GMOs are not an issue which is confined to the WTO and the close attention of states, other international organisations, civil society, industry and others, rests on the work of this Panel.

4.526 The European Communities is confident that, apart from the absence of any moratorium, the Panel will also find that in applying a regulatory process for effective and forward-looking governance, based on a precautionary approach, the European Communities has acted in accordance with its obligations under the WTO agreements.

M. SECOND WRITTEN SUBMISSION OF THE UNITED STATES

1. Introduction

4.527 The United States in its first written submission showed that the European Communities' moratorium on biotech approvals (both across-the-board, and with respect to individual pending product applications), as well as the member State product-specific bans, are inconsistent with the European Communities' fundamental obligations under the WTO Agreement. The European Communities' response to these clear showings of breaches of its WTO obligations have been remarkable: the European Communities has failed to address the central issues. With regard to the moratoria, the European Communities' only defence is that no such measures ever existed. In taking this position, the European Communities asks the Panel to ignore the statements, and indeed actions, of the EC political-level decision-makers. The European Communities makes this argument even though it has informed the Panel that there indeed is a key political component in the European Communities' approval system. By asking the Panel to find that the moratoria never existed, the European Communities is requesting that the Panel adopt – solely for the purpose of this dispute and based only on the assertions of the EC representative in this dispute – a factual finding that is directly contrary to reality as understood throughout the European Communities and the worldwide agricultural trade community. In so requesting, the European Communities would seek to undermine the credibility of the WTO dispute settlement system.

4.528 Instead of acknowledging the reality of the moratorium and then attempting to justify it under the legal standards set out in the *SPS Agreement*, the European Communities has submitted a substantial volume of communications between member States and applicants for biotech approvals. None of this information, however, is inconsistent with the fundamental reality that the European Communities had adopted moratoria on biotech approvals. To the contrary, staff-level information exchanges regarding product applications are entirely consistent with a moratorium adopted on a political level, under which no product was allowed to reach final approval. Moreover, the very

information that the European Communities has submitted confirms that certain member States simply were not going to allow final approvals, regardless of the underlying science.

4.529 With regard to the member States measures, the European Communities has asserted that there "may" be scientific bases for the product bans, but to date the European Communities has failed to identify any of them. This is understandable, since the European Communities' own scientific committees have reviewed the products and have found that they meet the requirements of the European Communities' biotech approval system.

2. The European Communities' statement of facts is misleading

(a) The European Communities' statement on the purported risks of biotech products is misleading

4.530 Even though the European Communities' factual presentation on biotechnology is not tied to the legal issues in this disputes, the United States would like to note that the European Communities' statements regarding the purported risks of biotechnology are fundamentally misleading. Contrary to the European Communities' assertion, there has, in fact, been consensus over the types of risks potentially posed by agricultural biotechnology products since the late 1980's. The consensus among international experts is that, qualitatively, the types of risks potentially posed by products of modern biotechnology are essentially the same as those posed by similar products produced through other, more traditional technologies.

4.531 In other words, the types of risks that regulators assess for foods produced through biotechnology are qualitatively the same as for foods produced through other methodologies—for example, the production of toxins, significant changes in composition, and the presence of food allergens. Similarly, the types of environmental risks – for example, the production of plant pests, and effects on beneficial non-target organisms – are not qualitatively different between biotechnology and non-biotechnology agricultural products.

4.532 In 1986, the OECD Ad Hoc Group on Safety and Regulations in Biotechnology concluded that any potential environmental impacts of recombinant DNA organisms are "expected to be similar to effects that have been observed with introductions of naturally occurring species or selected species used for agricultural applications." In 1987 the US National Academy of Sciences (NAS) published a white paper that stated that the risks posed by biotech organisms are the "same in kind" as those associated with organisms that have been modified through other techniques.

4.533 In 1993, the OECD, through work commissioned by the Group of National Experts on Safety in Biotechnology, concluded that the risks potentially posed by plants produced through modern biotechnology should be approached within the context of the potential risks of plants produced through traditional plant breeding. While the OECD and NAS may have been the earliest scientific bodies to come to these conclusions, the same conclusion has been reached by other international scientific organizations and national scientific advisory bodies. In 1996, a joint FAO/WHO expert consultation on biotechnology and food safety concluded that "Food safety considerations regarding organisms produced by techniques that change the heritable traits of an organism, such as rDNA technology, are basically of the same nature as those that might arise from other ways of altering the genome of an organism, such as conventional breeding." The Royal Society of the United Kingdom came to essentially the same conclusion that "as with genetic modification, conventional plant breeding technology (which can involve chemical or radiation-induced mutagenesis or cross-species hybridization) might also cause rearrangements of the genome, and therefore might also cause the activation of previously unknown toxins, anti-nutrients or allergens."

4.534 The scientific advisory bodies of the European Union have also confirmed the conclusion that, for both food and environmental risks, plants produced through modern biotechnology do not present new or novel risks. In 2003, the Scientific Steering Committee of the European Commission acknowledged that both the Scientific Committee on Plants and the Scientific Committee on Food have concluded in their published risk assessment that for the "GM crops" reviewed no new safety issues to humans or the environment have been presented. The Scientific Steering Committee also stated that the "published review of data do not indicate the GM crops presently in cultivation pose any more risks for humans, animals and the environment than do their conventional counterparts."

4.535 The level of scientific uncertainty claimed by the European Communities to exist around the risks posed by biotechnology products is both inconsistent with the history of the international discussion of this issue and with the actions of individual government regulatory authorities. In its 2003 report, the International Council for Science (ICSU) concluded after a synthesis of more than 50 independent scientific reviews that there is "convergence of science" that "Presently available genetically modified foods are safe to eat. GM foods presently on the market have been assessed for any risks of increased allergenicity, toxicity, or other risks to human health, using internationally agreed food safety standards. … This is the consensus view of several reports by national and international agencies."

4.536 In addition, government regulatory authorities with experience in regulating plants produced through modern biotechnology routinely use a case-by-case approach. For example, the United States, Canada, the European Communities, Japan, Australia, and South Africa have completed risk assessments on plants produced through biotechnology – essentially addressing the same types of risk assessment end points on a case-by-case basis. The foundation for this case-by-case approach to the regulation of biotechnology plants is the widely held scientific consensus that: 1) the risks potentially associated with biotech plants are essentially the same as those of plants produced by other techniques and 2) the assessment of risk should not focus on the methodology used in the breeding process but rather on the results of that process; *i.e.*, on the characteristics of the product itself.

4.537 To further illustrate the scientific consensus surrounding the types of risks potentially posed by biotech plants, both the Codex Alimentarius and the International Plant Protection Convention have adopted guidances that provide recommendations on the type of data that should be considered when conducting safety assessments for biotech plants. Both of these standard setting bodies were able to conclude these guidelines because of the already existing consensus on the types of risk issues that should be addressed in the risk assessment for biotech plants.

4.538 If scientific uncertainty concerning the risks of biotech plants had been as great as claimed by the European Communities, it is unlikely that any of these products would have successfully completed the regulatory process in any country. The assertion that the complexities – and uncertainties – of assessing the risks of the biotech plants currently in the EC system are far greater than non-biotech products is not born out by experience.

(b) Neither the biosafety protocol nor the precautionary approach serves as a defence to the European Communities in this dispute

4.539 The only way other sources of international law could be pertinent to this dispute is if, under Article 3.2 of the DSU, those other sources of law would assist the Panel in "clarifying the existing provisions of the [covered] agreements in accordance with customary rules of interpretation of public international law." But the European Communities has not identified how the Biosafety Protocol or a "precautionary principle" would be of relevance to interpreting any particular provision of the WTO Agreement.

4.540 Moreover, in the *EC – Hormones* dispute, the Appellate Body examined at length nearly identical arguments presented by the European Communities regarding the relationship between a purported "precautionary principle" and the *SPS Agreement*. The European Communities has not presented, and cannot argue, that any different results should apply here. Thus, even if a precautionary principle were considered a relevant rule of international law under Article 31(3) of the Vienna Convention, it would be useful only for interpreting particular treaty terms, and could not override any part of the *SPS Agreement*. So, for example, the notion of precaution could not excuse the European Communities from complying with the requirement under Article 5.1 that SPS measures be based on risk assessments. In addition, Article 5.7 of the *SPS Agreement* already allows for the European Communities to adopt a precautionary approach to regulating biotech products.

4.541 Just as the Appellate Body found it unnecessary and imprudent to make a finding on the status of the precautionary principle in international law, this Panel also should have no need to address this theoretical issue. Nonetheless, the United States notes that it strongly disagrees that "precaution" has become a rule of international law. In particular, the "precautionary principle" cannot be considered a general principle or norm of international law because it does not have a single, agreed formulation. In fact, quite the opposite is true: the concept of precaution has many permutations across a number of different factors. Thus, the United States considers precaution to be an "approach," rather than a "principle" of international law.

4.542 Moreover, if – as the United States submits – precaution is not a principle of international law, then it is *a fortiori* not a rule of customary international law. Customary international law is a binding rule that results from: (1) a general, consistent, extensive, virtually uniform practice of States; (2) followed by them from a sense of legal obligation. Precaution does not fulfil any of these requirements. Precaution cannot be considered a "rule" because it has no clear content and therefore cannot be said to provide any authoritative guide for a State's conduct. Second, it cannot be said to reflect the practice of States, as it cannot even be uniformly defined by those who espouse it. Third, given that precaution cannot even be defined and, therefore, could not possibly be a legal norm, one could not argue that States follow it from a sense of legal obligation.

4.543 For the purposes of interpreting the WTO Agreement in accordance with the principles in Article 31(3) of the Vienna Convention, the United States also strongly disagrees with any notion that the Biosafety Protocol is a rule of international law. To be relevant under Article 31(3), the international rule must be "applicable in the relations between the parties." In this case, however, the Biosafety Protocol is not applicable to relations between the United States and the European Communities, because the United States is not a party to the Biosafety Protocol.

4.544 Finally, the United States would not agree that the Panel would need to look to the Biosafety Protocol in interpreting the WTO Agreement even in a dispute between WTO Members that were both parties to the Protocol. The Protocol has a clear and unequivocal statement that it does not change the rights and obligations under any existing international agreement. In addition, the European Communities does not argue that any provision of the Protocol is in any way inconsistent with the European Communities' full compliance with its WTO obligations.

(c) The European Communities' description of its biotech approval regime is inaccurate

4.545 In describing the "European Communities' regulatory Framework," the European Communities conveniently leaves out a number of mandatory procedural steps, omits several deadlines by which specific action is required, and implies that the Commission has discretion – which the legislation does not grant – not to act on product notifications. But an accurate presentation of the EC system is important, because this serves as the baseline for understanding that the European

Communities' delays under the moratorium are inconsistent with the European Communities' own laws. The inconsistency of the European Communities' moratorium with the underlying biotech approval legislation further highlights that the delays resulting from the moratorium are undue.

3. The *SPS Agreement* applies to all measures in this dispute

4.546 In its first written submission, the European Communities argues at length, and in the hypothetical, that the European Communities might adopt measures with respect to one or more biotech products that are not covered within the scope of the *SPS Agreement*. But, once again, the European Communities' discussion is not linked to any of the legal issues in this dispute.

4.547 The pertinent question is whether the measures that the European Communities has actually adopted, and that are covered in this dispute's terms of reference, are within the scope of the *SPS Agreement.* But the European Communities does not even appear to contest this fundamental point. First, the European Communities has not disputed that both its Novel Foods regulation and Deliberate Release directive are covered within the scope of the *SPS Agreement*. Furthermore, with respect to the member State measures, the European Communities acknowledges that each of the member State measures was adopted for "some reasons" that fall within the scope of the *SPS Agreement*.

4.548 The European Communities' agreement that its measures were adopted for "some reasons" covered within the scope of the *SPS Agreement* is more than sufficient to bring those measures within the scope of that Agreement. Annex A to the *SPS Agreement* makes clear that "any measure" applied to protect against one of the enumerated risks falls within the scope the *SPS Agreement*. The Annex does not state that the measure needs to be exclusively applied to protect against only the enumerated risks. In fact, in the *EC – Hormones* dispute, the EC directive was not solely adopted to address alleged affects on human health. To the contrary, as the Appellate Body explained, the European Communities was also motivated to adopt its Hormones Directive by the perceived need to harmonize beef regulations in order to prevent distortions in the conditions of competition between producers in various EC member States. The harmonization of product standards is a goal expressed in the *TBT Agreement*. Yet, despite the variety of rationales, all parties in the *EC – Hormones* dispute agreed that the Hormones Directive fell within the scope of the *SPS Agreement*.

4.549 The detailed European Communities' discussion purporting to classify various alleged risks of biotech products as within or without the scope of the *SPS Agreement* is not tied to the legal issues in this dispute and is thus hypothetical. Nonetheless, the United States has responded to these arguments in an attachment to its second written submission, and notes that the European Communities' analysis would result in an overly narrow scope of the measures intended to be covered by the *SPS Agreement*.

4. General moratorium violates the *SPS Agreement*

4.550 The European Communities' discussion of the general moratorium is remarkable in that it is concerned solely with whether or not the general moratorium qualifies as a "measure" under the *SPS Agreement*. Should the Panel find, as the complaining parties all submit, that the general moratorium is indeed a measure under the *SPS Agreement*, the European Communities has not contested that the general moratorium is inconsistent with the European Communities' obligations under the WTO Agreement. Indeed, in its answers to Panel's questions, the European Communities concedes that there was no overall risk assessment for biotech products that could serve as a basis for the general moratorium.

4.551 The evidence that the general moratorium exists is overwhelming. In addition to the evidence that the United States cited in its first written submission and opening statement, official documents of the European Parliament also confirm the existence of the moratorium. For example, a February 2001 parliamentary Report: "Observes that the existing *de facto* moratorium particularly harms small and medium sized enterprises which, unlike multinational corporations, are often unable to perform their research work in countries outside the EU"; "Welcomes the agreement reached between Council and Parliament in the conciliation committee on the amendment of the directive on the release of genetically modified organisms and the assurances given by the Commission in that connection with regard to labelling and traceability, and considers that a clear framework now exists for the release of genetically modified organisms in Europe which will ensure maximum consumer protection and environmental protection, and that it would therefore not be justified to continue the *de facto* moratorium on the release of GMOs"; and notes that "Under this system approval takes an unacceptably long time. ... [N]o authorizations have been approved under this directive since October 1998. This demonstrates a lack of mutual recognition between member States and a *de facto* moratorium on all development. It calls into question the political will in Europe to support this industry."

4.552 More recently, a March 2003 resolution introduced in the European Parliament acknowledges the moratorium: "whereas, in view of the risks which GMOs represent, there are no grounds for lifting the *de facto* moratorium on GMO authorization, especially since no labelling and tracing system has been introduced and no assessment has been carried out of the impact which GMOs may have on organic/conventional farming." The same resolution then goes on to urge the continuance of the moratorium pending the launch of "a broad public debate."

4.553 The European Communities presents three arguments in its first written submission as to why this Panel should nonetheless find that there is no general moratorium. First, the European Communities argues that it cannot be "legally affected" by "casual statements of any of its numerous representatives." But the complaining parties are not relying on "casual statements of numerous representatives"; the statement cited by complaining parties are statements made by the European Communities' highest officials, by its member States, and by its official bodies. Moreover, the European Communities itself concedes, as it must, that such statements can be considered as evidence of the existence of a measure.

4.554 Second, the European Communities argues that even if the European Communities did adopt a general moratorium on approvals of biotech products, such a moratorium is legally precluded from qualifying as a "measure" under the *SPS Agreement*. The European Communities' argument, however, is based on two panel reports that are inapposite to this dispute. The United States does not contend that the European Communities' suspension of its approval process constituted a "practice" as described in the *US – Steel Plate* and *US – Export Restraints* reports cited by the European Communities. Although the European Communities' measure was not adopted in a transparent manner and officially published as a formal law, decree or regulation, the European Communities' decision to indefinitely suspend its approval procedures falls within the SPS definition of a measure and blocks biotech approvals just as effectively as would a written amendment to EC legislation.

4.555 Third, the European Communities claims that the application histories for certain products covered in the US panel request disprove the existence of the moratorium. To the contrary, the information submitted by the European Communities is entirely consistent with the European Communities' imposition of a general moratorium. First, the information submitted by the European Communities confirms that there were in fact no approvals of biotech products between October 1998 and the establishment of the Panel's terms of reference in August 2003. Second, not only do the

product histories confirm that no product was submitted for final approval, many of the product histories – as described below – illustrate just how the moratorium operated.

5. Product-specific moratoria violate the *SPS Agreement*

4.556 The primary basis for the European Communities' denial of the product-specific moratoria is the vague statement that "what has happened in many of these applications is that, at different stages of the procedure, requests for additional information have been put to applicants." The European Communities ignores, however, that product histories exhibiting requests for information are entirely consistent with the existence of a general and product-specific moratoria. The United States has not claimed that each and every application stopped all progress beginning in 1998. To the contrary, the moratorium was a decision by the European Communities not to move products to a final decision in the approval process. Certain progress in the process, short of final decision, is not the least bit inconsistent with a moratorium on final approvals.

4.557 Moreover, the European Communities' product histories provide further, compelling evidence of the existence of both a general and product-specific moratoria. First, a number of applications – particularly those nearing the final stage of approval – exhibit lengthy, unwarranted delays, unrelated to any requests for additional information. Second, a number of product histories contain statements from member States acknowledging – in writing – that regardless of any scientific issues regarding the particular application at issue, the member State simply was not going to vote for approval unless and until the European Communities had adopted new forms of legislation. Such statements illustrate that, contrary to the European Communities' assertions, the moratorium applied to each and every application, regardless of whether or not particular regulators had particular questions about individual applications.

(a) Examples of applications which faced lengthy delays, without any pending requests for information

4.558 *Oil-Seed Rape MS1, RF1 and Oil-Seed Rape, MS1, RF2*: In these two cases, France never allowed the product to be placed on the market, and thus these products in fact were never approved for cultivation, import, and marketing in the European Communities. In Question 99, the Panel asked the European Communities to confirm that France withheld its consent. The European Communities responded "Yes." The European Communities then goes on to argue that, nonetheless, an individual "can directly assert his or her right by directly relying on the Community law in question." This excuse is entirely unpersuasive. The European Communities does not assert that either of these products is in fact on the market in the European Communities; that EC Customs officials – in France or elsewhere – would admit either of these oil-seed products without the final step (the French consent) in the approval process; or that any biotech applicant has ever successfully asserted this right. Nor does the European Communities even attempt to explain what mechanism – such as a legal challenge – might be used to assert this right, or explain how a product can be considered approved if additional legal proceedings are required to allow the product to be placed on the market.

4.559 *BT-Cotton*: In February 1999 the regulatory committee did not approve the application by a qualified majority vote. Under the European Communities' own rules, an application that fails to achieve a qualified majority of votes in the regulatory committee must be submitted to the EC Council for an additional vote, and such submission must be made, to quote Article 21 of the EC Directive, "without delay." But, the European Communities' own chronology states that the next action is nearly three months later, in May 1999. And the action taken is not, as required under EC legislation, the submission of the application to the EC Council. Instead, the chronology states: "Launching of Inter-

Service Consultation on draft Council Decision." This term, and this step, is not provided for under the European Communities' regulations. The chronology is then blank until July of 2001.

4.560 *Roundup Ready Cotton*: In February 1999, the Roundup Ready cotton application, like Bt cotton, did not receive a qualified majority vote in the regulatory committee. Like for Bt cotton, the next step in the European Communities' chronology is the "Launching of Inter-Service Consultation on draft Council Decision" in May 1999. There is no further entry in the chronology until January 2003, which is more than two and one-half years later. Again, this is another example of a major delay that was not caused, as the European Communities' claims, by a pending request to the applicant for additional information.

4.561 *Oilseed rape tolerant for glufosinate-ammonium*: According to the European Communities' chronology, this product received a favourable opinion from the scientific committee on plants in November 2000. Under the European Communities' approval system, the next step should have been to submit the application for approval by the European Communities' Regulatory Committee. But the European Communities' chronology shows that no action was taken on the application until November 2002, a full 2-year delay. This 2-year gap belies the European Communities' assertions that under its supposed "interim approach," it was moving ahead on processing applications in advance of the entry-into-force of 2001/18.

4.562 *Maize BT-11*: In the chronology of BT-11, there is no action on the application for 2 years after a favourable opinion of the Scientific Committee on Plants in November 2000. The next entry, an "evaluation of updates by the lead CA" in October 2002, is unexplained and unsupported by any exhibit or attachment.

(b) Product histories in which member States acknowledge opposition to approval regardless of the merits of the individual application

4.563 The exhibits accompanying the product histories provide numerous examples in which member States noted in writing that they would oppose approvals until some type of new legislation was adopted, even though under EC law any objection had to be based on the merits of the application. These statements by member States stand in stark contrast to the European Communities' argument that it had adopted an "interim approach" under which final approvals were to be granted prior to the adoption of new legislation. They also directly contradict the European Communities' arguments that the delays with respect to individual products were justified by fact-specific considerations unique to the individual products, such as conflicting science, or delays on the part of applicants.

4.564 *Novel Food and Feed Regulation.* Some member States have used the implementation of new food and feed regulations (which did not become effective until April 2004) as an excuse for halting this process. Pioneer/Dow's Bt corn application: The Austrian Federal Ministry of Health and Women notes in its letter to the EU's DG XI, dated 24 October 2003, that any registration of Pioneer/Dow's product "should also take into consideration the two new EU regulations concerning traceability and genetically modified food and feed which will enter into force in April 2004." Roundup Ready corn (NK603): In a letter from the Austrian Federal Ministry for Social Affairs and Generations to the EU's DG XI regarding Monsanto's application for Roundup Ready corn (NK603), the Ministry cites several scientific concerns, but states that "Irrespective of the above mentioned scientific objections raised, Austria is of the opinion, that products shall not be placed on the market before the new regulations concerning genetically modified food and feed as well as on traceability and labelling of GMOs will enter into force." Syngenta's Bt11 biotech sweet corn: On 10 August 2000, the French authorities cited the yet to be implemented food and feed regulations as a reason for

withholding support for Bt11, choosing to disregard comprehensive scientific findings and instead continue the moratorium on biotech reviews.

4.565 *Traceability and Labeling Legislation.* Member States opposed to re-starting the review process for biotech crops also used the proposed new traceability and labelling regulations (which also did not become effective until April 2004) as a reason for continuing the moratorium. Syngenta's Bt-11 biotech sweet corn: several member State competent authorities statements clearly require that the new traceability and labelling regulations be in place prior to the lifting of the moratorium on biotech reviews and approvals. The German competent authority's objections, dated September 26, 2003, provided that "In accordance with the French position, the German CA is of the opinion that no consent should be given until both regulations are in force. In particular, the regulation on traceability and labelling of GMOs will provide for additional transparency and the possibility of choice for consumers." Likewise, Denmark, in late September 2003 stated that its support for Bt-11 was contingent on the implementation of the new traceability and labelling regulations. In doing so, it reminded the EC authority of the March 2001 declaration of six member States (the "March 2001 declaration") reaffirming the moratorium until traceability and labelling rules, as well as a system for environmental liability, are adopted. Again in February 2004, the Danish competent authority writes: "Furthermore, Denmark finds that approval for placing on the market cannot take place before the regulation on traceability and labelling is fully into force." Oilseed rape (GT-73): The Danish, Italian, Austrian and Belgian competent authorities all cite the need for traceability and labelling regulations to be in place before they will support the approval of any biotech crops. The Austrian competent authority wrote: "As a matter of principle, this product should not be placed on the market before the entry into force of the Regulation of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC." Roundup Ready corn (GA21): Denmark acknowledged that "the assessment of the health and nutritional aspects of this application gives Denmark no reason to object to the approval of the GA21 maize nor to products derived from the maize." However, "in spite of the favourable assessment ... , Denmark will submit a reasoned objection to the approval of the genetically modified GA21 maize, reference being made to the statement submitted by this country and four other member states at the Environmental Council on 24 and 25 June 1999 [declaring a suspension of new GMO authorizations until labelling and traceability rules are adopted]." Bt-11 sweet corn: Denmark states that "[w]ith regard to the issue of food safety as such, Denmark sees no problem in allowing the Bt11 maize for food purposes ... Apart from this however, Denmark will refer to the Declaration concerning the suspension of new GMO authorizations made by five member States (France, Greece, Italy, Luxembourg, and Denmark) at the Environmental Council of 24 and 25 June 1999. With reference to this Declaration, Denmark therefore wishes to submit a reasoned objection concerning the Bt11 maize."

4.566 *Co-Existence and Environmental Liability Legislation.* Several member States have used the lack of coexistence and environmental liability laws as a reason to continue the moratorium. Such rules have no bearing on decisions or assessments regarding the environment or human or animal health or safety, and a desire for such rules cannot justify delay. Otherwise, a Member could always say it would like a better regulatory regime in other aspects and delay approvals indefinitely, rendering the SPS "undue delay" discipline meaningless. Glufosinate tolerant and Bt resistant (Bt-11) corn: The Austrian competent authority states: "As this product is in particular destined for cultivation in all countries of the European Union, Austria – apart from the need for further information – raises an objection against the putting of this product on the market, as long as all conditions for coexistence with GMO-free cultivation methods are not cleared in a sound legal way." Belgium makes the same objection for the same product: "Belgium is of the opinion that the placing on the market of this product should not be granted before a coexistence regulation is not yet entered

into force." Denmark once again cites the March 2001 declaration of six member States reaffirming the moratorium until traceability and labelling rules, as well as a system for environmental liability, are adopted. Roundup Ready oilseed rape GT73: Austria objected to Roundup Ready oilseed rape GT73, as a "matter of principle," requiring that "further issues concerning liability and the coexistence of genetically modified, conventional and organic crops remain to be resolved." Also, on 24 March 2003, Denmark objected, citing the March 2001 declaration. Pioneer/Dow AgroSciences Bt corn (Cry1F 1507): The Austrian CA, as late as 17 October 2003, objected to the placing on the market of Pioneer/Dow AgroSciences Bt corn (Cry1F 1507), citing coexistence. The specific reasons cited by the CA are generally economic in nature, rather than issues of environmental safety: "Import, processing and cultivation of GM 1507 maize will result in the presence of adventitious and/or technically unavoidable GMO traces in non GMO maize. Although maize has limited capabilities to survive, disseminate or outcross, this may lead to effects on the implementation of co-existence of different agricultural systems (with or without GMO). As long as the conditions for co-existence are not clarified on the EU level, Austria holds the opinion that no consent for the placing on the market of 1507 maize should be given." Roundup Ready corn (NK603): Austria states that not only should biotech product approvals continue to be suspended until feed and traceability and labelling legislation becomes effective, but also, that no biotech products may be placed on the market without coexistence rules: "In addition the issue of co-existence of genetically modified, conventional and organic farming is at the moment under discussion and has to be resolved." Denmark also objects, again citing to the March 2001 declaration.

(c) The European Communities' product histories are incomplete

4.567 The European Communities relies almost exclusively on its product histories to support its claim that – despite the statements and actions of EC officials – there were in fact no general or product-specific moratoria. But the European Communities' product histories are incomplete in three important ways. First, the product histories do not cover any products that were withdrawn prior to establishment of the Panel. These failed product applications are direct, compelling evidence of the existence of a general moratorium. In its first written submission, the United States noted that applications under both the environmental release and novel food legislations had been indefinitely delayed by the general moratorium and consequently withdrawn, and gave nine specific examples. The European Communities has failed to provide any chronologies for these products.

4.568 The European Communities' product histories are also incomplete in that the European Communities has not provided the underlying documentation for each step in the process. Instead, in selecting what exhibits to provide to the Panel, the European Communities has picked and chosen among the various chronological entries.

4.569 Finally, the product histories are incomplete in that they do not include every step in the product histories. Although only the applicants and the European Communities have access to all correspondence, the United States has learned that at least some of the product histories are missing significant entries. For example, the application history for Fodder Beet A5/15 excludes a reference to at least one significant document. In particular, at a point in the process where the applicant believed that it had complied with all outstanding information requests, the chronology omits a letter from the lead competent authority to the applicant, stating that: "Since we met the new directive [2001/18] has been adopted and as you probably already know Denmark and five other member states have confirmed their opinion on suspending new authorizations for cultivation and marketing until effective provisions concerning complete traceability which guarantees reliable labelling has been adopted."

6. Member State measures violate the *SPS Agreement*

4.570 The nine measures imposed by six member States are sanitary or phytosanitary measures which are not "based on" "risk assessment[s]" as required by Article 5.1 of the *SPS Agreement*. Although each of the six member States that have imposed bans on approved biotech products offered reasons for their measures – though unjustified according to the scientific committees – none of the member States put forth a "risk assessment" as defined in Annex A, paragraph 4. In response to the Panel's Question (No. 107) on this issue, the European Communities claimed that "the member States have made their own assessments and further risk assessments may be forthcoming" (emphasis added). The United States submits that, in fact, no such risk assessments supporting the member State measures have been provided.

4.571 In particular, the European Communities has provided on their second CD-ROM a folder titled "Safeguard Measures," in which the European Communities purports to provide EC member State justifications for the member State measures. A review of the documents confirms that none of the member State bans is based on a risk assessment.

4.572 In fact, the only risk assessments put forth for the banned products are the positive scientific assessments rendered by member States to which the products were submitted, and then by the European Communities' own scientific committees. In the case of each member State ban, these favourable assessments were reaffirmed when the scientific committees considered and rejected the information provided by the member States. Thus, the member State measures do not bear a "rational relationship" to the European Communities' positive risk assessments, and are not "based on" a risk assessment, in violation of Articles 5.1 and 2.2 of the *SPS Agreement*.

4.573 The European Communities' argument in defence is that each of the member State measures falls within the scope of Article 5.7 of the *SPS Agreement*. But the European Communities does not specify how Article 5.7 might apply. Its only argument is that under the terms of the EC legislation, the member State measures are labeled as "provisional." The mere label of a measure, however, is most certainly not sufficient to bring it within the scope of Article 5.7.

4.574 Before turning to the specific criteria of Article 5.7, the United States would note that the European Communities is incorrect in claiming that the United States was obliged to include an explicit Article 5.7 argument in its first written submission. This argument fundamentally misunderstands the structure of the *SPS Agreement*. The United States in its first written submission most certainly did explain that the member State measures are inconsistent with Article 2.2 of the *SPS Agreement*, and this necessarily means that the United States submits that Article 5.7 does not apply. In other words, Article 5.7 provides not the basis for a claim of an alleged breach of a WTO obligation, but acts as a defence to shield measures that would otherwise violate Articles 2.2 and 5.1. As explained by the Appellate Body in *Japan – Agricultural Products II*, "Article 5.7 operates as a qualified exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence."

4.575 In *Japan – Agricultural Products II*, as well as in *Japan – Apples*, another dispute in which Article 5.7 was considered, the Respondent invoked the provision to defend the challenged measure against alleged violations of Articles 2.2 and 5.1. The Complainant (the United States in both cases) did not assert Article 5.7 as an independent claim in either dispute, nor did the Panels suggest that the Complainant should have invoked Article 5.7. Indeed, the United States is not aware of any dispute in which the Complainant has based a claim on the Respondent's violation of Article 5.7.

4.576 The EC member State measures do not meet any of the four criteria set out in Article 5.7. First, the scientific evidence with respect to the products subject to the member State measures is not "insufficient". Scientific evidence is "insufficient," according to the Appellate Body, if it "does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*." Here, the evidence is plainly sufficient to perform a risk assessment, because the European Communities itself has conducted positive risk assessments for each product subject to a member State measure.

4.577 Second, the member State bans were not adopted on the basis of "available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members." As the United States noted in its First Written Submission, the relevant Scientific Committee in the European Communities reviewed each of the member State bans and concluded in each case that the information provided by the member State did not warrant any change in the Scientific Committee's earlier favourable risk assessment. Thus, the European Communities' own scientific committees have confirmed that the member State measures are not based on "available pertinent information."

4.578 Third, the member States have not sought "to obtain the additional information necessary for a more objective assessment of risk." In fact, there is no information in the record that the member States have sought to perform any risk assessments that would support their bans. To the contrary, as noted above, the European Communities' additional CD of documents contains no new information that could constitute an assessment of the risks by the member States.

4.579 Fourth and finally, neither the member States nor the European Commission has reviewed the import and marketing bans within a reasonable period of time. When asked by the Panel whether the member State measures were "reviewed within a reasonable period of time," the European Communities answered, without providing any evidence or elaboration, that the "measures are constantly subject to review." The conclusory statement that a measure is "constantly subject to review" does not come close to meeting the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption.

N. SECOND WRITTEN SUBMISSION OF CANADA

1. Introduction

4.580 In defending its measures in these proceedings, the European Communities has resorted to obfuscation or mischaracterization of the salient facts and scientific evidence, and has presented legal arguments regarding obligations under the WTO Agreements that find little, if any, resonance in either logic, accepted principles of treaty interpretation, textual construction or the relevant jurisprudence. In its Second Written Submission, Canada demonstrates, through reference to the European Communities' own documents, relevant documents from international organizations and case law, that the European Communities' defences to Canada's claims are untenable in fact and in law.

4.581 Canada notes that the European Communities has not yet presented any arguments with respect to the consistency of the moratorium with a number of provisions in the *SPS Agreement*. The European Communities, other than to simply assert that the moratorium does not exist, and never did, has not presented any arguments or evidence to refute Canada's *prima facie* case with respect to violations of Articles 2.2, 2.3, 5.1, 5.5, 5.6, 7, 8, paragraph 1 of Annex B and paragraph 1(a) of Annex C. Similarly, the European Communities has failed to present any arguments to counter

Canada's *prima facie* case that the product-specific marketing bans violate Articles 2.2, 2.3, 5.1, 5.5, 5.6, 8, and paragraph 1(a) of Annex C.

2. The moratorium

4.582 The European Communities' sole defence to Canada's claims regarding the moratorium is the astonishing claim that there is not and never was a moratorium. The European Communities admits that there have been delays in the processing of biotech applications over the last 5 years, but asserts that these delays are not a result of a systemic suspension of approvals for biotech products. The European Communities attempts to rationalize the delays on several grounds, including:

- The need for legislative changes to strengthen inadequate risk assessment and risk management provisions;
- The need for legislative changes necessary to comply with the European Communities' other international obligations, such as those under the Biosafety Protocol;
- The distinction between risk assessment and risk management;
- The existence of scientific uncertainty; and/or
- Requests for more information and objections by regulatory authorities.

4.583 These attempts to rationalize the obvious delays in the approval procedures for biotech products are, in effect, veiled attempts to rationalize the moratorium.

(a) The European Communities' assertion that the moratorium does not exist is without merit

4.584 Given the facts in this case and in the light of some of the European Communities' own assertions or explanations presented in these proceedings, that there has been a moratorium on the approval of biotech products since October 1998 is indisputable. The critical factual issue in this case is not whether there has been a moratorium, but whether the various attempts by the Commission to re-start or "relaunch" the authorization process for biotech products, prior to the establishment of this Panel in August 2003, succeeded. Canada asserts, not only that those attempts did not succeed, but that subsequent efforts to relaunch the approvals process have also been unsuccessful, and that the moratorium remains in place.

4.585 Various EC member States have demanded a succession of new conditions on the marketing of biotech products before they would agree to new authorizations. As a result, the European Communities has failed to process pending applications, decision-making on approvals of pending product applications has come to a stand-still, and, despite attempts by the Commission to break this log-jam, it has failed to convince the member States to restart the approval process.

4.586 The Commission's stated reason for proposing its so-called "interim approach" in July 2000 was precisely because the approval process had stalled. The Commission in its press release at the time indicated that "[t]he objective [of the interim approach] is to resume the authorization process for GMOs in the near future…" However, the "interim approach" failed because it did not have the political support of enough EC member States.

4.587 Then, as the European Communities got closer to enacting and implementing the revised approval legislation, additional conditions for restarting the approval process emerged. Just prior to the adoption of Directive 2001/18, Denmark, France, Greece, Italy, Luxembourg and now Austria reaffirmed their commitment to suspend approvals, essentially claiming that the new procedures were not adequate.

4.588 Despite the reassurances of the Commission, the entry into force of Directive 2001/18 did not result in the lifting of the moratorium. EC member States continued to refuse to lift the moratorium until new legislation regarding traceability and labelling was in place. In the context of specific biotech product applications, some EC member States continued to object to the approval of products that had been positively assessed by the lead competent authority under Directive 2001/18, not on the basis of safety concerns, but on the grounds that approval of GMOs should be suspended pending the adoption of new legislation on traceability and labelling.

4.589 Five EC members States – France, Belgium, Denmark, Greece and Italy – also indicated that they would insist on yet other prerequisites for restarting the approval process: the formulation of a special environmental liability scheme and the adoption of EC-wide legislation to regulate the "co-existence" of genetically modified crops with conventionally bred and organic crops – conditions which are not even relevant for pending approvals for food use or import and processing.

4.590 Given the evidence in this case, the European Communities' assertion that "the approval procedures have never been suspended or stalled" is completely baseless. Despite the Commission's numerous attempts to lift the moratorium, the "goalposts" keep shifting as EC member States keep introducing new conditions.

(b) Rationalizations for the moratorium

4.591 The European Communities asserts there was a "pressing need" to revise Directive 90/220 because that Directive did not "address all issues raised by new scientific understandings and the regulatory developments which were taking place at the international level" and did not include "common/harmonised criteria on the risk assessment to be performed and did not provide for any post-market surveillance measures." None of these *ex post facto* rationalizations for the moratorium is supported by the evidence.

4.592 The European Communities' claim that "new scientific understandings" required new legislation is without merit. The opposite is true, as demonstrated by legislative developments that made the European Communities' biotech approval procedures *less onerous* in the light of the advanced state of scientific understanding that had evolved since the adoption of Directive 90/220 in 1990. Commission Directive 94/15/EC, simplifying the information requirements for notifications, and Commission Decision 94/730/EC, simplifying the procedures for approval of field trials for biotech products, are examples of such developments.

4.593 Turning to risk management issues, the European Communities' attempt to portray the revisions to Directive 90/220 as necessary to address risk management needs is equally without merit. Directive 90/220 already provided for "detection and identification techniques", "monitoring plans and techniques" and labelling requirements. Moreover, Directive 90/220 already enabled regulators to impose conditions in relation to these issues as part of the consent to market the biotech product in question.

4.594 The European Communities' rationale for amending Directive 90/220 is contradicted by the Commission's 1996 Report on the Review of Directive 90/220. That report suggests that changes to

Directive 90/220 were required because the approval procedure was "difficult to implement, time-consuming and cumbersome to follow both for users and authorities." One of the principal difficulties underlying the "cumbersome" procedure was the absence of a means to resolve conflicting scientific views by member States. The European Communities later revised Directive 90/220 to make consultation with an independent scientific committee at the Community level mandatory in cases where objections are raised. Contrary to the European Communities' assertion, the role of the scientific committee at the Community level was precisely to act as an "independent system of conflict resolution" to resolve disagreements amongst member States on the basis of science. In short, the rationale the European Communities now puts forward for revising Directive 90/220 is inaccurate and cannot be a legitimate justification for the moratorium.

4.595 Turning to Regulation 258/97, the European Communities argues that the "delays" in processing applications under Regulation 258/97 were not due to an inadequate framework for risk assessment, but rather inadequate risk management provisions. This argument is flawed for several reasons. Regulation 258/97 already requires that GMO novel foods and food ingredients be labelled. More importantly, the European Communities has failed to identify any risks arising from the scientific assessment of pending biotech applications that would justify adopting traceability and detection measures as "risk management measures" in every case, regardless of the risks involved. Consequently, to "delay" the approval of products under Regulation 258/97 on the basis that the existing legislation does not provide for risk management measures, where the risk assessments for those products have not identified any risks that need to be managed, is unjustifiable.

4.596 For the three products that were, in the words of the European Communities, "partially affected by this situation," (maize Bt11, GA21, NK603) the relevant risk assessments conducted by the European Communities' independent scientific committees under Regulation 258/97 did not identify any risks for which risk management measures would be justified. In all three cases, the risk assessments, taking into consideration the objections raised by member States, concluded that the product in question was a safe as conventional maize. Accordingly, based on the outcome of the risk assessments, there was no justification for imposing "risk management" measures. Consequently, the "delays" in approving biotech products under Regulation 258/97 were not a result of the necessity to adopt "risk management" measures; they were a result of the moratorium on the approval of biotech products imposed by the European Communities.

4.597 In an effort to minimize the importance of the conclusions of its own independent scientific committees, the European Communities goes to great pains to stress the distinction between risk assessment *strictu sensu* and risk management and the respective roles of the scientific committees and Regulatory Committee. The European Communities stresses that risk management decisions are made by the Regulatory Committees and risk assessment *strictu sensu* falls to the scientific committees. In other words, the Regulatory Committees are responsible for selecting the appropriate SPS measure. This is not particularly surprising, problematic or relevant to the issues in this case.

4.598 Even if one takes the European Communities' misleading portrayal of its regulatory regime at face value, it follows logically that the Regulatory Committees must have evaluated the various risk management options that might be applied in light of the risks that were identified in the risk assessment. It is telling that the Regulatory Committee has failed to do so in every instance.

4.599 In any event, the issue in this dispute is not the respective roles of the various bodies comprising the European Communities' regulatory process, nor is it whether the European Communities is adhering to its own legal requirements. The issue is the failure of the European Communities to consider and approve biotech products as a result of an across the board moratorium and the European Communities' failure to base its measures – the moratorium, the product-specific

marketing bans, and the safeguard measures – on a risk assessment that meets the requirements of Annex A and Article 5.1 of the *SPS Agreement*.

4.600 The European Communities also attempts to use the Biosafety Protocol to rationalize the moratorium. The European Communities insinuates that measures regulating GMOs should be dealt with "outside" the WTO Agreement because GMOs have their own "special agreement", the Biosafety Protocol. This position is obviously without merit. Nothing in the WTO Agreements suggests that EC measures to regulate biotech products should be exempt from obligations contained in those agreements. Given that the complaining parties to this dispute are not parties to the Protocol, the Protocol is not a "relevant rule[] of international law applicable in the relations between the parties." Consequently, in this case, the Protocol should not be taken into account in the interpretation of the obligations under the WTO Agreement. Moreover, given that the Protocol's own terms emphasize that "this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements," it is difficult to see how the Protocol can be used to override the obligations of the WTO Agreement.

4.601 In any event, there is no inconsistency between the obligations of the Protocol and the WTO obligations relevant to this dispute. The European Communities' measures – its moratorium, its product-specific bans and its member State national bans – are stark refutations of the Protocol's central premise that decisions regarding the importation of LMOs should be made on a case-by-case basis, and be based on a transparent, scientifically-sound risk assessment. Furthermore, the European Communities' assertion that it adopted its new legislation for biotech approvals only after the Protocol was concluded, "in order to be sure that its own legislation was consistent with the international approach" is inconsistent with the facts. The risk assessment provisions of Directive 90/220 were far more detailed and onerous than those of the Protocol. That the European Communities submitted numerous decisions, concerning the approvals of products under Directive 90/220, to the Bio-safety Clearing House implies that the European Communities considered these decisions to be based on risk assessments that were consistent with the requirements of the Protocol. Thus, if the risk assessments conducted under Directive 90/220 met the requirements of the Protocol, amendments to Directive 90/220 could not have been necessary "in order to ensure that its own legislation was consistent with the international approach."

4.602 The European Communities further attempts to rationalize the moratorium on the basis of "scientific uncertainty." However, the European Communities presents an incomplete and misleading portrait of the state of the relevant scientific evidence, exaggerating the risks of biotech products in comparison to their conventional counterparts. It is particularly striking that in presenting this scientific context, the European Communities ignores the conclusions of its own scientific committees reviewing individual product applications and the conclusions of more than 20 years of EC-sponsored research in the field of biotechnology. In essence, the European Communities, without directly saying so, is questioning the validity of the conclusions of its own scientific experts.

4.603 In fact, the European Communities' independent scientific committees, in evaluating specific product applications, addressed the hypothetical risks raised by the European Communities in this proceeding. The European Communities' scientific committees did not identify an absence of sufficient scientific evidence as a justification for being unable to make an objective assessment of the evidence and reach a conclusion as to the risks presented. To the contrary, the European Communities' scientific committees were able to form firm conclusions as to the safety of the products in question.

4.604 In its Written Rebuttal, Canada reviews each of the hypothetical risks raised by the European Communities and highlights how the European Communities' scientific committees have addressed

these issues. Despite the European Communities' attempts to mischaracterize and exaggerate the risks of biotech products and to insinuate that there exists significant and intractable scientific uncertainty, it is abundantly clear that the European Communities' scientific committees have thoroughly and carefully assessed, on a case-by-case basis, each of these risks in the context of specific applications and on the basis of sound and adequate scientific evidence. The unambiguous conclusion of the European Communities' own scientists is that the biotech products with pending applications do not pose any greater risk to human health or the environment than their conventional counterparts.

(c) The European Communities mischaracterizes risks associated with biotech products in comparison to non-biotech products with novel traits in an attempt to justify the moratorium

4.605 The European Communities makes a number of unfounded allegations regarding the comparability of the risks associated with biotech plants and non-biotech plants with novel traits. In doing so, the European Communities ignores the repeated conclusions of its own scientific bodies.

4.606 Many of the scientific issues raised by the European Communities, while true for biotech plants, are, in fact, similar for plants derived using more conventional breeding technologies available to plant developers. International organizations such as the FAO, the WHO and the OECD have concluded that the use of modern biotechnology does not inherently result in foods that are less safe than those produced by conventional techniques. Unexpected effects can occur with any method of breeding. Nevertheless, in comparison to crops developed through traditional breeding or mutagenesis, biotech crops in the European Communities are subjected to a very extensive pre-market evaluation for potential hazards. While new varieties of traditionally bred crops are evaluated for agronomic and morphological traits, most have not been subjected to any kind of food safety evaluation. In fact, the more rigorous assessment of biotech plants has highlighted the need for further evaluation of "traditional" varieties of plants, which have been developed using a trial and error approach. Many of the potential risks associated with conventional crops received very limited attention prior to the evaluation of transgenic crops.

4.607 In terms of genetic stability, the European Communities states that genetic engineering introduces new genes in random locations in the genome of a plant. This is not a phenomenon unique to genetic engineering and can be observed in cases where plant breeders have broken the barriers that prevent species from mating using conventional techniques.

4.608 The European Communities further asserts that there are major differences in the potential allergenicity of GM foods as compared to other novel foods, making numerous vague, and ultimately unmeritorious, allegations to suggest that GM foods hold a much greater potential for containing allergens that have been unintentionally introduced via the insertion of new genetic material. Any novel food, regardless of the method of production, could result in the introduction of proteins to the human diet for which there has been no previous significant exposure and, consequently, for which the allergenic potential is unknown.

4.609 The European Communities also asserts that "[t]here are however significant differences for the issue of potential invasiveness or persistence in the environment between herbicide/pesticide resistance in GM plants and in conventional crops …" There is no legitimate scientific basis to this assertion and it is noteworthy that the European Communities does not reference any scientific authority for the proposition.

4.610 As a general point, the strategies for managing herbicide resistance are the same regardless of whether the herbicide-tolerant crop was produced using rDNA techniques, mutagenesis or conventional selective breeding. As herbicide-tolerant crops do not have a selective advantage unless

the specific herbicide to which the crop is tolerant is applied (*i.e.* the "relevant selection pressure is present"), the invasiveness or persistence of a herbicide-tolerant crop in the natural environment will be no different from its non-herbicide-tolerant counterpart if the herbicide is not applied.

4.611 The European Communities' distinction between non-selective and selective herbicides is misleading. Herbicides fall on a spectrum of selectivity; some herbicides only control a very limited number of plant species, while others control for a wider range of species. The European Communities neglects to mention the several varieties of herbicide-tolerant crops resistant to the broad spectrum herbicide imidazolinone that have been developed through conventional breeding and mutagenesis. Consequently, the use of broad spectrum herbicides is not limited only to herbicide-tolerant biotech crops. Furthermore, the European Communities discounts the fact that many selective herbicides are far more harmful to the environment than the broad spectrum herbicides the European Communities singles out, glyphosate and glufosinate ammonium. Similarly, the European Communities fails to mention any of the environmental benefits associated with the use of herbicide tolerant biotech crops. As the UK Royal Society has documented, herbicide tolerant biotech crops may be used to benefit wildlife and provide biodiversity in the agricultural environment. Lastly, the European Communities fails to point out that the various risks associated with herbicide use are comprehensively reviewed under the generally applicable EC legislation concerning plant protection products, Directive 91/414/EEC. Even more surprisingly, the European Communities fails to mention that the safety of glyphosate has been fully assessed under Directive 91/414/EEC as recently as 2001.

3. Product specific marketing bans

(a) Oilseed Rape Ms1xRF1 and Ms1xRf2

4.612 Whatever the *ex post facto* rationalization offered by the European Communities in relation to these particular products, the fact remains that the European Communities failed to complete the approval procedure under Directive 90/220; the applicant has been unable to market its products in the European Communities as a result of the failure of France to issue the letters of consent and the consequent uncertainty regarding the legal status of the products. Therefore, the European Communities has failed to "complete" the approval procedure without "undue delay" in patent violation of Article 1(a) of Annex C of the *SPS Agreement*. Moreover, by failing to complete the approval procedure, the European Communities has instituted and maintained effective product-specific marketing bans for Ms1xRf1 and M1xRf2. As these product-specific marketing bans are not based on a risk assessment (the risk assessments that were conducted supported the approval of these products rather than the imposition of marketing bans), these measures are inconsistent with Articles 5.1 and 2.2 of the *SPS Agreement*.

(b) Oilseed Rape Ms8xRf3

4.613 Oilseed rape Ms8xRf3 remains subject to a product-specific marketing ban and continues to serve as an example of how the European Communities has given effect to the moratorium. Eight years after an initial submission for approval – to Belgium in 1996 – six years after the SCP issued its opinion in May 1998 – and after years of safe commercial use in other parts of the world, the product remains unapproved either for import and processing or cultivation, despite reasonably available risk management measures. The product-specific marketing ban violates Articles 5.1 and 2.2 of the *SPS Agreement* as it is not "based on" a risk assessment and violates Article 5.6 as being more trade restrictive than necessary to achieve the European Communities' appropriate level of protection. By any reasonable standard, the extraordinary length of time to process this application constitutes "undue delay". Accordingly, the European Communities has acted inconsistently with paragraph 1(a) of Annex C of the *SPS Agreement*, and by extension, has violated Article 8.

4.614 The European Communities' description of the history of this application is both misleading and incomplete. A review of the Chronology and Attachments submitted by the European Communities in Exhibit EC-63 reveals that over the last eight years, the notifier has made sustained and good faith efforts to respond to the ever-shifting and increasingly unreasonable demands of the member States. The processing of this application illustrates how the European Communities has effectively used its approval procedures to thwart the approval of this product, irrespective of the risks to human health and the environment and regardless of attempts by the notifier to address the concerns of member States. The logical conclusion to draw from this documentation is that, regardless of the risks, the European Communities was and is intent on blocking the approval of this product for cultivation and is intent on imposing such onerous and unnecessary conditions as to make the importation of the product for processing uneconomical.

(c) Oilseed Rape GT73

4.615 Oilseed rape GT73 remains subject to a product-specific marketing ban and continues to serve as an example of how the European Communities has given effect to the moratorium. Nine years after an initial submission for approval – to France in 1995, and, as a result of France's inaction, to the Netherlands in 1998 – and after years of safe commercial use in other parts of the world, the Commission submitted the file to the Regulatory Committee for Directive 2001/18 for a vote on 16 June 2004. Neither the Commission's proposed decision to approve the product – nor a rejection of this decision – obtained the required qualified majority. Despite entry into force of the new regulatory framework, despite positive review by the member State competent authority, and despite the positive opinion by EFSA issued as recently as February 2004, the member States are still refusing to approve GT73 for import and processing.

4.616 The obvious fact that the moratorium is still in place today cannot be disputed by simply arguing that, after years of delay, there still remain two further procedural steps after which, theoretically, approval for this product could be granted. Even if one were to argue that approval might ultimately be granted – assuming another failure by the European Communities' Council of Ministers to come to any conclusion at a potential Council vote in or around October 2004, and subsequent approval by the Commission – the fact that approval would occur after nine years of mostly stalled procedures, and at the very last possible procedural step, after countless delays beyond legal timelines and beyond scientific justification, would be further proof for the continued *existence* of the moratorium rather than anything else.

4. Mootness is not relevant

4.617 The European Communities' assertions with respect to the relevance of the concept of "mootness" are factually and legally incorrect or misleading. WTO jurisprudence is replete with instances where panels made findings with respect to measures that were either removed or modified by the responding party after the terms of reference had been established. A panel's jurisdiction to consider a measure is first determined by its terms of reference. If the measure falls within its terms of reference, the panel is to exercise its discretion and make findings on those measures necessary to fulfil the dispute settlement objective of "securing a positive resolution of the dispute". In cases where the measure in question existed at the time of the establishment of the terms of reference of the panel, the consistent practice of panels has been to at least make findings on the WTO/GATT consistency of that measure.

4.618 From a factual standpoint, Canada contests vigorously the European Communities' assertion that the measures before this Panel never existed or were withdrawn by the European Communities prior to the establishment of this Panel's terms of reference. Similarly, Canada disputes that the

European Communities' suggestion that "a case on a measure that is not in existence any longer would be devoid of any practical purpose" applies to a situation, like the one at hand, where there is a real possibility of the measure recurring.

5. The European Communities' appropriate level of protection

4.619 As the European Communities appears to admit that its appropriate level of protection in respect of biotech products is a "high level of protection," Canada submits that the Panel should first review the moratorium and the product-specific marketing bans in relation to the obligations under Article 5.6 of the *SPS Agreement*. The evidence demonstrates that the moratorium and product-specific marketing bans are more trade restrictive than required to achieve the European Communities' appropriate level of protection.

6. EC member State national measures ("safeguard measures")

(a) Article 5.7 of the *SPS Agreement* does not apply

4.620 The European Communities argues that the safeguard measures are provisional and are therefore subject only to Article 5.7 of the *SPS Agreement* to the exclusion of the other provisions cited by Canada as having been violated. The European Communities further claims that the burden lies on the complaining party to establish a *prima facie* case that the measures in question are inconsistent with the requirements of Article 5.7, and that Canada has not met this burden. The European Communities' arguments in this regard are completely without merit.

4.621 First, the Appellate Body has not defined the relationship between Article 5.7, and Article 2.2 and 5.1 is "one of exclusion, not exception". Equating the relationship between Articles 2.2 and 5.1, and Article 5.7, with the relationship between Articles 3.1 and 3.3 is inappropriate because the purposes, and therefore the relationships between these Articles, respectively, are different.

4.622 The European Communities' argument with respect to Article 5.7 distorts the basic architecture of the *SPS Agreement*, as reflected in Articles 2, 3 and 5. The European Communities bifurcates the SPS regime on the basis of whether measures are "definitive" (or "permanent") or "provisional". There is no basis for a bifurcation of this nature in either the text of the *SPS Agreement* or the relevant jurisprudence. To the contrary, the basic architecture of the *SPS Agreement* demonstrates that the bifurcation occurs in Article 3, between measures based on international standards, and other SPS measures. Article 3 provides Members with two equally legitimate options. A Member can adopt a measure that is based on a relevant international standard, where such a standard exists. Alternatively, a Member can adopt a measure in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5, where it seeks a level of protection that is higher than the level of protection implied by the international standard.

4.623 In essence, Articles 3.1 and 3.3 represent "separate but equal" tracks to follow in adopting an SPS measure. Article 3.3 is not merely a "qualified exemption" from the basic obligation in Article 3.1 to base such measures on international standards. It is the expression of the "autonomous right" of WTO Members to establish their own appropriate levels of protection, including levels of protection that are higher than those implied by the relevant international standards. However, a Member choosing the second option is obliged to meet the requirements of Article 5.1 and base its measures on a risk assessment consistent with the definition found in Annex A.1 of the *SPS Agreement*.

4.624 Where a measure is not based on a risk assessment, and therefore inconsistent with Article 5.1, it will also, by implication, be inconsistent with the general requirement in Article 2.2 not to maintain SPS measures without sufficient scientific evidence. If it is found that the measure in question is being maintained without sufficient scientific evidence, it is open to the Member defending the measure to argue that sufficient scientific evidence does not exist to enable it to complete a risk assessment. This is where Article 5.7 enters the picture.

4.625 As the Appellate Body has explicitly noted, Article 5.7 "operates as a *qualified* exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence". Article 5.7 enables the WTO Members, in certain, limited circumstances, to adopt and maintain SPS measures despite the fact that they are not supported by sufficient scientific evidence. Article 5.7 does not exist as an option that can be freely chosen by the Member concerned in place of Article 2.2.

4.626 The European Communities' argument that the threshold (or "demarcation line") for the applicability of Article 5.7 lies with the provisional nature of the measure rather than with the "sufficiency or insufficiency of scientific evidence" is also without merit. The European Communities' position is based on a number of dubious textual arguments and the flawed assertion that the four conditions set out in Article 5.7 have "equivalent status". These assertions ignore the fact that the first condition, insufficiency of scientific evidence, is expressed as a threshold.

4.627 While the European Communities' legislation indicates that "safeguard" measures are meant to be temporary, the same legislation requires that a decision on the justifiability of such measures shall be taken in reasonably short order. Of the five safeguard measures being challenged by Canada, none has been in place less than 45 months. If such measures are provisional, they are so in name only.

4.628 In any event, the mere fact that a Member labels a measure as provisional does not permit that Member to escape the other obligations of the *SPS Agreement*. It is not the provisional nature of the measure that matters, but whether the measure is being maintained without sufficient scientific evidence. Only if the measure, whether provisional or otherwise, is found by a panel to be maintained without sufficient scientific evidence do the considerations under Article 5.7 come into play. Obviously, it would be the Member invoking the provision that would have the initial burden of demonstrating a *prima facie* case.

(b) Even if Article 5.7 were to apply to the EC member State national measures, it would not exclude the application of Articles 5.5 and/or 5.6

4.629 The issue in relation to Article 5.5 is consistency in the application of appropriate levels of protection in comparable situations. This is a different matter from the putative inability of the European Communities to complete a risk assessment with respect to a particular product because of the insufficiency of scientific evidence. As the establishment of an appropriate level of protection logically precedes the selection of the risk management tool – that is, the measure in question – the main issue is whether it is possible to determine if comparable situations exist. This is a factual matter that goes to whether the conditions of Article 5.5 have been met and does not have a bearing on the legal interpretation of the relationship between the Articles 5.5 and 5.7.

4.630 Similarly, the European Communities' answer with respect to the relationship between Article 5.7 and 5.6 is based upon a false premise. Nothing in the text of either Articles 5.6, 5.7 or 2.2 supports the European Communities' argument. As a matter of practice, there can be many situations where the risk manager, when faced with insufficient evidence, nevertheless has risk management

options from which to choose. In this light, Article 5.6 still has a valid role to play, even if, in a given situation, a determination that it has been violated is factually more complicated.

(c) The EC member State national measures are not based on a risk assessment, as required by Article 5.1

4.631 The European Communities asserts that the phrase "as appropriate to the circumstances", as used in Article 5.1, means that, in the context of the safeguard measures, the Panel would have to go back to Article 5.7 "because … the circumstances are that the scientific evidence is insufficient for the specific legislator and its specific level of protection". The European Communities' interpretation of "as appropriate to the circumstances" in this regard is completely unsupported by the jurisprudence and any reasonable textual construction of the terms. While these words provide the WTO Member flexibility in conducting the risk assessment, as the panel is *Australia – Salmon* concluded, the words cannot annul or supersede the substantive obligation of Article 5.1 to base the measure on a risk assessment. Moreover, Article 5.7 operates as an exception to Articles 2.2 and 5.1. It is only where a panel has found that a measure is inconsistent with Article 5.1 and/or Article 2.2 that Article 5.7 comes into play, and then only if the Member seeking to uphold the measure invokes it.

4.632 The European Communities' argument that Article 5.1 does not "expressly require a 'risk assessment' – it only requires that the Member take into account risk assessment techniques developed by the relevant international organisations", is a blatant distortion of both the clear text in Article 5.1 and its related jurisprudence.

4.633 In the alternative, the European Communities argues that the member States' safeguard measures are based on risk assessments. In pointing, astoundingly, to the risk assessments that formed the basis for the European Communities' approval of these products, the European Communities claims that these risk assessments can serve as the basis both for the original Community consent and for the member State bans. However, in these circumstances, the risk assessments in question cannot serve this dual function. The publicly available scientific opinions do not equivocate in their conclusions, nor do they present diverging views of the potential risks associated with these products. To the contrary, they clearly and unambiguously find that there is no evidence to indicate that the products in question pose a threat to human health or the environment.

4.634 The European Communities then states that, "[f]urthermore, the member States have made their own assessments and further risk assessments *may be* forthcoming." However, for the most part, the European Communities has failed to submit any documentary evidence of either the member State "assessments" or "further risk assessments" in relation to the five safeguard measures challenged by Canada in this proceeding until requested to do so by the Panel. A review of the additional information submitted by the European Communities in this regard demonstrates that the safeguard measures do not even come close to meeting the standard established by WTO jurisprudence for meeting the requirements of Article 5.1, and, by implication, the requirements in Article 2.2 that SPS measures must be based on scientific principles, and not be maintained without sufficient scientific evidence.

(d) The EC member State national measures violate the *TBT Agreement*

4.635 The European Communities' arguments that the safeguard measures do not violate the *TBT Agreement* are excessively narrow and reflect a jurisprudentially untenable conception of the scope of the definition of a "technical regulation", and the ambit of the obligations set out in Articles 2.1, 2.2 and 2.9. To the extent that the EC member State measures are based on ostensible

risks that are not covered by the *SPS Agreement*, the measures are technical regulations, and are therefore subject to the *TBT Agreement*.

(i) The EC member State national measures are "technical regulations"

4.636 The European Communities' assertion that individual decisions taken pursuant to the European Communities' legislative instruments – referred to by the European Communities as "administrative acts" – "are not themselves technical regulations", is bereft of any textual or jurisprudential support. The only part of the text that the European Communities cites – the phrase "applicable administrative provisions" – is not particularly instructive; the absence of "applicable administrative provisions" does not, by itself, signify that a particular measure is not a technical regulation. The similarities between the measures at issue in this dispute and the measure at issue in *EC – Asbestos* support the conclusion that the safeguard measures are indeed "technical regulations" as interpreted by the Appellate Body in *EC – Asbestos* and *EC – Sardines*.

4.637 The safeguard measures meet all three criteria established by the Appellate Body to determine whether a particular measure falls within the definition of a "technical regulation". First, all of the safeguard measures either identify the specific products subject to the prohibitions, or are expressed in terms that render those products readily identifiable. Second, each safeguard measure proscribes oilseed/rape and corn possessing certain characteristics or genetic materials. This is similar to the proscription in *EC – Asbestos* of products – such as cement – containing the asbestos fibre. For these reasons, the European Communities' assertion that these measures do not prescribe or proscribe product characteristics is untenable. Third, compliance with the product characteristics set out in the safeguard measures is compulsory. The European Communities' argument that "[t]here is no way for the notified product to comply with the member State measure" misses the point. The issue is not whether the notified product can comply, but whether oilseed/rape or corn products can comply, in the same sense that, in *EC – Asbestos*, the issue is not whether asbestos cement can comply with the prohibition, but whether cement can comply.

(ii) The measures violate Article 2.1

4.638 Canada rebutted the arguments made in the European Communities' First Written Submission in Canada's answer to Panel's Question 69.

(iii) The measures violate Article 2.2

4.639 While Canada would agree with the rather obvious statement that whether a particular measure fulfils its objective depends on what that objective is, Canada does not agree with the European Communities' implied argument that the safeguard measures are necessary. Canada notes that the European Communities' argument must be implied because nowhere does the European Communities explicitly argue – nor does it provide any evidence – that the safeguard measures actually fulfil a legitimate objective; the European Communities does not even indicate what level(s) of acceptable risk the "relevant legislators" in the respective EC member States are applying.

4.640 In the light of the objectives of the safeguard measures – in so far as those objectives can reasonably be discerned from the measures themselves and the European Communities' legislation relating to the assessment and approval of biotech products – and in the light of the scientific and other evidence, Canada has demonstrated that the measures in question do not meet the requirements of Article 2.2 of the *TBT Agreement*. The European Communities has not presented any arguments with respect to the specific safeguard measures that counter Canada's *prima facie* case. The additional information relating to the safeguard measures finally provided by the European Communities at the

request of the Panel only strengthens Canada's legal position that those measures are more trade restrictive than necessary.

(iv) The measures violate Article 2.9

4.641 The European Communities does not contest the substance of Canada's arguments with respect to the inconsistency of the safeguard measures with Article 2.9, confining itself to making additional arguments for why the safeguard measures are not technical regulations. To illustrate why these arguments are without merit, the Panel need not look any further than the measure in issue in *EC –Sardines*. The measure in that case, Regulation 2136/89, a measure that the European Communities conceded is a technical regulation, applies to a single product: preserved sardines. Clearly, therefore, whether a measure applies to a single product or a multiplicity of them is not determinative of whether that measure is a technical regulation or not. It also undermines the European Communities' contention that a measure must be of a "general nature" in order to qualify as a technical regulation.

O. SECOND WRITTEN SUBMISSION OF ARGENTINA

1. Arguments

(a) The *de facto* moratorium

(i) Introduction – The existence of a de facto moratorium

4.642 In this stage of the proceedings, Argentina will argue that the European Communities has not refuted any of the arguments that the complaining parties put forward in this dispute. The European Communities' attitude towards our arguments consists, for instance, in dogmatic statements to the effect that there simply is no *de facto* moratorium nor any suspension of the treatment of specific applications for approval. Moreover, the European Communities affirms that, even assuming that there were such a measure, it would not be a challengeable measure under the WTO Agreement. Nonetheless, the European Communities simply declares that there is no measure at all, without refuting any of the arguments concerning its existence and inconsistency developed by the complaining parties.

4.643 The European Communities has indicated that events occurring after the establishment of a panel should be taken into account because the challenged measure may have ceased to exist, thus implicitly admitting the existence of a *de facto* moratorium, at least before the establishment of this Panel.

4.644 The European Communities also asserts that the *SPS Agreement* would not apply to this dispute, because, as the European Communities understands the *SPS Agreement* , the issues relating to agricultural biotech products go beyond the scope of the *SPS Agreement*. Despite this, the European Communities does indeed admit that the agricultural biotech products are partially covered by the *SPS Agreement*. According to Argentina, the *SPS Agreement* **is** the Agreement to be applied, since it refers to protection against certain risks and not against certain products.

4.645 In addition, the European Communities considers that there is legislation relevant to this dispute outside the WTO rules, and that this should be taken into account by the Panel in settling this case. In any event, Argentina considers that the "extra-WTO" legislation invoked by the European Communities does not relieve the European Communities of its obligation to have a scientific backing for its measures.

(ii) The de facto moratorium measure

4.646 The existence of a *de facto* moratorium measure has been amply demonstrated, and the European Communities has not refuted the evidence submitted, but rather tried either to reinterpret or deny it.

4.647 The *de facto* moratorium has the following characteristics: (i) it has never been set forth in the form of positive legislation; (ii) it has prevented the approval of any new agricultural biotech product in the European Communities since 1998, through the systematic suspension of proceedings and the failure to consider individual applications for authorization or approval of agricultural biotech products; (iii) it has led to a systematic and unjustified delay in the time-frames set forth in the European Communities' legislation, so that proceedings are never concluded; and (iv) it entails discrimination against agricultural biotech products.

4.648 The existence of a *de facto* moratorium is obvious because there have been neither approvals nor rejections of applications for agricultural biotech products in the European Communities since 1998, despite the fact that several applications have received a favourable scientific opinion from the European Communities' scientific committees.

4.649 Moreover, it is relevant that the existence of a *de facto* moratorium has been acknowledged by senior EC officials with direct responsibility for the matters considered in this dispute. Furthermore, at the EC member State level the existence of a *de facto* moratorium continued to be acknowledged even as late as June 2004.

4.650 More recently, at the time of the curiously opportune Bt11 maize approval, reference was made in the official document to the existence of a *de facto* moratorium, which states that the Bt11 maize approval "*would* bring to an end the *current* moratorium on genetically modified food and feed in Europe" (italics added). The document not only rejects the European Communities' argument regarding the non-existence of a *de facto* moratorium but also the argument regarding "mootness". The European Communities' statement on "mootness" also contradicts the WTO jurisprudence concerning Article 19.1 of the DSU.

4.651 The European Communities tries to play down the statements of its own senior officials by arguing that they are not binding on the European Communities. In this respect, the European Communities quotes jurisprudence relating to "casual statements". Nevertheless, it does not explain how the statements of senior EC officials with direct competence in the matter can constitute "casual statements".

4.652 Furthermore, with regard to the European Communities' statement that *"it may constitute additional evidence that the Member in question applies that measure in a specific way"*, if the European Communities is referring to the recent decision on Bt11 maize, Argentina would point out that this decision relates to only a single product and does not end the existence of the *de facto* moratorium. This approval may have occurred precisely because of the establishment of the Panel and should not be regarded as the normal way in which the European Communities was conducting its approval procedures.

4.653 The European Communities also states that there have been approvals under Regulation 258/97 after 1998. According to the European Communities, this shows that the proceedings were not suspended. Nevertheless, Argentina would like to make it clear that these "approvals" mentioned by the European Communities are not true approvals but only notifications under the simplified procedure of Regulation 258/97.

4.654 Regarding the argument that the complaining parties have failed to identify any instrument or text on the basis of which the moratorium was established, Argentina has already explained in its first written submission that the moratorium was not set forth in the form of positive legislation. The measures referred to in Annex A:1 to the *SPS Agreement* are not the only sanitary or phytosanitary measures covered by that Agreement. The European Communities also argues that, in any case, a measure not set forth in the form of positive legislation could not be questioned in the WTO. On the contrary, as described in Argentina's submission, GATT/WTO jurisprudence has consistently taken a broad approach to the concept of "measure". In fact, the tendency has always been to extend this concept in such a way that Members' obligations cannot be circumvented.

(iii) Not simply a delay – Disregard of scientific evidence

4.655 In these proceedings, the European Communities is trying to cut short the period which began in 1998, thereby denying the existence of a *de facto* moratorium and turning all into a mere question of delay. Argentina does not agree with the European Communties' claim that any delay would have to end with the application of Directive 2001/18. This Directive entered into force in October 2002, and no approvals were issued afterwards despite the scientific evidence at hand.

4.656 The European Communities keeps trying to make out that the clock should be put back to zero from that moment, regardless of the fact that no approvals were given and it stalled on all applications by claiming that more stringent legislation was necessary, namely, on traceability and labelling. The same applies to the European Communities' response to the Panel's Question 36, in which it states that *"the re-submission represents the starting date for the reasonable period of time needed to examine the new information and to conduct a risk assessment of the newly identified issues"*. Setting the clock back to zero with Directive 2001/18 would imply disregarding the whole period that had elapsed since the initial submissions of the applications, including the moment when the positive scientific opinions were issued.

4.657 In its response to the Panel's Question 37, the European Communities is again trying to reduce the claim to a simple question of delays. Argentina strongly objects to this "reductionist" view. Argentina relies heavily on the scientific evidence on which any SPS measure must be based, and this substantive requirement goes far beyond the simple question of undue delay. Both the *de facto* moratorium and the "suspension and failure to consider" must meet substantive requirements, i.e. the need for scientific evidence, and thus be consistent with Articles 5.1, 2.2, 5.5, 2.3 and 5.6 of the *SPS Agreement*.

(iv) The European Communities implements and maintains a de facto moratorium

4.658 As Argentina has already pointed out, the European Communities has constantly made the adoption of more stringent legislation a precondition for lifting the moratorium. Nevertheless, the European Communities has systematically imposed additional requirements with the result that proceedings could never be completed. As soon as they had met one set of requirements, applicants were being asked to meet another. In fact, the European Communities stopped approving or rejecting applications as from 1998 because it deemed that its legislation – at that time Directive 90/220 and Regulation 258/97 – was inadequate. As an immediate consequence, on 4 September 1998 the European Communities began the so-called "Inter-Service Consultation".

4.659 The European Communities keeps on denying the existence of a *de facto* moratorium or a suspension of proceedings. According to the European Communities, because of the legislative insufficiency, a transitional mechanism – the so-called "interim approach" – was established, to facilitate the move towards a new regime.

4.660 This was the context in which the European Communities began the legislative procedure that ended with the adoption of Directive 2001/18. However, before Directive 2001/18 entered into force in October 2002, the European Communities again argued the need for more appropriate legislation. This prompted the beginning of the discussion on traceability and labelling, so there have been no approvals – or even rejections – of agricultural biotech products under Directive 2001/18 either. In December 2003, a new "Inter-Service Consultation" phase was initiated.

4.661 Argentina will now address these issues and their importance in agricultural biotech product approval proceedings, thereby demonstrating how the lack of approvals since 1998 was deliberately decided upon and maintained by the European Communities.

a.- The "Inter-Service Consultation" phase

4.662 From the information on the CD ROMs provided by the European Communities it is clear that the European Communities and/or its member States tried to refute or ignore the positive scientific opinions of its scientific committees, in order to stall the approval or marketing of agricultural biotech products. Furthermore, the information submitted on the above-mentioned CD ROMs gives us a clear picture of the relevant procedural stages for each agricultural biotech product. There are stages with no legal basis in the approval procedures but with political relevance as a means of stalling the procedure. This shows that the European Communities was treating agricultural biotech products "in baskets".

4.663 The "Inter-Service Consultation phase" effectively prevented all the applications – with positive scientific opinions in 1998 – from moving forward. In short, all the applications with positive scientific opinions from year 1998 were stalled in the "Inter-Service Consultation phase", with no exception. A first group of products (Falcon GS40 Oilseed rape, MS8xRF3 Oilseed rape, and A5/15 Fodder beet) was placed in a common "basket" in September 1998 and prevented from reaching the Regulatory Committee voting stage until June and October 1999, when they were not even voted on. The remaining two products (Bt 531 cotton and RRC 1445 cotton) did go to a vote but due to the lack of the required majority they were put in a second "basket" in May 1999. The two "baskets" were effectively stalled in the proceedings until the applications had to be resubmitted under Directive 2001/18 in January 2003.

4.664 In its response to the Panel's Question 94, the European Communities describes how "Interservice Consultation" might work. Argentina must conclude that this "Interservice Consultation" stage is further evidence of both a *de facto* moratorium and of the "suspension and failure to consider", specifically with respect to Bt-531 cotton and RRC 1445 cotton.

b.- The "Common Position" and the declaration by various member States

4.665 As has been proved, in 1998 the procedures for approvals and rejections of applications were stopped because the European Communities' legislation was considered inappropriate. In this context, in June 1999, the EU Council of Environmental Ministers drew up a document called the "Common Position" for the reform of Directive 90/220. This document stated that there would be no approvals until there was new legislation. The Declaration by Denmark, Greece, France, Italy and Luxembourg stated their intention of not allowing more biotech approvals. This position was reiterated in July 2000 during an informal Environment Council meeting in Paris.

4.666 In Argentina's view, the "Common Position" reveals the European Communities' intention not to approve any more agricultural biotech products. This element of will and intent shows that the *de facto* moratorium is not merely the sum of simple delays in the approval proceedings.

4.667 In September 1998 and May 1999, the European Communities began to stop approving agricultural biotech products by means of the "Inter-Service Consultation" phase. Shortly after that, in June 1999, came the "Common Position" and the Declaration of the five member States, arguing the need for reform of the approval legislation. At that point, the approval procedures were all stopped and the European Communities had entered a "discussion phase". Some member States – France, Belgium, Denmark, Greece and Italy – asked for additional requirements before the approval proceedings were restarted, this time calling for an environmental liability scheme. This regime had also been recognized within the European Communities as capable of continuing the *de facto* moratorium.

c.- Regarding the "Interim approach"

4.668 The European Communities' consideration of a change in the legislation created uncertainty about the approvals. As a consequence, several applicants offered to fulfil the requirements contained in the "Common Position", since they had no other choice. After that, in July 2000, the Commission proposed the so-called "Interim approach". This came after a long period of time without approvals and was the result of the applicants' concerns – not of any initiative by the European Communities, as the European Communities would have the Panel believe.

4.669 During July 2000, the Commission considered several options regarding the approval of agricultural biotech products. The options were: (a) the application of Directive 90/220 as it stood at that date; (b) waiting until the member States internalized Directive 90/200/EEC; and (c) a proactive position to re-launch the approval system. The European Communities chose the option apparently aimed at re-launching the approval procedure – "Interim approach" – which consisted in anticipating the stricter requirements of the future Directive 2001/18, specially those relating to monitoring, labelling and traceability. In this context, the concerns manifested by the European Communities and by the member States referred to labelling and traceability, and these issues were made a *conditio sine qua non* for the approval of agricultural biotech products. Under the "Interim approach" there were neither approvals nor rejections. Moreover, the entry into force of Directive 2001/18 brought the "Interim approach" stage to a close. To sum up, the "Interim approach" became just another manifestation of the *de facto* moratorium.

d.- Further applications receive positive scientific opinions, before the entry into force of Directive 2001/18

4.670 While all the applications with a positive scientific opinion dated 1998 were stalled, new applications were in position to be approved thanks to the positive opinion of the scientific committees. Both Phoe6/Ac Oilseed rape and Bt11 maize received a positive opinion on 30 November 2000 and were to be resubmitted under Directive 2001/18. Thus, both applications were stalled for two years. The same can be argued with reference to the potato, though within a shorter time frame since the positive scientific opinion was issued in July 2002.

4.671 In February 2001, six member States – Denmark, France, Greece, Italy, Luxembourg and Austria – reaffirmed their commitment to suspending approvals, on the grounds that the new procedures were inadequate.

4.672 By the end of October 2001, the majority of member States essentially agreed that the moratorium should not be lifted until the full traceability and labelling provisions had entered into force. At an informal meeting of the Environment Council, eight member States – France, Austria, Finland, Luxembourg, Denmark, Italy, the Netherlands, and Sweden – effectively rejected the Commission's plan to consider new authorizations, by demanding that the new regulations be in force

first. At that time, the Commission estimated that it would be an additional two years before any traceability and labelling requirements could be enacted. In December 2001, Belgium declared once again that the *de facto* moratorium would have to be maintained until there was proper legislation on traceability and labelling.

4.673 Consequently, the European Communities was clearly announcing its intention to maintain the *de facto* moratorium, even if Directive 2001/18 entered into force. This refutes the European Communities' claim that any delays should have ended with the entry into force of Directive 2001/18.

e.- Claims concerning the review of Directive 90/220

4.674 With respect to the European Communities' excuses for repealing Directive 90/220, these have basically consisted in the following: "new scientific understandings", the lack of harmonized criteria on the risk assessment to be performed, and the lack of post-marketing surveillance measures and labelling provisions.

4.675 The lack of harmonized criteria on risk assessment, had already been addressed in the "Report on the Review of Directive 90/220/EEC" in the context of the Commission's Communication on Biotechnology and the White Paper.[82] Notwithstanding what this document states, in its response to the Panel's Question 17 the European Communities asserts that there is currently no pre-eminence of the European Communities' scientific committees over the rest.

4.676 Argentina wishes to point out that in its response to the Panel's Question 17, the European Communities also makes reference to the jurisprudence of the European Court of Justice, which establishes the criteria used to determine whether a scientific opinion of the relevant scientific committee may be disregarded. The European Communities has not observed the rules laid down by its own Court of Justice. In fact, the European Communities has not provided any reason of a scientific nature for disregarding the opinions of its own scientific committees, which favoured the approval of agricultural biotech products.

4.677 Argentina considers this circumstance confirms the lack of scientific support for the application of the *de facto* moratorium and shows that what at a certain point was advanced as an argument for changing the European Communities' approval system has turned into an excuse inconsistent with WTO obligations.

4.678 Another argument used by the European Communities to justify the modification of Directive 90/220 is that relating to "post-market surveillance measures". Directive 90/220 already dealt with "post-marketing monitoring measures" in its Annex II (V), so we are again faced with an argument that is really just another excuse. With respect to the issue of the lack of labelling provisions, Directive 90/220 already had such a provision, which applicants could only evade on good scientific grounds.

f.- Entry into force of Directive 2001/18

4.679 In November 2003, once Directive 2001/18 had entered into in force, NK 603 maize received a positive scientific opinion, while GT73 oilseed rape received one in February 2004. By that time, this WTO Panel had been established.

[82] COM(96) 630 final, Brussels, 10 December 1996, "Report on the Review of Directive 90/220/EEC".

4.680 There were no approvals under Directive 2001/18 either. Moreover, at a meeting of Agriculture Ministers held in January 2003, several EC member States set conditions on the implementation of. Directive 2001/18, this time concerning the adoption of a labelling and traceability regime. Additionally, a co-existence regime was also requested.

4.681 In this connection, the EC authorities have indicated their intention to resort to the European Court of Justice because most member States have failed to internalise Directive 2001/18.

4.682 This is another fact which demonstrates the existence of a *de facto* moratorium.

g.- Regarding the traceability and labelling legislation

4.683 The need for a new traceability and labelling regime was specifically invoked in the case of Regulation 258/97. In this respect, the European Communities pointed out in its response to the Panel's Question 91 that the aforementioned Regulation was appropriate to matters relating to "risk assessment" but that "it became clear in 1999 that there would have to be new legislation addressing some issues such as labelling and traceability, and also the development and validation of detection methods. These issues have been addressed through Regulations 1830/2003 (labelling and traceability) and 1829/2003 (food and feed)".

4.684 In this case, too, the European Communities' argument has become an excuse. In fact, Regulation 258/97 does contain provisions concerning "labelling".

4.685 With respect to "traceability" and "detection methods", the European Communities has failed to identify the existence of a risk as prescribed by the Codex Principles for the Risk Analysis of Food Derived from Modern Biotechnology. Thus, the European Communities' claims regarding traceability and detection methods are in fact excuses to justify the *de facto* moratorium.

h.- Regarding the European Communities' arguments based on the Cartagena Protocol and the so-called "precautionary principle"

4.686 The European Communities argues the relevance of an "extra-WTO" instrument and of the so-called "precautionary principle" for dealing with the issues raised in this case.

4.687 According to Article 3.2 of the DSU, as interpreted by the Appellate Body, any treaty interpreter must resort to the Vienna Convention on the Law of Treaties in order to interpret the covered agreements. In this case, with respect to the "extra-WTO" rules invoked by the European Communities, we need to resort to Article 31 of the Vienna Convention.

4.688 The rules referred to by the European Communities are clearly not an agreement "relating to the treaty which was made between all the parties in connection with the conclusion of the treaty" – Article 31.2 (a). Nor are they an "instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty" – Article 31.2 (b). Clearly, the rules cited by the European Communities are not a "subsequent agreement between the parties regarding the interpretation of the treaty or the applications of its provisions" – Article 31.3(a). Nor can the Cartagena Protocol be regarded as "any relevant rule of international law applicable in the relations between the parties" – Article 31.3(c), since the European Communities is the only party in this WTO dispute bound by the provisions of the Protocol.

4.689 The European Communities also refers to the so-called "precautionary principle". It should be pointed out that the Appellate Body has addressed the status of this so-called "principle" in *EC-Hormones*.

4.690 Finally, the Cartagena Protocol states, in one of its recitals:

> "Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements"

What it is relevant in this case is that the Cartagena Protocol does not allow the European Communities to circumvent its WTO obligations, and that the European Communities' arguments in this respect have been just another excuse to maintain the *de facto* moratorium, because the European Communities has also said that Directive 2001/18 would not be adopted until the conclusion of the Cartagena Protocol, to enable it to adapt its legislation to that Protocol.

4.691 It should be recalled that the Cartagena Protocol establishes the obligation to undertake a risk assessment. Comparing Annexes I and III to the Cartagena Protocol with Directive 90/220, we note a great consistency.

4.692 From the above it is clear that the European Communities' arguments are, once again, mere excuses.

(v) The de facto moratorium is inconsistent with Article 10.1 of the SPS Agreement

4.693 As a developing country, Argentina must again stress the relevance of the SPS Article 10 provisions as they establish special and differential treatment for developing country Members.

4.694 Argentina would like to comment on the European Communities' statement to the effect that "The European Communities does not doubt the importance of these provisions and can assure Argentina that it bears them in mind when developing and applying its legislation, including, where relevant, its GMO legislation". First of all, Argentina welcomes that the European Communities recognizes the importance of these provisions. Nevertheless, we do not agree with the rest of the statement, especially the words "*where relevant*". Argentina must again point out that Article 10 is mandatory for WTO Members.

4.695 Argentina reiterates that the European Communities has failed to present any proof that it took into account the special needs of developing country Members when drafting and applying its legislation relating to agricultural biotech products.

4.696 Furthermore, Argentina disagrees with the European Communities' characterization that "Argentina's argument seem to come to nothing more than saying that since the European Communities has violated other provisions of the agreements and this affects Argentina, a developing country, it has consequently also failed to comply with its obligations of special and differential treatment towards developing countries". The European Communities is wrong in claiming that Argentina's argument is based on an interpretation of a consequential obligation. Argentina has argued that the European Communities' adoption of the *de facto* moratorium omitted all consideration of the obligations of developed countries arising out of Article 10.1 of the *SPS Agreement*, and specifically the obligation to take account of the special needs of developing country Members. Furthermore, even taking into account the EC legislation itself, a reading of the main provisions on the subject – Directives 90/220, 2001/18 and Regulation 257/98 – reveals no reference to developing

country Members' biotech products, still less any reference to those countries' special needs being taken into account.

4.697 Argentina reiterates that the *de facto* moratorium applied by the European Communities since 1998 has had the effect of closing the EC market to agricultural biotech products not approved before that date. The trade flows or imports to which the European Communities appears to refer cannot actually include any new post-1998 agricultural biotech products since no product has been approved – or rejected – because of the way in which the *de facto* moratorium has been operating.

4.698 Neither has the European Communities denied Argentina's claim that the lack of consideration of the special needs of developing countries is aggravated in the case of the European Communities because it is not just a national market but a market that now has 25 member States. In addition, the last ten States to join the European Communities have had to accept the *"acquis communautaire"*, which includes the *de facto* moratorium.

4.699 Argentina thus reiterates its request for the Panel to find that the European Communities is violating Article 10.1 of the *SPS Agreement*.

(b) The "suspension of processing and failure to consider individual applications for specific products of particular interest to Argentina"

(i) General comments

4.700 As previously stated, since the *de facto* moratorium affects all applications, these relevant additional stages also apply to the products of interest of Argentina, namely, Bt-531 cotton, RRC 1445 cotton, NK 603 maize, GA 21 maize and soy lines A2704-12 and A5547-127.

4.701 On the other hand, having examined the information finally submitted by the European Communities in the CD ROMs, Argentina finds that this information does not match the positive scientific opinions from the European Communities' scientific committees. First of all, most of the information provided by the European Communities is political rather than scientific in nature. Secondly, most of the documents listed by the European Communities are dated before the issuance of the positive scientific opinions. Accordingly, Argentina believes that the scientific committees were aware of all these documents and issued a positive opinion anyway. Furthermore, as only observations published in indexed scientific journals with peer review procedures should be considered in the analysis, opinions without this basis are not to be taken into account.

4.702 In any event, as regards specific comments on issues Argentina considers to be relevant from a scientific point of view, we enclose comments confirming that the additional information which the European Communities kept talking about, which the European Communities never submitted until the Panel and the Parties requested it in the First Substantive Meeting, which it provided without proper translations thereby delaying the procedures, and on which the European Communities said it had based its measures on the specific products of interest to Argentina, nevertheless does not refute the positive scientific opinions issued by the European Communities' scientific committees which favour the approval of all these products.

4.703 This having been said, we will now deal with the applications individually.

(ii) Specific products

a.- Bt 531 cotton and RRC 1445 cotton

4.704 The European Communities has acknowledged that the application for approval of both cotton types was stalled in the proceedings: these products obtained a positive opinion from the European Communities' Scientific Committee on 14 July 1998 and were submitted to the Regulatory Committee, where there was no qualified majority, in February 1999. The European Communities admitted this, but it also acknowledged that there were certain stages within the proceedings with no legal basis that were capable of stalling the proceedings: specifically, the European Communities admits that, after the positive scientific opinion of 14 July 1998, on 4 September 1998 the so-called "Inter-Service Consultation" phase began. In February 1999, in the absence of a qualified majority, the Regulatory Committee had to submit, without delay, a draft measure to the Council. Instead of that, the so-called "Inter-Service Consultation" phase took place again – 7 May 1999 – stalling the procedure. The applications had to be resubmitted under Directive 2001/18 in January 2003.

Comments on the information provided in the CD ROMs

4.705 In Argentina's view, the information provided by the European Communities does not refute the decisive, positive scientific opinions dated 14 July 1998.

4.706 Regarding Bt-531 cotton under Directive 90/220, the documentation provided by the European Communities is the following: the objections from Germany (February 1998); the outcome of the written procedure (April 1999); the statement by Austria; Denmark's position; the Opinion of the Commission du Génie Biomoléculaire (January 1999); the letter by the Commissie Genetische Modificatie (December 1998); the statement of the Swedish Board of Agriculture (February 1998); the letter to the Commission from Swedish Board of Agriculture (February 1998); the response to the European Communities by the United Kingdom (February 1998 and February 1999). These documents are either of a non-scientific nature or pre-date the issuance of the positive scientific opinion by the EC Scientific Committee in July 1997 or do favour the approval of Bt-531 cotton or are specifically refuted by the scientific arguments submitted by Argentina.

4.707 Regarding RRC 1445 cotton under Directive 90/220, the documentation provided by the European Communities is the following: the outcome of the written procedure (February 1998); the statement by Austria; Denmark's statement; the objections from France (February 1998); the Opinion of the Commission du Génie Biomoléculaire (January 1999); the letter by the Commissie Genetische Modificatie (December 1998); the excerpt from the minutes of the ScP meeting of COGEM (January 1998); the statement by Swedish Board of Agriculture (February 1998); and the response of the United Kingdom. These documents are either of a non-scientific nature or pre-date the issuance of the positive scientific opinion by the EC Scientific Committee in July 1997 or do favour the approval of RRC 1445 cotton or are specifically refuted by the scientific arguments submitted by Argentina.

Rebuttal of European Communities' responses to the Panel

4.708 The European Communities states in its response to the Panel's questions that "the internal procedures for the preparation of a Commission proposal for decision were ongoing"; referring to paragraphs 225 (Bt-531 cotton) and 232 (RRC 1445 cotton). Argentina considers that: (a) both specific products had obtained a positive scientific opinion in July 1998; (b) the European Communities' comment relates to the period after the positive scientific opinions had been issued; and (c) that period was followed by the "Common Position" when applicants were asked to prepare

for the future legislation – Directive 2001/18. This being the case, Argentina doubts that the internal procedures were ongoing, since so many additional requirements were constantly introduced.

4.709 Furthermore, the entry into force of Directive 2001/18 did not change the fact that the applications were not ongoing, since both Bt-531 cotton and RRC 1445 cotton were stalled in their respective procedures.

4.710 In its response to the questions put by the Panel, the European Communities describes how "Interservice Consultation" might work. Argentina considers that this "Interservice Consultation" stage – dealing with informal steps, seeking opinions from other areas on a text to be proposed, and capable of being repeated for a second time if needed – is proof of "suspension", specifically with respect to Bt-531 cotton and RRC 1445 cotton.

b.- NK 603 maize

4.711 This procedure was started in the year 2000 and received a positive scientific opinion from the scientific committee in November 2003. Despite this, shortly afterwards, on 8 December 2003, the European Communities once again started an "Inter-Service Consultation".

4.712 Argentina recalls that the "Inter-Service Consultation" phase was used to stall the procedures for Bt-531 cotton and RRC 1445 cotton under Directive 90/220, until the applications had to be resubmitted under Directive 2001/18. In the case of NK-603 maize, with a positive scientific opinion "already" issued under Directive 2001/18, the European Communities recommenced this procedural stage, thereby declaring once again its political intention of not allowing the approval proceeding to be completed: in fact, on 18 February 2004, there was no qualified majority within the Regulatory Committee.

Comments on the information provided on the CD ROMs

4.713 Regarding NK 603 maize under Directive 2001/18, with reference to the information provided by the European Communities on the CD ROMs, Argentina considers that none of these documents match the positive scientific opinion of the scientific committees dated November 2003. Although the European Communities submits information of a scientific nature, almost all of it pre-dates the positive scientific opinion: the response by Austria to the European Communities (August 2003); the additional comments of the SBB (April 2003); the SBB evaluation (no date); the SBB evaluation of the additional information (August 2003); the Opinion of AFSSA; the Opinion of the Commission du Génie Biomoléculaire; and the letters by AFSSA (March 2003, March 2003 and July 2003, respectively); the statement by the Swedish Board of Agriculture (February 2003); the ACRE advice (March 2003 and August 2003); the Annex B of ACRE advice (March 2003). The Scientific Committee must have taken all this information into account when it issued its positive opinion.

4.714 Regarding NK 603 maize under Regulation 258/97, though some of the information provided may be of a scientific nature, it pre-dates the positive scientific opinion of November 2003: the objection by Austria (no date); the SBB letter (February 2003); the SBB evaluation (no date); the Opinion by AFSSA (February 2003). The Scientific Committee must have taken all this information into account when it issued its positive opinion. The only remaining document – dated April 2004 – explains the minutes of the meeting within the Regulatory Committee and does not refute the positive scientific opinion.

c.- GA 21 maize

4.715 Although the application for GA 21 maize was withdrawn in September 2003, Argentina regards its withdrawal as a perfect illustration of the effect of the *de facto* moratorium and the "suspension or failure to consider". As already stated, GA 21 maize received a positive scientific assessment both under Directive 90/220– September 2000 – and under Regulation 258/97 – February 2002. Five years and two months had elapsed under Directive 90/220 and Directive 2001/18, and three years and eight months had elapsed under Regulation 258/97, before the applications were withdrawn.

Comments on the information provided on the CD ROMs

4.716 The European Communities only submits information regarding the procedure under Regulation 258/97. None of this information refutes the positive scientific opinion by the Scientific Committee of February 2002, since it is all dated earlier: the position of Austria (no date); the SBB report (September 1998); the letter and paper from the Danish Ministry for AGRI (April 2000); the letter from the National Food Administration (April 2000); the letter from the United Kingdom to the Commission (April 2000). The scientific committee must have taken all this information into account when it issued its positive opinion.

(c) "Undue delay"

4.717 Argentina reiterates that the European Communities has infringed its obligations under Article 8 and Annex C of the *SPS Agreement* in applying its control, inspection and approval procedures to the treatment of the various agricultural biotech product applications filed since 1998. Argentina will not repeat arguments already submitted, but feels it necessary to clarify and answer some of arguments contained in the European Communities' first written submission and oral statement.

4.718 Argentina completely agrees with the statement that: "The European Communities does not exclude that an omission or failure to act could be subject to the *SPS Agreement* (...)", and certainly Argentina also agrees that: "Whether a specific omission or failure to act constitutes a violation of the *SPS Agreement* depends on the nature of the obligation in question which is alleged to have been violated".

4.719 The European Communities argues that two conditions must be met for a determination of undue delay: firstly, the approval system must be a sanitary or phytosanitary measure within the meaning of Article 1 of the *SPS Agreement* and, secondly, the delay must be inconsistent with the corresponding obligations set out in the *SPS Agreement*. Argentina agrees with this EC explanation, and believes that both conditions are met. The European Communities itself, as well as the complaining parties, have accepted that the approval system set up under the relevant EC GMO legislation is "a procedure to check and ensure the fulfilment of sanitary or phytosanitary measures".

4.720 The EC legislation specifically contemplates time-frames for the different institutions involved in the complex and detailed procedure. The European Communities has not even tried to specify the reasons for its failure to consider, approve or reject products within the time-frames provided by its own legislation.

4.721 The Article 8 also requires all Members, "in the operation of control, inspection and approval procedures", to "ensure" the consistency of their procedures with the provisions of the *SPS Agreement*. Argentina reiterates its contention that the European Communities has not followed

the procedures envisaged in its legislation, and this has led to infringements of Article 8 and Annex C of the *SPS Agreement*.

4.722 Argentina stresses that the European Communities has not refuted the evidence with regard to undue delay, either generally or in particular, for each product of particular interest to Argentina.

4.723 Among the arguments put forward by the European Communities, one relates to force majeure, and this obviously cannot be applied to the present case; another expresses the idea "that delays are due to scientific considerations". Nevertheless, the basis of the scientific considerations is not identified in the European Communities' submissions with respect to any of the products of special interest to Argentina. The opinions of the scientific committees demonstrate precisely the opposite, since the majority of these committees issued their scientific opinions within the time limits foreseen by the legislation. Despite that, there was a lack of consideration or approval by the "non-scientific" institutions.

4.724 With respect to Annex C, paragraph 1(a), in order to verify and ensure how sanitary and phytosanitary measures are implemented, Argentina has compared the different treatments given to agricultural biotech products before and after 1998. The European Communities has failed to demonstrate that from 1998 onwards the proceedings to verify and ensure the implementation of sanitary and phytosanitary measures were begun and completed without delay, and, at the same time, in such a way as to result in a situation not less favourable for the imported agricultural biotech products.

4.725 With respect to Annex C, paragraph 1(b), Argentina rejects the European Communities' claim that "Argentina and the United States offer nothing beyond mere assertion that the European Communities has not done what it is required to do under the different obligations". In its First Written Submission, Argentina analyses Annex C, paragraph 1(b). Argentina rejects the European Communities' interpretation and reiterates the arguments proposed in its First Written Submission with reference to Annex C, paragraph 1(c). The procedures and information requirements are established within this legislative framework. A close scrutiny of the chronologies reveals the numerous occasions on which additional information was required from the applicant in connection with the products of special interest to Argentina. With regard to Annex C 1(e), Argentina again points out that paragraph 1(e) applies the term "reasonable and necessary" to the requirements for the control, inspection and approval of individual specimens of a product.

4.726 In this case, as previously explained, there is no basis for the European Communities' claims about the need to introduce changes in the control, inspection and approval procedures for agricultural biotech products. Argentina does not find it reasonable to ask for "additional" requirements, since these supposedly "additional" requirements were already envisaged in the former legislation and/or in the scientific committee opinions.

4.727 In conclusion, Argentina respectfully requests the Panel to find the European Communities' "undue delay" in each of the respective approval proceedings for agricultural biotech products of particular interest to Argentina to be inconsistent with Article 8 and with Annex C, paragraphs 1(a), 1(b), 1(c) and 1(e) of the *SPS Agreement*.

(d) Bans by various member States

4.728 Finally, with reference to the measures imposed by Germany, Austria, Italy and Luxembourg, Argentina first reaffirms what it stated in its First Written Submission. Moreover, since in its First

Oral Statement Argentina reserved the right to develop arguments relating to Article 5.7 of the *SPS Agreement*, we would also like to make the following observations.

(i) Article 5.7 as a defence for measures that would otherwise infringe Articles 2.2 and 5.1

4.729 Argentina does not accept the role that the European Communities proposes to attribute to Article 5.7, when it states that the complaining parties should have begun with an infringement of that Article before considering an infringement of Articles 5.1 and 2.2. Article 5.7 is a defence against the alleged infringement of, in this case, Articles 5.1 and 2.2, and is not to be invoked otherwise. The Appellate Body in *Japan – Agricultural Products II* has explicitly confirmed the character of Article 5.7 as an exception. It is up to the European Communities to invoke this defence, not up to the complaining parties to raise any infringement of Article 5.7.

4.730 With respect to the application of Articles 5.7 and 5.1, Argentina takes the following view of the European Communities' statement that Article 5.7 applies to "provisional measures": Article 5.7 is not applicable to any measure merely called or deemed to be "provisional" but rather establishes a first and fundamental requirement for any measure to be adopted provisionally; there has to be insufficient relevant scientific evidence.

4.731 This being said, Argentina maintains that as far as the member State measures are concerned the relevant scientific evidence was not insufficient, since there were specific scientific opinions by the EC committees first favouring the approval of these products and later rejecting the member State measures. Secondly, Argentina does not agree with the European Communities' affirmation that the phrase "as appropriate to the circumstances" in Article 5.1 would send the Panel back to Article 5.7. Therefore, we believe that Article 5.1 does apply in this case. Furthermore, we do not agree with the European Communities' statement that the risk assessment "carried out at the time when the original Community consent was given" can "serve, at least temporarily, as a basis both for the original Community consent, and for the member State provisional measures".

4.732 With regard to the relationship between Articles 5.7 and 2.2, Argentina would like to comment on the European Communities' assertion concerning the "demarcation line" between provisional measures under Article 5.7 and definitive measures under Article 2.2, which emphasizes the words "maintained" and "provisionally adopt" . We do not agree with this. The "demarcation line" should rather be based on whether there is or is not sufficient scientific evidence for the intended measure – Article 2.2 establishes basic rights and obligations, and in particular that "any" sanitary or phytosanitary measure must be based on scientific principles, and not on whether the measure is intended to be "definitive" or "provisional".

4.733 When a Member meets the four conditions of Article 5.7, this Member is entitled to adopt a measure under Article 5.7, but a failure to meet the first of these conditions will not cause an infringement of Article 5.7, but rather prevent the Member from "flipping out" of the general conditions of Article 2.2.

4.734 As indicated above, it is up to the European Communities to invoke Article 5.7 as a defence, and hence to bear the burden of proof. Argentina therefore considers that the member State bans infringe Article 5.1 and Article 2.2 and are not covered by the exception of Article 5.7 of the *SPS Agreement*.

4.735 Thus, there was a positive scientific opinion in favour of approving these products. Nevertheless, the member States may have considered this not to be sufficient and therefore adopted their own measures. Two of the four measures were not even meant to be provisional, although the

European Communities claims that they were meant to be: the Austrian and Luxembourg measures explicitly refer to "prohibitions". And the other two, despite referring to "suspensions" had not even been lifted as of June 2004.

4.736 We rebut the European Communities' claim that "the issue of fact is whether or not the member States are or are not provisional measures". Argentina considers that the issue of fact is whether the scientific evidence was or was not sufficient. We also strongly reject the European Communities' suggestion that "On the contrary, the complaining parties have actually asserted that the member State measures are provisional measures". Argentina has never asserted this.

(ii) Article 5.7, Article 5.5 and Article 5.6

4.737 Referring to the European Communities' response to the Panel's Question 19, Argentina once again points out that, Article 5.7 does not preclude the application of Article 5.5 of the *SPS Agreement*. Argentina considers that these articles relate to different obligations: whereas Article 5.7 relates to the amount of information needed to apply a measure and to the provisional character of that measure, Article 5.5 refers to distinctions in levels of protection which entail discrimination or disguised trade restrictions, and Article 5.6 concerns the degree of trade restriction resulting from the measure. On the same grounds, Argentina rebuts the European Communities' attempt to represent Article 5.7 as an article capable of excluding Articles 5.1, 5.5 and 5.6. We consider that Article 5.7 is not the pivotal article.

(iii) Article 5.7

4.738 With regard to the requirements of Article 5.7, we recall the WTO jurisprudence, according to which (1) the four requirements of Article 5.7 must be fulfilled in order to establish a valid provisional measure, and (2) should the first two requirements not be fulfilled, there is no need to analyse the other two, since resort to Article 5.7 cannot be justified if two of the requirements are not met. Indeed, the nonfulfilment of just one of the requirements precludes the invocation of Article 5.7 of the *SPS Agreement*.

4.739 With respect to the first requirement, the scientific evidence was not insufficient, since each product had received at least two positive scientific opinions, firstly in favour of approval and finally specifically rejecting the member States' attempt to introduce a "special safeguard". With respect to the second requirement, the member States did not base their measures on the "available pertinent information", since they disregarded the positive scientific opinions of the scientific committees. The evidence submitted by the European Communities in this case does not reflect these positive opinions, either because it is non-scientific or because it pre-dates the respective scientific opinion – which rejected it. With regard to the third requirement, the member States did not seek to obtain the further information necessary for a more objective risk assessment, because the evidence provided in this case does not reflect the positive scientific opinions given by the scientific committees. With the fourth requirement, as already mentioned, the member States did not review their measures: on the one hand, Austria and Luxembourg established prohibitions which they did not even envisage lifting. On the other, Germany and Italy formally established "suspensions" but never lifted or reviewed them.

(iv) No invocation regarding the de facto moratorium or the "suspension of processing and failure to consider specific applications of products of interest of Argentina"

4.740 Argentina recalls that the European Communities has invoked Article 5.7 only in relation to the member State measures. Were the Panel to find that the *de facto* moratorium and the suspension

and failure to consider are inconsistent with Article 5.1 or Article 2.2, Article 5.7 would not apply as a defence.

P. SECOND WRITTEN SUBMISSION OF THE EUROPEAN COMMUNITIES

1. Horizontal issues

(a) Burden of proof

4.741 A correct allocation of the burden of proof is fundamental for this dispute. The parties disagree on a number of factual and legal issues which are at the core of this dispute, but complaining parties seek to ignore. They seek a Panel finding based on the assumption that the risks posed by all the relevant GMOs are clear, and that the only reason why they have not all been approved is the "moratorium." Complaining parties do not engage in any meaningful product-by-product discussion. That does not mean that the European Communities has the burden of proof. Complaining parties must prove for each application that the absence of risk has been established and that no useful further investigation into the risks is underway. The case-law on burden of proof is consistent: the party invoking the existence of a certain situation bears the burden of proving it; to shift the burden, a *prima facie* case must be established. The establishment of the *prima facie* case cannot be reduced to mere assertion, without supporting evidence. The Panel must first verify if complaining parties have established a *prima facie* case in relation to each of their claims, before ascertaining whether the European Communities has refuted it.

(b) Risk assessment and the role of scientific opinions

(i) The meaning of "risk assessment" in the SPS Agreement

4.742 The term "risk assessment" in the *SPS Agreement* has to be understood in the broad sense of "risk analysis" as defined by the Codex Alimentarius and other international instruments. Risk assessment therefore encompasses three different aspects: (1) risk assessment in the narrow sense, i.e. as a "scientifically based process"; (2) risk management; and (3) risk communication. This conclusion follows from the definition of risk assessment given in paragraph 4 of Annex A. It also follows from paragraphs 2 and 3 of Article 5, which make it clear that in making an assessment of the risks, Members must take into account not only scientific but also economic and regulatory considerations. The list of factors to be taken into account is not exhaustive.

4.743 The United States and Canada seem to agree that at least some risk management considerations must be taken into consideration in an approval procedure. In particular, Canada takes the position that management considerations may only apply with regard to risks that are identified based on relevant scientific evidence. The European Communities disagrees. Particular risks can only be assessed and potentially identified in the risk assessment process on the basis of the available scientific information *at the time of the assessment*. Scientific knowledge may not be sufficient to clearly identify the risk. Moreover, risks may become known or relevant at a later stage. In this way the precautionary approach (or principle) becomes highly relevant. Prudent governments as risk managers and regulators are entitled to develop and apply appropriate safeguards to protect citizens and the environment. They are entitled to adopt risk management options, such as an appropriate general surveillance scheme, which are able to detect and identify any negative impact that was unforeseen or unidentified in the initial process of risk assessment. This approach is entirely consistent with international developments.

(ii) Risk assessment and the role of scientific opinions

4.744 Complaining parties generally seek to rely on the theory that the European Communities is bound to authorize GMOs for which European Communities' scientific committees have issued "favourable" scientific opinions. This position is flawed in a number of respects.

4.745 First, scientific opinions are only part of the risk assessment in a narrow sense, i.e. the scientifically based process of (a) hazard identification (b) hazard characterisation (c) exposure assessment and (d) risk characterisation. On the other hand, risk management and risk communication considerations are assessed by the regulator itself and not by those who deliver a scientific opinion (in contrast with the usual practices in North America). A complete risk assessment, within the meaning of the *SPS Agreement*, includes also these latter aspects.

4.746 Second, the scientific opinions by "EC committees" are not binding. There are several scientific committees with different mandates and at different levels in the European Communities. In case of scientific disagreement, the opinions of the European Communities' scientific committees do not overrule other scientific opinions, such as those issued by member States' scientific bodies. There is no obligation in SPS law – or indeed in any WTO law – for a regulatory power to effectively delegate to a single scientific committee only. This conclusion becomes particularly relevant in a federal or quasi-federal regulatory context.

4.747 Third, scientific opinions are limited in scope and, therefore, often do not conclude the risk assessment process, even in a narrow sense. The science on GMOs being in constant evolution, new risk considerations sometimes arise spontaneously and change the scope of the risk assessment, as in this case. The process of addressing risk/scientific issues, which are unresolved or new, may require the authorities to go back for a further assessment by an independent scientific body that had issued an earlier positive opinion, much later in the process of analysing a particular application.

(c) The *SPS Agreement*

(i) The scope of the SPS Agreement

4.748 The scope of the *SPS Agreement* is determined by Annex A.1, first paragraph. The list of risks or matters subject to the *SPS Agreement* is exhaustive, as it is clear from the text of Annex A.1, contrary to the more flexible approach taken with regard to the form of the measures subject to the agreement (Annex A.1, second paragraph, contains the word "includes", which is absent from the first paragraph).In determining the material scope of the *SPS Agreement*, it is necessary to rely on internationally accepted definitions of the terms in Annex A.1. On this issue, complaining parties are inconsistent among themselves, and individual complaining parties are internally inconsistent, as they rely on the definitions in other international instruments only when it suits their case. In any event, it is clear that the "common and ordinary" meaning approach advocated, in some instances, by complaining parties, to the exclusion of the international definitions, would not be sufficient. The common language definitions of SPS terms are often so vague and broad as to deprive of any meaning the categories and distinctions set out in Annex A.1. For instance, the definition proposed by the United States of the term "toxin" ("any substance which, when introduced into or absorbed by a living organism, destroys life or injures health") is capable of encompassing anything, from a chemical residue to a lead bullet.

4.749 There is a strong relationship between the *SPS Agreement* and the texts of specialised international organisations and bodies. Article 3 contains obligations on Members with regard to international standards, guidelines or recommendations. Some of the key terms in Annex A.1 are

themselves international standards (the Codex definition of contaminant is a "standard": Codex Standard 193, rev 1, 1995). Furthermore, Article 12(3) refers to the objective of securing from the relevant international organisations the best available scientific and technical advice for the administration of the *SPS Agreement*. This must include advice on the technical concepts that those organisations have developed and that were adopted by the drafters of the *SPS Agreement*.

4.750 In their attempt to stretch the scope of the *SPS Agreement*, complaining parties pay also little attention to the literal wording of Annex A.1, which carefully defines the specific circumstances in which the Agreement is to be applied. For instance, complaining parties continue with the careless assumption that it would be sufficient for them to establish that a measure concerns a "toxin" (or an "additive", or a "contaminant") for that measure to fall within the scope of the *SPS Agreement*. That is wrong as a matter of law. Annex A.1(b) refers to toxins "in foods, beverages and feedstuffs". Toxic characteristics of seeds or crops, or effects on non-target organisms, do not therefore fall within that provision, when the GMO does not fall within the concept of "food, beverage or feedstuff." Similarly, as regards the issue of antibiotic resistance, complaining parties disregard the fact that antibiotic resistance may be developed through ways other than the uptake of food or feed by humans or animals, so this issue could in any event not be apprehended solely under sub-paragraph (b) in so far as human health is concerned. Furthermore, complaining parties do not attempt to attribute a proper meaning to the terms "disease-causing" or "disease-carrying", ignoring the plain fact that the development of antibiotic resistance cannot be said to be a "disease" "caused" or "carried" by a GMO.

4.751 A measure can only fall within Annex A.1 if it is applied to protect human, animal or plant life or health. Therefore, the effects of the relevant GMO on non-living components in the environment, such as biogeochemistry, particularly carbon and nitrogen recycling through changes in soil decomposition of organic material, clearly fall outside the scope of the *SPS Agreement*. The same comment may be made with respect to micro-organisms or micro-flora which do not affect human, animal or plant life or health, but which are nevertheless part of the ecological equilibrium.

4.752 The negotiating history confirms that it was intended to have a precisely limited scope. Of particular note are the discussions that took place on whether environmental risks should be covered. Those that opposed this stressed that environmental risks were of a different nature and that rules designed for SPS measures would not necessarily be appropriate for environmental risks. This view ultimately prevailed, and consequently the *SPS Agreement* does not cover measures for the protection of the environment *as such* (or based on consumer concerns, moral grounds etc.)

(ii) Mixed acts

4.753 How to deal with measures that protect against the risks defined in the *SPS Agreement*, but that pursue also other legitimate objectives not covered by the *SPS Agreement*, is an important threshold issue. Nothing obliges Members to refrain from adopting single acts, incorporating two or more measures regulated by more than one WTO Agreement or provision. When a WTO Member adopts a single, indivisible act that pursues multiple legitimate objectives, some falling under the *SPS Agreement* and some falling under other WTO Agreements, that Member cannot be directed to withdraw or revise its measure unless it is found to be inconsistent with *all* relevant agreements.

4.754 In the case of a mixed act, the challenged act is not itself an SPS measure. It contains or includes an SPS measure. But it also contains or includes a TBT measure. To find that the TBT measure, because it is in the same act as an SPS measure, is itself transformed into an SPS measure, would be an error of reasoning and of law. Article 1.5 of the *TBT Agreement* does not change this conclusion. It is a jurisdictional conflict rule. The methods used to delimit the scopes of the Agreements are different. So a "technical regulation" could fall within the *SPS Agreement*. In that

case, Article 1.5 means that such a measure falls to be considered only under the *SPS Agreement*. This situation is different from the case in which a "technical regulation" pursues *not only* SPS objectives, but also *other* types of legitimate objectives.

(iii) Article 2 and Article 5.7 of the SPS Agreement

4.755 Article 2.2 contains an express cross-reference to Article 5.7. Article 5.7 is thereby incorporated by reference into the text of Article 2.2, which is entitled "Basic Rights and Obligations.". Thus, read in the context of Article 2, the text in Article 5.7 sets out basic rights and obligations, of equivalent status to the other basic rights and obligations set out in Article 2. The text of Article 2.2 shows that the drafters saw Article 5.7 as excluding the application of the substantive obligations in Article 2.2. The comma after the word "evidence" means that the words that follow exclude all the words up to the word "evidence." This is entirely logical. A concept of "necessity" is already referred to in Article 2.1 and is in any event built into the text of Article 5.7, because a Member may only act on the basis of available pertinent information, and only provisionally, in order to allow sufficient time for sufficient scientific evidence to be collected.

4.756 The relationship between the text of Article 2.2 and the text of Article 5.7 is therefore one of exclusion, not exception. Complaining parties disagree among themselves on this point, and their arguments are confused and unclear. *If it were true* that there is sufficient scientific evidence, the provisional measure would be inconsistent with Article 5.7, not fall to be assessed under Article 2.2. The exclusionary demarcation line between Articles 2.2 and 5.7 is based on whether or not the measure is provisional. The provisional nature of the measures must be motivated by the insufficiency of the scientific evidence, but an Article 5.7 measure is still provisional.

4.757 Provisional measures continue to be subject to the requirements of Article 2.3. They may not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members; and measures may not be applied in a manner that would constitute a disguised restriction on international trade.

(iv) Article 5.7 and the rest of Article 5 of the SPS Agreement

4.758 Once the text of Article 5.7 is considered in the appropriate context, its relationship with the other provisions of Article 5 becomes clearer. The fact that Article 5.7 is positioned after Articles 5.1 to 5.6 (and not after Article 5.1) also confirms its nature as a special regime applying specifically to provisional measures. Articles 5.5 and 5.6 would be difficult to apply if an acceptable level of risk still has to be established on the basis of a more objective assessment of risks.

4.759 Provisional measures are still subject to a full set of controls under the *SPS Agreement*. They must comply with the requirements of Article 5.7, as well as with Articles 2.1, 2.3 and 2.4. These provisions contain rules and obligations that are analogous to those set out in Articles 5.1 to 5.6, adapted appropriately to the provisional measures scenario. Thus, Articles 5.1 to 5.6 are irrelevant: provisional or temporary measures (whether the member State measures or the alleged temporary "standstill or moratoria") fall to be considered under Article 5.7; and delays are to be considered in accordance with Annex C. Even if Article 5.1 would be considered relevant, the words "as appropriate to the circumstances" enshrine an important degree of flexibility, whether in relation to the member State measures, or in relation to the alleged product specific delays. The obligation under Article 5.1 is only that measures be "based on" an assessment. This does not mean that the assessment itself necessarily automatically dictates the terms of the legislative measure to be adopted.

4.760 Complaining parties accept that under the *SPS Agreement* it is permissible for an EC member State to have a different level of protection compared to that applying elsewhere in the European Communities. Complaining parties are wrong to assert that, in the context of the safeguard measures, the member States are applying the same level of protection as at Community level. They are applying a level of protection that reflects their own particular circumstances. In the context of Articles 5.5 and 5.6, Members enjoy more flexibility in cases where they lack the elements to assess the nature or the extent of a risk. A comparison with other situations is difficult if each situation cannot be precisely defined or evaluated. In the context of Article 5.6, it is difficult to calibrate a measure if the extent of the risks or the availability or effectiveness of protection measures is unclear. In these circumstances, consistency with Articles 5.5 and 5.6 can only be considered taking into account the degree of flexibility present in those provisions.

(v) Article 5.7 of the SPS Agreement

4.761 Complaining parties assert that there is no relationship between the acceptable level of risk – or the analogous concept in the context of provisional measures – on the one hand, and the question of whether or not relevant scientific evidence is insufficient on the other hand. The European Communities does not agree. In the context of provisional measures, a full risk assessment has yet to be completed and the level of acceptable risk may yet to be finally determined by the legislator. However, the concept of sufficiency in Article 5.7 is relational, and must therefore refer to the matters of concern to the legislator. Members may not necessarily react identically with regard to potential risks and uncertainty. Depending on the specific circumstances prevailing in each country, scientific information may or may not be deemed sufficient to decide appropriate measures. A matter of concern for one legislator may not be of equal concern to other legislators because of climatic factors, eating habits, social (environmental) values, etc. There is no magic moment at which the available science become sufficient for *all purposes*. Rather, the actions of a legislator, whether definitive or provisional, in response to the available science, are a function of what that legislator is concerned about.

(vi) Article 2.3 of the SPS Agreement

4.762 Article 2.3 applies to measures, and is therefore irrelevant to any consideration of alleged delay. It refers to a situation in which identical or similar conditions prevail between Members, or between the territory of the importing Member and that of other Members. Complaining parties have not even alleged that identical or similar conditions prevail between their own territories and the territory of some other Member. Nor have they alleged that the European Communities discriminates between Members, including its own territory, in respect of its treatment of GMOs. The European Communities deals with GMOs in an even-handed way, without discrimination. Article 2.3 also states that measures should not be applied in a manner which would constitute a disguised restriction on international trade. The present case concerns the ongoing discussions within the European Communities about how to respond to the risks posed by GMOs, whatever their origin, any trade effects being entirely incidental. This is a basic right of the European Communities under the *SPS Agreement*.

(d) The *TBT Agreement*

4.763 Complaining parties assert that the Panel can resolve all the issues before it by reference only to the *SPS Agreement.* Only Canada and Argentina have invoked, in the alternative, several provisions of the *TBT Agreement*, but only in connection with the alleged product specific marketing delays and the member State measures. There is no inconsistency with the *TBT Agreement*.

(i) The meaning of the term "technical regulation"

4.764 The member State measures are not "technical regulations". The same applies to the alleged product specific delays. It is impossible to understand how an alleged delay – that is, silence or inaction – could lay down mandatory product characteristics. The observations of the European Communities in respect of Articles 2.1, 2.2, 2.9.1, 2.9.2 and 2.9.4 of the *TBT Agreement*, as regards the member State measures, apply *mutatis mutandis* as regards the alleged product specific delays.

(ii) Article 2.1 of the TBT Agreement – the issue of likeness

4.765 Neither the member State measures nor the alleged product specific delays are technical regulations. The Panel should reject the assertions made by Canada and by Argentina as regards the issue of "likeness". Under Article 2.1 of the *TBT Agreement*, "likeness" is properly understood as relating to products within the field of application of the technical regulation. Furthermore, GMOs are not like products to conventional products.

(iii) Article 2.2 of the TBT Agreement

4.766 The general EC GMO legislation might be a technical regulation but is not before this Panel. Complaining parties have not established that any actual *application* of the EC legislation – any delays or member State safeguard measures – is more trade restrictive than necessary. Complaining parties refer to the prohibition on marketing, pending authorization, but that is the very essence of the GMO legislation – not an application of it. The provisional absence of a final decision cannot be turned into an alleged measure.

4.767 There is no obligation to conduct a risk assessment under Article 2.2 of the *TBT Agreement*. In any event, the European Communities is currently in the process of assessing the risks in order to decide whether to authorize these products. The European Communities also contests the suggestion that Article 2.2 includes an obligation according to which the legitimate objective must actually be fulfilled. Whether or not the objective is actually fulfilled in fact is irrelevant, provided that the measure is capable of contributing to that objective. Opinions issued by the European Communities' scientific committees reflect questions posed at the time, and are themselves qualified. They may or may not be sufficient for the Commission or the Council, and may at the same time be insufficient for the member States.

(iv) Article 5 of the TBT Agreement – The meaning of "conformity assessment procedure"

4.768 The European Communities does not agree with the assumption that the EC GMO legislation constitutes a conformity assessment procedure within the meaning of Article 5 of the *TBT Agreement*. A conformity assessment procedure does not exist where there is room for the exercise of discretion, or the weighing of complex and to some extent conflicting considerations. It rather relates to the situation in which precise criteria have already been laid down, and it is simply a question of verifying whether or not a specific product meets those objective and precise criteria (such as weight, dimension, material composition, strength, electrical resistance, and so on).

4.769 In the light of the preceding observations, the European Communities does not agree that Canada and Argentina have demonstrated the relevance of Articles 5.1.1, 5.1.2, 5.2.1 and 5.2.2 of the *TBT Agreement*. Furthermore, there has been no "less favourable treatment" of GMO products, within the meaning of Article 5.1.1. Nor there has been any unnecessary obstacle to trade, within the meaning of Article 5.1.2, as the risks to the environment have a character of irreversibility that makes a stricter approach necessary than would be the case for reversible risks. Neither Canada nor

Argentina have discharged their burden of proving, with regard to the specific facts of each specific product application, any moment at which the European Communities has not acted "as expeditiously as possible", as required by Article 5.2.1. Argentina has made assertions concerning Article 5.2.2 which it has failed to substantiate with specific evidence.

(e) GATT 1994

4.770 If the *SPS Agreement* and the *TBT Agreement* are not applicable to the risks or "measures" contested by complaining parties, their claims will fall to be considered under the GATT 1994. The European Communities considers that Article XX of the GATT 1994 may in any event be relevant.

(f) WTO and other international agreements

4.771 The Panel must interpret the relevant rules of WTO law consistently with other rules of international law relevant to these proceedings, in accordanve with *US – Shrimp*. The 1992 Convention on Biological Diversity and its 2000 Biosafety Protocol "are relevant to this case", and that the provisions of *inter alia* the Codex Alimentarius Commission and other equivalent standards are relevant to these proceedings as *inter alia* "international standards, guidelines and recommendations" within the meaning of both the *SPS Agreement* and the *TBT Agreement*. None of complaining parties disavow the approach taken in *US – Shrimp*. However, they are inconsistent as to the consequences. On the relevance of international instruments, they provide inconsistent answers amongst themselves. Having proposed that no international instruments are relevant, they rely on the relevance of international conventions and texts if it suits them.

(g) Mootness

4.772 The alleged "general moratorium" has never existed. The present dispute has not become moot: rather, it lacked material object *ab initio*. The same applies to product applications that were no longer pending at the time of the establishment of the Panel. There can be no Community decisions on those products, and this was true at the time of Panel establishment, consultations, and before.

4.773 Mootness is relevant for the product specific claims where product applications have been withdrawn or decided *after* establishment of the Panel. Complaining parties urge that the Panel to rule on measures that no longer exist, but do not explain why the Panel should not apply a legal principle – mootness – that is recognized in jurisdictions around the world and commonly applied by international tribunals, including the ICJ. The WTO is *not* an exceptional case impermeable to the application of such a basic principle. The GATT/WTO case-law invoked by complaining parties does not support their claims. If the Panel decides to make findings on measures that no longer exist, the European Communities submits in the alternative that the Panel should not make any recommendations in respect of those measures.

2. Complaining parties' claims

(a) Product-specific delays

4.774 Complaining parties claim that there is a suspension of the approval system in respect of a number of specific applications. These acts are said to constitute at the same time a violation of certain provisions of the *SPS Agreement* and of its Article 8 and Annex C, as well as of provisions of the *TBT Agreement* and the GATT. They merely repeat their assertion that the alleged "general moratorium" has impeded the operation of the European Communities' approval process. They make generalised contentions, claiming that "x" number of years are "excessive" or "patently excessive".

They have failed to identify for each and every product-specific application the instances in which this "failure to apply or suspension" has materialised. They ignore the facts.

(i) Factual issues

The individual product-specific applications/notifications

4.775 There is no specific analysis of each application – only a few specific arguments in relation to a limited number of applications. Of these, several concern applications that have been withdrawn or, as in the case of Bt11 and NK603, brought to a conclusion by way of approval. Claims concerning those applications are not properly before the Panel: if the withdrawals or approvals took place before the Panel was established, the Panel has no jurisdiction; if they took place subsequently they have become moot. The European Communities therefore limits its second written submission to the small number of individual applications which remain outstanding. For all those products in respect of which no specific comments have been made, complaining parties must consider that all time spans in the chronologies submitted by the European Communities do not constitute delay or, if they do, that they are justified.

4.776 An analysis of the procedural steps taken in relation to the pending product applications shows that the few arguments put forward by complaining parties are either plainly mistaken or a misrepresentation of the facts. Some of the issues complaining parties typically ignore include the development of Stewardship programmes for post marketing guidance and monitoring (as recommended by European Communities' scientific committees themselves), the development and validation of detection methods, the update of applications *in agreement* with the applicant companies (the so-called 'interim approach'), and even the applicant companies' delays in providing necessary information. Complaining parties have therefore deliberately chosen not to discuss any of the scientific and technical issues that were raised and discussed during the approval procedures, and which explain the alleged "delays". The European Communities has provided full details about the pending product applications.

The time element

4.777 The specific facts of the specific cases demonstrate that any generalisation is misplaced because each application has its own specificities. In particular, the analysis of the facts show clearly that there are no "concerted acts and omissions that stall applications at key decision making stages in the approval process regardless of the scientific evidence demonstrating the safety of the product." The time taken for each product-specific application is documented as being used in respect of the following activities:

(a) To allow review by an organ of the European Communities on the basis of the requirements established by the EC legislation;

(b) To allow debate between the applicant, the member States (both as Competent Authorities and in the Regulatory Committee), and the Commission on scientific and/or technical issues;

(c) To address efforts to deal with risk management concerns (elaboration of monitoring requirements, adequate agricultural practices, etc.) as well as risk communication (labelling, etc.);

(d) To respond to delays voluntarily caused by the applicant and not attributable to the European Communities (multiple notification; insufficient data; bad quality of the data (e.g. molecular data); time to compile requested information or data etc.).

The scientific and technical nature of the reasons for the delays

4.778 The activities involved in the assessment of GMOs are scientifically and technically justified. Therefore, should the Panel have any doubt on whether the time which has elapsed for each product-specific application was necessary and justified to address scientific and technical issues, independent scientific and technical advice must be sought. The parties dispute this factual issue.

(ii) Legal issues

Burden of proof

4.779 Complaining parties have not discharged their burden of proof. Their factual arguments are generic (general suspension, general failure, overall time elapsed, stalled/delayed at member State level, etc.), or just wrong (Commission's failure to submit proposal to Regulatory Committee, imposition of interim approach, indefinitely suspended, etc.). Assertion is no substitute for rigorous presentation of facts. They also tend to standardise their arguments and repeat them for several product-specific applications. Whenever complaining parties attempt to look at individual facts, they fail to indicate which period of time should be considered a delay and, in all cases, why the delay would be considered unjustified in the specifics of each application.

4.780 In all cases, all three complaining parties fail to address and comment on the numerous risk assessment and risk management issues that were discussed and advanced in the specific proceedings. All those issues should have been known to complaining parties before the initiation of these proceedings, through their contacts with applicant companies. Complaining parties do not appear to have available to them the information that would have enabled them to "exercise their judgement as to whether action under these procedures would be fruitful" in accordance with Article 3.7 of the DSU. The European Communities regrets the unwillingness of complaining parties to engage in meaningful consultations prior to requesting the establishment of this Panel.

Applicable law

4.781 Events in each specific application procedure may originate with considerations within the scope of different WTO agreements. The analysis to be applied to "mixed delays" is the same as that to be applied to mixed acts. Action and inaction are two different sides of the same coin. The European Communities therefore submits that the Panel cannot lawfully reach a final conclusion on the European Communities' behaviour, and make recommendations accordingly, on the basis of Annex C only.

4.782 The European Communities has set out the concerns that have arisen in respect of various product-specific applications together with the relevant WTO Agreement or Agreements that cover them. In almost all cases, the GATT, the *TBT Agreement* and the *SPS Agreement* are all potentially applicable by virtue of the regulatory concerns that underlie the European Communities' procedures. The superficially neat approach of complaining parties is inconsistent with the WTO Agreements. First, and as explained above, the approval procedure itself – which is not contested by complaining parties – does not only address SPS concerns. Second, disregarding the concerns actually addressed in the specific application procedures in effect ignores the provisions of Annex A.1. Complaining parties' approach must therefore be dismissed.

The *SPS Agreement*

4.783 The *SPS Agreement* contains two types of provisions, those disciplining the development of the sanitary or phytosanitary measures and those dealing with their application. Challenging the way in which applications for authorization are dealt with is a challenge against the application of a sanitary or phytosanitary measure. Thus, among the various provisions which complaining parties allege to have been violated, only Article 8 together with Annex C can be applied to the facts of this case. Articles 2.2, 2.3, 5.1, 5.5 and 5.6, on the contrary, all contain obligations concerning the development of a sanitary or phytosanitary measure (i.e. the SPS measure itself).

4.784 The distinction between provisions on development and on application of measures addresses two different regulatory needs arising at two different points in time: the need to ensure the creation of procedures which respect certain parameters and the need to ensure the management of these procedures according to other parameters. This is confirmed by Article 8, which contains two distinct legal provisions. In its first part, it submits "the operation of control, inspection and approval procedures" to the provisions of Annex C. In the second part, it provides that the procedures themselves must be in conformity with all other provisions of the *SPS Agreement*.

4.785 All parties agree that not every delay triggers a violation, and that both the "justification for" and the "duration of" the delay are relevant to determine whether the delay is "undue". That requires a case-by-case assessment. In the case of approval procedures for novel products, each product presents characteristics and specificities peculiar to it. These also vary according to the specific habitat/environment in which the product is going to be produced and marketed, and according to the level of protection that is sought. That a product may have been previously approved in other jurisdictions is not necessarily relevant.

4.786 The time limits in the legislation setting up the approval procedure cannot be but "standard", i.e. average, indicative. Members may not always abide by the standard processing periods, depending on the specific circumstances of each case. That is why paragraph 1(b) of Annex C only requires Members to publish the *standard* processing period or to communicate to the applicant the *anticipated* processing period. The purpose of this provision is one of transparency and is not linked in any way to the concept of "undue" in paragraph 1(a). The European Communities' legislation contains an indication of standard processing times but, at the same time, it has a built-in flexibility. Thus, any period of time during which further information is awaited from the applicant, or during which the scientific committee is analysing the dossier, is not taken into account.

4.787 In the absence of any serious analysis by complaining parties, who simply try to reverse the burden of proof, the European Communities would suggest a possible classification of delays and their justification, as follows:

(a) *The delay is caused by risk considerations which do not fall within the scope of Annex A*

(b) *The delay has been voluntarily accepted by the applicant*

(c) *The delay is caused by the entry into force of new legislation with stricter requirements*

(d) *The delay is not attributable to a Member (e.g. caused by the applicant)*

(e) *The delay is necessary to ensure compliance with existing legislation and relevant international standards*

(f) *The delay is caused by efforts to elaborate monitoring requirements, adequate agricultural practices and similar efforts to manage SPS risks*

4.788 In addition to these justifications, the European Communities submits that delays in approval procedures can also be justified by (g) the analysis of scientific and technical issues, and (h) risk communication matters such as labelling. In none of these cases is delay to be considered "undue".

The *TBT Agreement*

4.789 For a rebuttal of the claims related to the *TBT Agreement*, the European Communities refers the Panel to the horizontal section above.

GATT 1994 – Articles III:4 and XX

4.790 If the Panel finds that any delay in a product-specific application is inconsistent with any of the provisions invoked by complaining parties, the European Communities' actions are nevertheless justified under Article XX of the GATT 1994.

(b) The alleged "general suspension" or "general moratorium"

(i) Measures at issue

4.791 This Panel is being invited by complaining parties to identify the existence of a measure which is alleged to be a "moratorium", and to decide the entire case on that basis. This is notwithstanding complaining parties' evident inability to identify a single decision on the part of the European Communities which reflects such a "moratorium". If the Panel is to assess the consistency with WTO rules of this so-called "moratorium" – and if the European Communities is to bring its actions into compliance with its WTO obligations – the Panel must first define with absolute precision what the "moratorium" consists of and what the measure at issue is. A measure that is a "moratorium" must therefore be shown to be a "plan or course of action" to suspend a procedure, or "a decision not to decide." On the other hand, the "absence of a decision" is not the same thing as a "decision not to decide." The facts which the European Communities has put before the Panel show that there has been no such decision. There may be expressions of individual opinion associated with specific persons, or views of individual member States. But the European Communities itself has not taken any such decision.

4.792 First, even though the European Communities' legislation was being revised in the period 1998 to 2001, the authorization procedures were never suspended to await it's entry into force. The existing applications continued to be assessed on the basis of an "interim approach" which sought to anticipate the new Community legislation, in particular as regards certain risk management requirements. Second, during the period in question the new legislation entered into force and the above period of transition ended (i.e. in the case of Directive 2001/18 well before the establishment of this Panel). While the application procedures, in some cases, may have suffered delays during the transition period, they are now proceeding normally.

4.793 Complaining parties attempt to obtain a factual and legal ruling against the European Communities based on their description of a factual situation that allegedly is the effect, result or consequence of a *presumed* moratorium. That attempt seeks to replace legal and factual analysis with

mere assertion. Panels do not rule on "effects" without establishing the existence of a measure for which the WTO member is responsible. The question of what measure caused an observed effect cannot be left open. Moreover, complaining parties reinvent the definitions and meaning of the terms "moratorium" and "measure." The issue now is no longer that of a suspension of the approval process, but that of a "blockage at key stages in the process", regardless of whether the product applications have moved from one stage to the next. Complaining parties present as a measure, i.e. as a plan or course of action, the most diverse reactions of different players in relation to different applications, and they conveniently leave out everything that does not fit that picture. Such reactions are part of an internal decision-making process and as such do not have external legal effect. In so far as there is no act or final outcome of the decision-making procedure, what could be attacked is a failure to act but, in so far as the *SPS Agreement* is concerned, the only obligation in that respect is to act without undue delay.

(ii) The issues the Panel would have to address if there were a measure

4.794 If the Panel takes the view that there is a measure, it would have to consider the following issues: (1) whether the measure existed when the Panel was established and if so, whether it still exists; (2) to what extent that measure comes within the scope of the *SPS Agreement*; (3) whether the measure is inconsistent with Article 5.7, as the measure would have to be considered to be of a provisional nature applied for reasons of insufficiency of scientific evidence; (4) to the extent that the measure does not fall under the *SPS Agreement,* whether it is a technical regulation falling under the *TBT Agreement* or whether Article III:4 of the GATT 1994 would be applicable; and (5) possible justification under Article XX of the GATT 1994.

(c) The EC member State safeguard measures

(i) Facts and legal argument before the Panel

4.795 To assist the United States, the European Communities gives the example of Bt-176. One of the reasons for the Austrian measure is the issue of antibiotic resistance. Austria's concern is that the antibiotic resistance marker gene might be transferred to bacteria in the human gut, and that this might reduce the effectiveness of antibiotics used in medicine. This issue falls, at least in part, outside the *SPS Agreement*. Therefore, some of the reasons for the Austrian safeguard measure fall outside the *SPS Agreement* and, in relation to these reasons, the Austrian safeguard measure cannot be considered inconsistent with the *SPS Agreement*. The same analysis applies in relation to the other measures.

(ii) The concerns of the member States

4.796 The Panel asked the United States to explain its position in relation to the concerns cited by the member States. The United States answered that question by reference to what it alleges "the member State measures cite" – which is different. The United States thereby changed the terms of reference of the Panel's question, and thus failed to respond to the question actually posed. What is or is not expressly referred to in the member State measures themselves is not the point. Those measures are in some cases relatively succinct, as is often the case with provisional measures. The United States deliberately selects what it knows to be a narrow presentation of the issues, as part of its general strategy to force as much as it possibly can into the scope of the *SPS Agreement*. A true appreciation of the member State concerns emerges from a fair and complete consideration of the histories of each of these measures, and the procedural steps leading up to, and following, their adoption. The European Communities has explained in detail to the Panel and complaining parties the true scope of the concerns that resulted in these measures being adopted and maintained. The European Communities has also explained in detail which of these concerns fall within the

SPS Agreement, and which do not, and why. The United States has not responded to these explanations, but attempts to change the underlying terms of reference. The assertions that the complaining parties do make in respect of specific issues are manifestly erroneous.

Q. THIRD WRITTEN SUBMISSION OF THE UNITED STATES

1. Introduction

4.797 The European Communities has not even attempted to explain how the moratorium is consistent with its SPS obligations. Rather, the European Communities' core defence remains that despite the fact that the moratorium was widely and openly acknowledged by EC member States and EC officials, no moratorium in fact ever existed. The European Communities attempts to support this position through the submission of CDs containing documents related to the processing of applications, and through brief narratives describing the processing of pending applications.

4.798 However, the mere fact that certain applications made some progress through the approval process, or that some of the delays may not have been unjustified, most certainly does not disprove the existence of the moratorium. The moratorium was a political-level decision not to allow any product to reach the final stage of approval; it was entirely consistent with that decision for EC regulators to allow certain applications to make some progress – short of final approval – through the approval process.

4.799 Nonetheless, the United States notes that the application histories submitted by the European Communities do not support the European Communities' view that the moratorium never existed. Rather, the chronologies provide numerous examples of how the moratorium operated to prevent decisions being reached on the different product applications and in different stages in the approval process. In several cases, applications were completely ignored either at the member State or the Commission level for years. In others, member States lodged baseless objections and requests for information that unduly delayed various applications. The EC documents further show that the only risk assessments for the products at issue were those conducted by the lead competent authority and the European Communities' scientific committee, and that the results from those risk assessments neither conflicted with each other nor otherwise justified failing to reach a decision on the products.

2. The second written submission of the European Communities fails to raise any meritorious arguments

(a) The European Communities' concept of "mootness" is not relevant to this dispute

4.800 The concept of "mootness" that the European Communities has articulated is not of relevance to this dispute. The Panel's terms of reference under the DSU are "[t]o examine ... the matter referred to the DSB" in the request for the establishment of the Panel. In this case, those matters are the general and product specific moratoria and the member State safeguard measures as they existed in August 2003. The United States is not aware of, and the European Communities has not identified, any panel that, absent an agreement of the parties, has declined to examine a measure that was in force when its terms of reference were set. To the contrary, past GATT and WTO panels have examined and made findings on measures even if they were discontinued during the panel's work. As the panel wrote in the *India – Autos* dispute: "A WTO panel is generally competent to consider measures in existence at the time of its establishment. ... Panels in the past have examined discontinued measures where there was no agreement of the parties to discontinue the proceedings."

4.801 The European Communities in its second written submission has two responses, both of which are entirely without merit. First, the European Communities argues that "Remarkably, the complaining parties have made no attempt to explain why WTO Panels are prevented from applying a legal principle that is recognized in jurisdictions around the world and commonly applied by international tribunals ... ." The European Communities makes no attempt at defining precisely what "legal principle" of mootness the European Communities claims that the WTO should adopt; the European Communities fails to explain why the GATT and WTO panels cited above have in fact considered terminated measures, and the European Communities makes no attempt to explain how such a principle would be consistent with the text of the DSU. In short, what is "remarkable" is that the European Communities criticizes the complainants for relying on the text of the DSU and on past GATT and WTO practice.

4.802 Second, the European Communities tries to confuse the issue by addressing yet another question: namely, whether a Panel issuing findings on a terminated measure should also recommend that the DSB request the defending Member bring its measure into conformity with WTO rules. Plainly, under that same consistent GATT and WTO practice, panels do issue such recommendations. Furthermore, Article 19.1 of the DSU specifically provides that "where a panel ... concludes that a measure is inconsistent with a covered agreement, *it shall recommend* that the Member concerned bring the measure into conformity with that agreement." While the European Communities cites the *US – Certain EC Products* dispute as an example to the contrary, that dispute in fact involved an entirely different situation: the measure at issue in that dispute had ceased to exist *before the date of the request for establishment of the panel*.

4.803 Moreover, this is not a case in which the measure at issue has terminated. The United States certainly does not agree that two token product approvals – made only after substantial delays and pursuant to Commission decisions after failures by both the Regulatory Committee and Council to take decisions – suffice to signal that the European Communities has begun to process other outstanding applications without undue delay, as required by the European Communities' obligations under the *SPS Agreement*.

4.804 It is particularly important for the United States, and for the WTO rules-based system as a whole, that the Panel in this dispute comply with past practice and issue findings on the European Communities' moratorium as of August 2003. All but two of the products caught up in the moratorium remain unapproved. Biotech product approvals remain a controversial political issue in the European Communities, and the recent expansion of the European Communities from 15 to 25 member States has not simplified the situation. In addition, a number of EC member States believe that yet additional legislation must be adopted before the granting of new biotech product approvals. And, although the European Communities has now approved two corn varieties for import and consumption, *the European Communities has yet to approve under 2001/18 a single biotech product for planting in the European Communities.* Accordingly, if the Panel were to depart from the DSU and past practice and apply the European Communities' concept of mootness, the possibility is substantial that the European Communities – once freed from the pressure of this ongoing proceeding – would halt all further approvals.

(b) The European Communities again fails to provide any argument rebutting the widely known fact that the European Communities has adopted a general moratorium

4.805 In its second written submission, the European Communities presents a number of arguments why – despite the widespread acknowledgment by EC officials of the imposition of a general moratorium – the Panel should nonetheless find that no moratorium ever existed. The European Communities' arguments in fact lend further support to the existence of the moratorium.

4.806 First, the European Communities defines a moratorium as existing where "the process of decision-making is temporarily stopped." The European Communities then argues that no moratorium existed, because some applications continued to make some progress through the European Communities' elaborate approval procedures. This is a straw-man argument, and simply dispensed with. The United States has never claimed that *all* processing stopped; rather that the European Communities adopted a decision to ensure that no product ever proceeded to the stage of final approval.

4.807 Second, the European Communities relies on its adoption of a so-called "interim approach," under which the Commission "sought to anticipate the new Community legislation." Upon examination, however, the European Communities' reliance on the "interim approach" in fact supports the existence of the moratorium.

4.808 On the one hand, the European Communities explains that: "The 'interim approach,' thus, is not an act that was 'adopted' in any form, it is merely a practice that was followed on the basis of a political intent to try and achieve results in the approval procedures despite the transitional period of legislative changes." On the other hand, the European Communities describes the interim approach as follows: "On [12 July 2000], the Commission agreed on an 'interim approach' for relaunching the authorizations of GMOs, entailing the anticipation of the key provisions (labelling, traceability, monitoring etc) of the forthcoming new environmental legislation. The new requirements would be incorporated into the individual authorizations of GMOs granted under existing legislation." Taken together, the European Communities is representing that under the interim approach, "new requirements" would be incorporated into individual applications; but that this decision was not "adopted in any form" and was "merely a practice that was followed on the basis of a political intent."

4.809 The European Communities' own description of the "interim approach" confirms a fundamental position of the United States: that the European Communities, "on the basis of political intent," made a decision to apply its biotech legislation in a manner that differed substantially from the text of the legislation. And, once it is understood, as the European Communities acknowledges, that the European Communities would feel free to depart from its legislation by changing the approval requirements, it is not at all hard to understand that the European Communities might also decide to delay its final decisions based on the same political considerations.

4.810 In addition, the European Communities states that the "interim approach" would involve applying requirements of unenacted legislation. Those requirements, however, would not be finalized for at least three years after the European Communities' purported adoption of an interim approach in 2000. Particularly in light of the European Communities' admittedly politically-based approval system, it is not credible to believe that the European Communities would decide to depart from the face of its approval legislation by adopting new requirements on an extra-legal basis, while at the same time allowing products to move to final approval when the contents of those new requirements were not yet decided upon. It is no mere coincidence that the European Communities' first biotech approval in over five years occurred in May 2004 – less than one month after entry into force of the European Communities' new legislation.

4.811 Third, the European Communities now tries to explain away the numerous official acknowledgments of the moratorium by claiming that "all these statements" refer simply to the fact that no biotech products reached final decision. To the contrary, the statements uniformly refer to the "moratorium." And, as the European Communities itself informs the panel, a "moratorium" "may be defined as 'a postponement or deliberate temporary suspension of some activity.'" The United States submits that EC officials used the term "moratorium" because it precisely fits the situation: namely,

that the European Communities had decided not to allow any biotech product application to move to final approval.

(c) The European Communities' theory of "mixed delays" is meritless

4.812 The European Communities' novel theory of "mixed delays" is illogical and not supported by the text of the *SPS Agreement*. The *SPS Agreement* provides that Members "shall ensure [that] procedures to check and ensure the fulfilment of [SPS] measures ... are undertaken and completed without undue delay." Nothing in the text of the *SPS Agreement* suggests, as the European Communities contends, that a Member is excused from this obligation if the delay stems from a consideration outside the scope of the SPS Agreement.

4.813 The European Communities has instead invented an entirely new approach to applying the obligations of the WTO agreements. According to the European Communities' approach, as long as a Member can show that its measure is not inconsistent with a different obligation (in this case obligations under the *TBT Agreement*), then that lack of inconsistency with one provision can excuse the inconsistency with another provision. Apparently the European Communities would reverse the usual rule of treaty interpretation that there is no conflict between two obligations if satisfying one of them (for example the stricter one) would also satisfy the other. Instead, for the European Communities, where two obligations apply, only the lesser of the obligations matters. Furthermore, in this dispute the European Communities has not answered the question of how both the *SPS* and *TBT Agreements* could apply to the same measure given the texts of Article 1.5 of the *TBT Agreement* ("The provisions of this Agreement do not apply to [SPS] measures as defined in Annex A of the [*SPS Agreement*]") and Article 1.4 of the *SPS Agreement* ("Nothing in this Agreement shall affect the rights of Members under the [*TBT Agreement*] with respect to measures not within the scope of this Agreement").

4.814 Moreover, the European Communities' argument, if taken to its logical conclusion, would severely undermine the "undue delay" obligation in Annex C. For example, take a case in which a WTO Member delayed an SPS approval procedure for years – for arbitrary reasons, or to protect a domestic producer. Under the European Communities' suggested interpretation, the Member would not be in violation of the *SPS Agreement*, because the delay did not arise from the evaluation of a risk enumerated in the *SPS Agreement*. Surely, in such circumstances, the drafters of the *SPS Agreement* did not intend to excuse a Member from its obligation under Annex C to undertake and complete approval procedures without undue delay.

(d) The European Communities has no basis for its argument that the Panel should depart from the definition of "risk assessment" set out in the Agreement

4.815 The European Communities spends considerable time addressing the definition of "risk assessment" for purposes of analysis under the *SPS Agreement*. As an initial matter, the United States notes that no issue in this dispute would appear to turn on the definition of "risk assessment." In particular, the European Communities has not even attempted to identify any risk assessments that might support the general moratorium, the product-specific moratoria, or the member States safeguard measures. In any event, the definition of "risk assessment" is clearly set out in Annex A.4 of the *SPS Agreement*, and that definition is dispositive. The European Communities' discussion of alternative definitions of "risk assessment" is without merit, and should be disregarded.

(e) The European Communities continues not to present a serious defence of its member State measures

4.816 In its second written submission, the European Communities again fails to point to any contrary risk assessments, nor does it attempt to explain how Article 5.7 applies in light of the full scientific evaluations of these products by the European Communities' own scientific committees. The only new material in the EC's second written submission addressed to the member State measures is an exhibit titled "Table summarising the position in relation to the member State measures, as set out in the first written submission of the European Communities." The table, which purports to show the various reasons why the member States adopted each safeguard measure, should be given no weight by the Panel. It is not supported by any footnotes or any other references, and it appears to be nothing more than an *ex post facto* attempt to justify those measures. Moreover, even if the new table could be considered to have some evidentiary value, it does not begin to show how the safeguard measures might be consistent with the *SPS Agreement*. For example, the table provides no citations to any "available pertinent information" that might be used as part of an argument under Article 5.7, nor does the table explain how scientific evidence might be sufficient when the European Communities has issued affirmative risk assessments for each product.

3. The European Communities cannot explain away the gaps in its product chronologies

4.817 In its second written submission, the European Communities provides brief and conclusory narratives concerning some, but not all, relevant biotech product applications. Those narratives were submitted prior to the European Communities' submission, at the Panel's request, of a more complete set of product application documents, and thus do not refer to the more complete record currently before the Panel. Moreover, the European Communities' narratives are in many cases misleading. An examination of the actual documents in the application histories confirm that many products were subjected to undue delays in the form of lengthy periods of inactivity.

(a) EC Exhibit 69: Glufosinate tolerant and insect resistant (Bt-11) corn

4.818 The Scientific Committee on Plants (SCP) issued a favourable opinion on the application for Bt-11 corn under Directive 90/220 on November 30, 2000. In the narrative in its second written submission, the European Communities attempts to explain away a 2-year gap following the SCP opinion by asserting that "the Scientific Committee recommended a monitoring plan, and the proposal by the applicant remains unsettled." The actual documents, however, reveal that this assertion is untrue. The opinion did not identify any missing information or other deficiency in the application.

(b) EC Exhibit 65: Bt cotton (531)

4.819 The application for Bt cotton (531) under Directive 90/220 suffered a 3-year period of inactivity by EC regulators. The European Communities' justification of this gap is baseless. That certain member States objected at the Regulatory Committee does not justify the European Communities' refusal to act on the application. Indeed, the European Communities' legislative framework provides a specific avenue for further action where the Regulatory Committee is unable to come to a decision: the Commission is to forward the application to the Council "without delay" for a decision. Moreover, nothing in the record indicates that the applicant was ever requested to submit additional information to address the member State objections, nor that the basis of these objections was ever even notified to the applicant. Furthermore, nothing in the record indicates why the member States objected despite the SCP opinion that addressed the very issues covered in the objections. In sum, nothing in the record indicates that the European Communities undertook any process whatsoever to resolve the member State concerns.

4.820 The EC's second written submission also incorrectly states that the applicant "finally provided ... required additional information," which incorrectly implies that delays were due to outstanding data requests. The applicant, however, was not responding to any request from the European Communities, but, on its own initiative, provided additional information to the lead CA as, not surprisingly, the state of scientific knowledge had advanced since the first written submission of the application more than four years before.

(c) EC Exhibit 91: Roundup Ready corn (GA21)

4.821 The novel foods application for Roundup Ready corn (GA21) under Regulation was delayed at the member State level for 10 months while the lead CA completed its risk assessment, and then delayed for 17 months at the Community level before the SCF rendered its positive opinion in February 2002. The European Communities charges that the 17 months it took for the SCF to render its opinion was caused by the applicant. The truth is reflected in the European Communities' own chronology: The Commission asked the SCF for an opinion on 18 May 2000. Eleven months later, the SCF contacted the applicant for the first time, asking for additional information. Within less than one month, the applicant provided an answer to all questions. The European Communities' chronology provides no explanation, other than a cryptic notation about "lack of time," for the further 11 months it took for the SCF to issue an opinion on 27 February 2002.

4.822 After the SCF issued its positive opinion on 27 February 2002, the Commission failed to forward a draft measure to the Regulatory Committee as is required to complete the approval process, resulting in further delay that lasted until the new GM Food and Feed regulation was passed in September 2003. Almost two months passed after the positive SCF opinion in February 2002 with no activity at all on this application. The applicant then sent a letter on April 23, 2002 offering to narrow the scope of the application in order to facilitate the European Communities' evaluation. Despite the efforts of the applicant to remove any possible impediments, the Commission still failed to forward the application to the Regulatory Committee. Instead, the Commission noted that although the next step was to take a Community Decision, "[i]t is desirable that such a Decision would take into account in an appropriate manner the legislative developments with respect to the authorization of GM food and feed as well as the labelling of GM products." In other words, the European Communities simply halted the processing of this application in anticipation of possible upcoming changes to its regulations.

(d) EC Exhibits 78 and 85: Roundup Ready corn (GA21)

4.823 The European Communities did not discuss the deliberate release applications for Roundup Ready corn (GA21) under Directive 90/220 in its second written submission, based on the European Communities' unilateral determination that the issues regarding these applications were moot. In response to the Panel's request for more complete information, the European Communities subsequently produced a chronology and supporting documentation for this and other withdrawn applications. These documents confirm that these applications in fact suffered extensive, undue delays. The European Communities delaying tactics also significantly delayed the parallel novel foods application for Roundup Ready corn (GA21) under Regulation 257/98.

4.824 The first application for GA21 under Directive 90/220, submitted in the UK in 1997, was delayed at the member State level for 7 months – from March to November 1999. The European Communities' chronology gives the false impression that activity actually occurred on this application after April 1999 by referencing an ACRE meeting on September 16, 1999. As the minutes to that meeting show, however, GA21 was not on the agenda and was not discussed.

4.825 The second application for GA 21 under Directive 90/220 abruptly halted when it reached the Commission level. The SCP rendered a favourable opinion on 22 September 2000. At this point, however, all activity unexpectedly ceased at the Commission level. The Commission did not submit the application to the Regulatory Committee for a decision, and there was no action or communication by the Commission on this application for the next 3 years, up to the time the application was finally withdrawn by the applicant on 15 September 2003.

(e) EC Exhibits 82 and 94: MaisGuard x Roundup Ready (MON810 x GA21) corn

4.826 MaisGuard x Roundup Ready maize is produced by conventionally hybridizing two "parental" biotech products, MON810 and GA21. Progress on GA21 maize was a limiting step on MON810 x GA21's progress in the regulatory process.

4.827 The deliberate release application for MON810 x GA21 corn under Directive 90/220 was submitted in August 1999, but never reached the Commission level stage of review. The lead CA requested further information on 30 November 1999, and the applicant responded in August 2001 to all requests, except for a scientifically unjustified study on the nutritional composition of milk from dairy cows fed this product. The applicant provided translated documents 5 months later in January 2002. Thereafter, for over 1½ years, until the application was withdrawn, the only activity by the lead CA was a meeting held in April 2002.

4.828 The novel foods application for MON810 x GA21 under Regulation 258/97 shares a similar history. The application was submitted to the lead CA in February 2000. As noted above, the novel foods application for the single trait parent GA21 under Regulation 258/97 stalled at the Commission level. In its comments on the application for MON810 x GA21, Italy stated that "examination of the documentation relating to authorization should only be carried out after the marketing of GA21 has been authorized." To date, the application for MON810 x GA21 is still pending.

(f) EC Exhibit 66: Roundup Ready cotton (RRC1445)

4.829 The European Communities suspended the deliberate release application for Roundup Ready cotton (RRC1445) under Directive 90/220 for nearly four years – from February 1999 until the new legislation, 2001/18, took effect in January 2003. The European Communities' only defence of this 4-year gap is its statement that "the Regulatory Committee failed to reach a qualified majority because a number of member States maintained objections." This observation fails to recognize that following the Regulatory Committee vote, Directive 90/220 obliged the Commission to refer the application to the Council for a decision "without delay," a step the Commission failed to take in this case. The EC's second written submission also incorrectly implies that the objections raised by member States had not been adequately addressed in the SCP. In fact, the SCP assessed the safety of the product at issue based on detailed scientific considerations. Moreover, none of the member States objecting at the Regulatory Committee offered any competing risk assessments or scientific evidence for such objections. Neither did the Commission nor the member States identify any specific inadequacies in the SCP review. Finally, nothing in the record indicates that the Commission communicated any scientific concerns to the applicant, or that the Commission identified to the applicant any shortcomings in the application.

(g) EC Exhibit 64: Roundup Ready fodder beet (A5/15)

4.830 The deliberate release application for Roundup Ready fodder beet (A5/15) has been in the EU approval process for over 7 ½ years, having been submitted to the lead CA in February 1997. The SCP issued a positive opinion on June 23, 1998. The Regulatory Committee, however, did not meet

on this application for over a year and a half and, even then, did not take a vote. Four months later, the Regulatory Committee met once again, on 9 March 2000, and once again, did not vote. After that, the application remained in limbo and was never submitted to either the Regulatory Committee or to the Council. Over 4½ years after the SCP positive opinion and deadlock at the Commission level, the applicant was forced to re-submit its application under the new Directive 2001/18 on 16 January 2003.

4.831 The European Communities attempts in its second written submission to defend the Commission's inaction by pointing to objections raised by member States. However, the SCP considered the existing scientific evidence and the information provided by the applicant to be sufficient to address the objections voiced by the member States. In addition, the European Communities' assertion that there were outstanding requests for information is not true. The applicant had voluntarily provided additional information in an attempt to remove any possible remaining obstacle to a Regulatory Committee vote. The actual reasons for the delay were stated in a January 2001 meeting with the applicant: "[h]aving the revised directive fully adopted will not be sufficient. The re-start of the regulatory process will depend on the willingness of the Commission to do it. It is commonly analysed that the Commission will not promote an Art 21 vote meeting, if there are no indications that the member-states are supporting the process and/or expected to vote positively. ..."

(h) EC Exhibit 76 and 96: Roundup Ready corn (NK603)

4.832 The NK603 deliberate release application was submitted in January 2000, and finally approved – although provisionally to a GM food and feed approval – in July 2004. The Commission approved the GM food and feed application for NK603 in October 2004. The processing of this application was delayed by the moratorium, and its ultimate approval does not signal the end of the moratorium.

4.833 The approval procedure did not progress "smoothly," as the European Communities contends. For both the GM food and feed and the deliberate release applications, the Regulatory Committee was unable to obtain a qualified majority vote. None of the documents provided by the European Communities support the European Communities' claim that those member States who abstained or voted against the approval of the product in the Regulatory Committee did so on the basis of "their own risk assessments." Member States' objections and the applicant's answers to these were taken into consideration by EFSA in delivering its positive opinions on NK603, and none of the member States questioned the validity of EFSA's favourable opinions. The Council similarly failed to reach qualified majority vote on the proposals. The fact that certain member States failed to cast their votes in accordance with the European Communities' own scientific committee's conclusions shows that member States continue to act based on political considerations.

(i) EC Exhibit 62: Oilseed rape (FALCON GS40/90)

4.834 The deliberate release application for oilseed rape (FALCON GS40/90) has been pending for over 8½ years. It was first submitted on April 1, 1996, and the lead CA forwarded it to the Commission on 25 October 1996. After member States objected during the review period, the SCP formally expressed a positive opinion on July 14, 1998. The Regulatory Committee did not meet until over a year later, on 29 October 1999, and, despite the positive opinion, failed to vote on the application. Four months later, on 9 March 2000, the Regulatory Committee met again, and again failed to vote on the application. Although the European Communities' chronology states that the failure to reach a vote was "due to further requests for information," the European Communities has failed to provide any document that confirms that statement. Instead, the record shows that the only request for information that could possibly have been made at that meeting was a request from Italy,

and the applicant responded to Italy's questions by 30 November 2000. The Commission never submitted a draft measure on the application to the Regulatory Committee again, and the application remained in this indeterminate state at the Commission for almost 3 years. The applicant finally had to submit an updated application under Directive 2001/18 on 16 January 2003.

(j) EC Exhibit 92: Bt-11 Sweet Corn

4.835 The novel food application for BT-11 Sweet corn was finally approved, under the GM Food and Feed directive that entered into force in April 2004, in May 2004. In its responses to the Panel's questions posed on 3 June 2004, the European Communities attempts to justify delays in the processing of the BT-11 application by claiming that "[b]etween October and early December 2003 [after the SCF positive opinion], three new risks assessment were issued by the member States, all of which conflicted with the SCF opinion." The European Communities' contention is unsupported by the record. No risk assessments were submitted during that time period.

4.836 The European Communities' incorrect assertion that competing risk assessments existed should not divert attention away from the real cause of the delays. When the BT-11 application was first evaluated at the Commission level in 2000, member States objected on the basis of the general moratorium. For example, as recalled by Denmark's Agriculture and Fisheries Council, "[i]n August 2000, Denmark submitted an objection to the approval of Bt11 maize in respect of the novel food regulation with reference to the declaration approved by Denmark, France, Italy, Greece and Luxembourg on the suspension of new GMO licences (the moratorium declaration), which was made at the Council meeting (environment) on 24-25 June 1999. The objection included a reference to the fact that, pending the approval of a regulation that would guarantee the labelling and effective tracing of GMOs and products derived from them, the moratorium countries would block any new licences for the cultivation and marketing of GMOs."

4. Many member State requests for information were not based on legitimate scientific concerns

4.837 The chronologies do not show – as the European Communities claims – legitimate scientific grounds for each request for information, and for the resulting delays, in the application histories. Rather, many supposedly scientific questions are requests that seek to force applicants prove the complete absence of hypothetical risks, in disregard of the safety data provided in the application. A pattern of deliberate delaying tactics is also illustrated by other types of scientifically baseless objections or requests for information that would have no relevance to an evaluation of the product's safety.

(a) Member State objections do not illustrate scientific disagreement or uncertainty

4.838 The record shows that none of the various member States' objections and requests for information qualify as competing risk assessments, "scientific disagreement" or "other scientific opinions" that would call into question the positive risk assessments conducted by the European Communities' own scientific committees. None of the objections made by the member States met the SPS definition of risk assessments. The objections were vague and general; did not identify and evaluate any specific risks posed; and were not supported by any scientific evidence that provided a basis for presuming a potential risk existed. Nor could the generic, vague statements in the member State objections and requests for information be considered "conflicting scientific opinion" of any weight that might counter the evidence presented in the product applications or in the risk assessments conducted by the lead Competent Authority or EC-wide scientific committees that demonstrated the safety of the products.

(b) Various member State objections relate solely to inappropriate "theoretical risks"

4.839 As the Appellate Body stated in *EC – Hormones*, "[T]heoretical uncertainty is not the kind of risk, which under Article 5.1, is to be assessed" under the Agreements. Yet the objections and related requests for additional information raised by member States were often based on just such theoretical risks, and this fixation on theoretical risks and their refutation is yet another manifestation of the general moratorium. For example, France objected to the approval of Bt Cry 1F corn, stating numerous times that additional animal studies were necessary "to prove the absence of risk," even though the existing data [*e.g.*, acute protein toxicity studies; compositional analyses] showed that no food safety risks could reasonably be anticipated. Yet, such proof is unattainable. As the Appellate Body explained, "[U]ncertainty [] always remains since science can never provide absolute certainty that a substance will not ever have adverse health effects." It is not possible for a risk assessment to evaluate every risk that a product might theoretically pose. It can, however, provide information that allows decision makers to make reasoned judgments about the risks it is reasonable to assume a product may present, based on the product's characteristics. Accordingly, these member State objections and requests for additional data are not the kind that could be used to justify a delay in an approval procedure under Annex C of the *SPS Agreement*.

(i) Requests for chronic toxicity tests, when acute studies show no effects

4.840 For all of the products at issue in this dispute, the results of the acute toxicity tests and the homology comparisons provide no indication for any concern and do not indicate the need for chronic toxicity tests. For the most part, proteins that would be expected to be toxic to mammals should express toxicity when tested at the high doses required in the acute oral test. None of the proteins at issue in these applications are similar to proteins known to have longer-term effects in mammalian species. In addition, the data submitted on all of the products at issue in this dispute indicate that the inserted proteins are rapidly degraded in mammalian gastric juices. These degradation products become nutrients, and there is no evidence that they specifically bind to or accumulate in mammalian tissues. Consequently, in the absence of any indication of concern in the acute toxicity tests, and in the absence of a structural relationship between the protein and any toxins, allergens or other proteins established to have longer-term toxicity, no further testing would normally be considered scientifically necessary to characterize any potential risks from the protein. Thus, requests for chronic toxicity tests can only be interpreted as a demand to disprove a theoretical risk – that, for some unknown reason, and contrary to all available data, the protein will behave differently than all other proteins.

4.841 Unwarranted requests for chronic toxicity studies contributed to delays in the consideration of the following applications: Roundup Ready Corn (Exhibits 76 and 96) and Roundup Ready (GA21) Corn (Exhibit 91).

(ii) Request for multiple whole food studies

4.842 Another example of requests to disprove hypothetical risks involves whole food studies. As a general matter, international consensus documents do not recommend the routine use of whole food studies. Rather, these documents indicate that such studies are not generally necessary in the absence of some indication for concern in the other data. Nonetheless, for all of the products at issue in this dispute, at least one whole food study was submitted as part of the application. In every case, the initial whole food study indicated no adverse effects. Based on the submitted safety data, as well as the scientific knowledge accumulated from experience with these products, there is no reason to believe that the results of the second – or in some cases third or fourth – whole food would differ in any way relevant to the safety of the product.

4.843 Unwarranted requests for additional whole food studies contributed to delays in the consideration of the following applications: Bt Cry 1F corn (1507) (Exhibits 74 and 75), Roundup Ready Corn (GA21) (Exhibits 78 and 85); MaisGuard (MON810) x RoundupReady (GA21) (Exhibits 82 and 94), Roundup Ready corn (GA21) (Exhibit 91), Bt-11 x Glufosinate Tolerant Sweet Corn (Exhibit 92), and Roundup Ready Corn (Exhibit 96).

(iii) Insistence that safety of hybrid products be proven independent of the data on the parent

4.844 Another example of demands by the European Communities that applicants disprove merely theoretical risks are repeated demands that separate assessments be conducted for each hybrid plant produced through conventional breeding from a previously evaluated biotech product. In these cases, member States requested additional evaluations without having a plausible scientific reason that the risk profile of the hybrid plant would be altered by breeding such that the existing safety data on the parents should be discounted. The products at issue were created by crossing (breeding) varieties of the same species. Both varieties are themselves used in food, and therefore are extremely unlikely to introduce traits that have not been in food before. In addition, plant lines used for such crosses generally have been subject to extensive backcrossing and field testing to ensure genetic stability. Finally, because the plant lines are closely related to each other, crosses between them are no more likely to be subject to unintended changes than conventional breeding between non-biotech plants.

4.845 A further consideration is that modern crop breeding relies on a knowledge base that has been developed over the last 50 years through breeding programs. Hybrid seed typically goes through at least 10 generations of breeding effort prior to the release of seed suitable for farmer cultivation. As a result, modern cultivars of major commercial crops are predictable in almost all aspects of performance (yield, disease resistance, maturity, etc.). The products at issue in this dispute use these hybrids and also employ the same methods of seed production. Consequently, any significant discrepancy that might theoretically arise from this cross would be expected to be detected in the field tests. The request for data on each hybrid corn developed also ignores all of the information about the safety of these plants that has been derived from the established processes in hybrid development, and their history of use. Thus, the mere fact that a product is the result of cross-breeding is insufficient to justify the need for additional studies to confirm the results of the existing data on the parents.

4.846 Unwarranted requests for additional studies of hybrid products contributed to delays in the consideration of the following applications: Bt-11 Corn (Exhibits 69 and 92), Bt Cry 1F corn (Exhibits 74 and 75), and Bt Cry 1ab x Roundup Ready Corn (Exhibits 82 and 94).

(iv) Vague requests for data on environmental effects

4.847 Another category of unwarranted information requests relate to the concerns expressed regarding various vague, potential environmental effects, which, upon examination, amount to yet additional requests to disprove wholly speculative risks. One primary example of these are concerns about potential changes to biogeochemical processes. For a number of reasons, these are risks that, based on what is generally known about the issue and the products, are so unlikely as to be purely theoretical. The available information does not indicate that any of these bioengineered plants present any potential for disrupting these cycles. The attributes of these products are such that there is no general scientific reason to expect that they would cause such effects; for example, the modification is not intended to function in a manner that affects these cycles. In addition, there is generally a duplication of function between many microbial groups, such that even in the unlikely event that there was a measurable effect on a particular group, it would have no effect on any global biogeochemical process. Moreover, given the immense variation in levels of biogeochemical processes due to such agricultural practices as cultivation, fertilization and no-till, it is difficult to envision that, absent a

truly massive change, any variation in biogeochemical processes that could be linked to the biotech plant could be determined to be significant. Any change of such a magnitude should have been discerned as part of the field trials. Absent any indication of unusual activity in the field trials, there is no reason to believe that positing such risks is anything more than mere speculation.

4.848 These types of vague and unwarranted requests for additional studies of environmental effects contributed to delays in the consideration of the following applications: Bt–11 corn (Exhibit 69), Bt Cry 1F corn (Exhibits 74 and 75), and Roundup Ready Corn (GA21) (Exhibits 78 and 85).

(v) Requests for studies on the composition of the food derived from the animal

4.849 A further example of requests related to unfounded and theoretical risk are requests for additional studies to provide confirmation that biotech animal feeds do not alter the composition of the food derived from animals consuming the feed. Where the compositional analyses demonstrate that the nutritional makeup of the feed falls within the normal biological range of variation that has been established for non-engineered, commercially available feeds, there is no general scientific reason to expect that any effects on milk or meat would occur. In addition, where it has been shown that the introduced protein is rapidly degraded or excreted, like any other dietary proteins, there is no scientific basis on which to speculate that these proteins would accumulate in meat or milk. Where a whole food study has been performed to confirm the results of the compositional analysis, and the study provides no indication of adverse effects or unexpected results, such concerns are wholly speculative.

4.850 Unwarranted requests for studies of the products of animals that consumed biotech feed contributed to delays in the consideration of the following applications: Bt (Mon810) x Roundup Ready Corn (Exhibit 82) and Roundup Ready Corn (GA21) (Exhibit 91).

(vi) Objections wholly without scientific merit

4.851 In several instances, member States asked for other types of additional studies that would yield information that would have no relevance in assessing the safety of the product at issue. These include: Bt-11 Corn (Exhibit 69) – information on potential weediness of maize; Bt Cry 1F (Exhibits 74 and 75) – Northern blot data on mature kernels and proteomic analysis; Roundup Ready Corn (Exhibit 76) – PCR analysis, additional allergenicity testing, protein conformation, and proteomic analysis; Bt Corn-Cry 1F (Exhibits 74 and 75) – additional field trials.

R. THIRD WRITTEN SUBMISSION OF CANADA

1. Introduction

4.852 In this submission, Canada responds to arguments and evidence advanced by the European Communities in its Second Written Submission, as well as arguments and evidence put forward by the European Communities in its earlier submissions to which Canada has not yet responded. Canada also addresses specific elements of the documentation made available by the European Communities that has not been specifically referenced or discussed in the European Communities' submissions. In doing so, Canada stands by its original claims and arguments, and this submission should be understood as an elaboration or clarification of those claims and arguments.

4.853 In what follows, Canada first addresses the issues characterized by the European Communities as "horizontal", systematically refuting the European Communities' arguments relating to risk assessment and the role or status of Community-level scientific opinions, as well as the

European Communities' interpretation of the relevant provisions of the *SPS Agreement*, the *TBT Agreement* and the GATT 1994. Canada then turns to the European Communities' arguments relating to Canada's claims and demonstrates, using the European Communities' own documents, why Canada's claims are well founded in fact and law.

2. Horizontal issues

(a) Burden of proof

4.854 Canada largely agrees with the summary of the case law set out in paragraphs 12-17 of the EC's Second Written Submission. Contrary to the European Communities' assertions, however, Canada has met its initial burden in respect of all its claims. The European Communities also misapplies the jurisprudence to the case at hand. Specifically, the European Communities' assertions regarding the need for the complaining party to demonstrate an absence of risk finds no basis in either the text of the WTO Agreements or the related jurisprudence. Finally, the European Communities claims that it has provided most of the evidence in this case. If the European Communities is suggesting that Canada has failed to produce adequate factual evidence to support its legal arguments, the suggestion is utterly without merit.

(b) The European Communities' mischaracterization of Canada's arguments

4.855 In its Second Written Submission the European Communities repeatedly mischaracterizes Canada's arguments. While Canada does its best to identify and correct all such mischaracterizations, it encourages the Panel to verify for itself the accuracy of the European Communities' "restatements" of Canada's arguments.

(c) Risk assessments and Community-level Scientific Committees

4.856 In what appears to be an effort to circumvent its obligations under the *SPS Agreement*, the European Communities claims that the risk assessments for the biotech products subject to the *moratorium* have not been completed yet. To support its argument, it: distorts the meaning of "risk assessment" as used in the *SPS Agreement*; downplays the role of the opinions of Community-level scientific committees; and, argues that the activities of the relevant regulatory committees should also be considered a part of "risk assessment".

4.857 The European Communities' attempt to equate the term "risk assessment" as defined in the *SPS Agreement* with "risk analysis" as defined by Codex Alimentarius relies on specious reasoning. First, the European Communities fails to advance a cogent rationale under the principles of treaty interpretation for relying on the Codex definition of "risk analysis". Second, the European Communities' suggestion that only part of "risk assessment" as used in the *SPS Agreement* must be a "scientifically based process" is at odds with the definition of "risk assessment" in Annex A and the requirements of Article 2.2 of the *SPS Agreement*. Third, the Codex definition of "risk analysis" is only relevant – if at all – to risk assessments in relation to food safety. Fourth, the European Communities' claim that, because the *SPS Agreement* includes labelling for food safety as an SPS measure, "risk communication" is a part of "risk assessment", is as incoherent as it is illogical.

4.858 The European Communities seeks to downplay the opinions of its own Community-level scientific committees by asserting that such opinions do not "over-rule" other scientific opinions. However, the European Communities fails to point out that the role of the Community-level scientific committees is precisely to address scientific disagreement amongst EC member States and to review the validity of objections raised by them. The Commission has consistently treated Community-level

scientific committee opinions as decisive and not as one opinion amongst many. Moreover, the European Communities fails to point to or provide any other "scientific opinion", by an objecting EC member State, that even approximates the rigour and thoroughness of the risk assessments conducted by the Community-level scientific committees or, in many cases, the original competent authority.

4.859 Although Canada agrees that, in principle, the concept of "risk assessment" provided for in the *SPS Agreement* involves both the identification and evaluation of risks and the evaluation of options to manage risks so identified and evaluated, by no stretch of the imagination can the activities of the European Communities' regulatory committees, or the EC member States, be considered as "risk management" activities. There is simply no evidence that the activities of the regulatory committees or the individual EC member States meet the standard set out in the *SPS Agreement*. The only examples of such activities that could conceivably meet that standard are to be found in the work of the Community-level scientific committees, including EFSA.

(d) Interpretive issues relating to the *SPS Agreement*

4.860 The European Communities' interpretive approach to the *SPS Agreement* is a sweeping assault on the obligations of that *Agreement*. The European Communities advances interpretations of the scope and obligations of the *SPS Agreement* that are inconsistent with the ordinary meaning of the text and undermine the *Agreement*'s object and purpose.

(i) The definition of sanitary and phytosanitary measures

4.861 The European Communities distorts Canada's arguments in relation to the meaning of "contaminants". In fact, Canada's arguments are consistent with Codex Standard 193. The European Communities' arguments about Stan 193 are also wrong in principle. The European Communities' assertion that "if the GMO is deliberately re-produced…in the full knowledge of the side effect, that side effect can no longer be described as 'unintentional'" is also flawed. Moreover, the European Communities' assertion that "'crop husbandry' does not cover laboratory work is at odds with the ordinary meaning of the term "husbandry".

4.862 To the extent that the European Communities' approval procedures are applied to protect against risks to human and animal health arising from toxins in food and feedstuffs, such procedures are SPS measures as defined in Annex A(1)(b) of the *SPS Agreement*. The European Communities suggests that the assessment of toxicity of seeds and crops could be undertaken for reasons unrelated to consumption by humans and animals, and that, by extension, such assessments of toxicity fall outside the scope of the *SPS Agreement*. However, apart from effects on non-target organisms, assessing for toxicity only makes sense if these products are used for human or animal consumption. This is reflected in the European Communities' legislation. The assessment of effects on non-target organisms, which typically involves the issue of toxicity, falls under either Annex A(1)(a) or (d).

4.863 The European Communities argues that that because allergens are neither "toxins" nor "diseases", they do not fall within one of the risks identified in Annex A(1)(b). However, the European Communities' own food safety legislation requires an assessment of potential allergenicity. Moreover, international standards, guidelines and recommendations for the safety assessment of biotech foods uniformly recognize the assessment of allergenicity as an integral component of food safety. In this light, it could not have been the intention of the drafters of the *SPS Agreement* to exclude from the scope of the *SPS Agreement* such an important aspect of food safety as the assessment of risks arising from allergens in food. Hence, for the purposes of the *SPS Agreement*, allergens in food and feedstuffs can and should be considered "toxins".

4.864 The European Communities advances interpretations of animal and plant life and health that are inconsistent with the ordinary meaning of these terms in their context and in the light of the object and purpose of the *SPS Agreement*. In particular, the European Communities claims that its legislation constitutes measures to protect the "environment" and "biodiversity" and that because these terms do not appear in the *SPS Agreement*, the approval regime, to the extent that it assesses risks to the "environment" and "biodiversity", is not an SPS measure. However, the types of risks relating to the "biodiversity" and "environment" that are addressed under the legislation are those that ultimately pertain to "animal or plant life or health." Moreover, the text of the *SPS Agreement* supports the conclusion that SPS measures include measures applied to protect the environment. In addition, any harm to biodiversity arising from the biotech products in issue amounts to harm to plant and animals, as defined in the *SPS Agreement*. The European Communities' argument that risks to "biodiversity" are not risks that fall within the scope of the *SPS Agreement* is at odds with the description of the scope of the Pest Risk Analysis (PRA) set out in International Standard for Phytosanitary Measures (ISPM) No. 11.

4.865 The European Communities argues for a narrow interpretation of the term "pests". Both premises of the European Communities' argument are without merit. First, the European Communities suggests that a "pest" must be a living organism and cannot be simply modified DNA. This is a straw-man argument. The focus of inquiry in terms of pest characteristics is the plant containing the transgene, not the modified DNA itself. Second, the European Communities' suggestion that "pest" under the *SPS Agreement* is limited only to organisms that cause injury to plants or plant products is inconsistent with the ordinary meaning of the term in its context.

4.866 The European Communities conflates concerns about the safety of biotech products with concerns about the use of herbicides in order to claim that the approval procedures for biotech products fall, at least in part, outside the *SPS Agreement*. This argument is without merit. The approval procedure for one type of product (crop) cannot be transformed into a non-SPS measure by linking the procedure to concerns related to the use of another type of product (herbicide).

(ii) Article 2 and Article 5.7 of the SPS Agreement

4.867 The European Communities' arguments relating to Articles 2 and 5.7 of the *SPS Agreement* are without merit. The European Communities seeks to juxtapose Articles 2.2 and 5.7 as separate but equal provisions, both representing basic rights and obligations. To lend credence to its arguments, the European Communities tries to establish a parallelism with Articles 3.1 and 3.3 and the Appellate Body's remarks in *EC – Hormones*. The European Communities' interpretive approach is bereft of logic, has no textual foundation and is untenable as a matter of treaty interpretation.

4.868 First, the European Communities tries to demonstrate that Article 5.7, through incorporation by cross-reference, is transformed into one of the "basic rights and obligations" of the *SPS Agreement*. This argument is completely at odds with any reasonable approach to treaty interpretation. Second, the European Communities seeks to rely on a comma to assert that the "necessity" and "scientific principles" elements of Article 2.2 are excluded from applying to an Article 5.7 measure. However, this argument would lead to the conclusion that Article 5.7 measures are not subject to any proportionality requirements, a proposition that is at odds with the jurisprudence, the structure of the *SPS Agreement*, and even the European Communities' own policy on the precautionary principle. Third, despite the European Communities' efforts to demonstrate that the relationship between Articles 2.2 and 5.7 parallels that between Articles 3.1 and 3.3, the reasoning finds no support in the text of the *SPS Agreement* or the existing jurisprudence. Fourth, the European Communities' proposition that provisionality is the "demarcation line" for the applicability of Article 5.7 is destined to fail for several reasons. The jurisprudence cited by the European Communities does not support its

proposition. Contrary to the European Communities' assertions, the complaining parties have never conceded that the measures in question are, in fact, provisional. The European Communities' observation that Article 2.3 continues to apply adds nothing to its arguments about the "demarcation line". The European Communities' attempted bifurcation between "provisional" and "definitive" measures is nowhere reflected in the text of the *SPS Agreement*. The cumulative nature of the four conditions set out in Article 5.7 does not support the European Communities' argument. To the contrary, the opening phrase of Article 5.7 supports Canada's argument that insufficiency of scientific evidence is the threshold. Finally, the European Communities contradicts its earlier statements when it claims it does not have the burden to demonstrate that the *EC member State national measures* are provisional.

(iii) Article 5.7 and the rest of Article 5

4.869 In trying to demonstrate that Article 5.7 excludes the application of the rest of Article 5, the European Communities mischaracterizes Canada's arguments. The European Communities also fails to explain convincingly why Articles 5.5 and 5.6 cannot apply to measures subject to Article 5.7. The European Communities demonstrates a complete misunderstanding of the structure of Article 5, misinterprets Articles 5.2 and 5.3, and misconstrues the role of the concept of "appropriate level of protection". Finally, the European Communities' arguments with respect to the relevance of Articles 5.5 and 5.6 contradict the European Communities' own policy statement on the application of the precautionary principle.

(iv) Article 5.1

4.870 The European Communities asserts that Article 5.1 of the *SPS Agreement* does not apply to the *EC member State national measures*, the *moratorium*, or the *product-specific marketing bans.* This is not supported by either the facts or the jurisprudence. The European Communities fails to cite any authority for the interpretive gloss that it seeks to impose on the phrase "as appropriate to the circumstances". Furthermore, the European Communities' assertion that, "in relation to the alleged product specific delays, there is no 'measure' within the meaning of Article 5.1" rings hollow in the face of the indisputable existence of a measure, namely, the *moratorium.* Thus, the European Communities' contention that the *product-specific marketing bans* are to be considered solely in relation to the requirements of Annex C of the *SPS Agreement* is incorrect. Finally, the European Communities relies on semantics in an effort to avoid the clear obligation set out in Article 5.1, but the fact remains that a rational relationship must exist between the selected measure and a risk assessment. In the case of the *moratorium*, there is no risk assessment at all, and in the case of individual product applications, no rational relationship exists between the *product-specific marketing bans* and repeated risk assessments of the products in question.

(v) Article 5.5

4.871 The European Communities misrepresents Canada's position in stating that the "Complaining parties accept that under the *SPS Agreement* it is permissible for a member State of the European Communities to have a different level of protection compared to that applying elsewhere in the European Communities". Canada has never stated this anywhere in its submissions. In any event, the European Communities' argument is purely theoretical. The European Communities has asserted, but not actually demonstrated, that the EC member States are imposing levels of protection that are different from that of the EC legislation. It has also failed to indicate in any way what these allegedly different levels of protection are and why they can be considered to be different from that reflected in the EC legislation. To the contrary the evidence supports the conclusion that the member States believe themselves to be applying the level of protection reflected in the EC legislation. More

generally, the European Communities' arguments with respect to the applicability of Article 5.5 are simply not relevant in this particular situation.

(vi) Article 5.6

4.872 Nothing in the European Communities' arguments in its Second Written Submission counters the *prima facie* case that Canada has already established.

(vii) Article 5.7

4.873 Canada has already demonstrated why Article 5.7 is not available to exempt the *EC member State national measures* from the requirements of Article 2.2, and why, in any event, those measures do not meet the requirements of Article 5.7. In contrast, the European Communities has not presented any detailed, measure-by-measure facts or arguments to demonstrate either that Article 5.7 applies so as to exempt the measures from Article 2.2, or that the measures in question meet the requirements of Article 5.7. The European Communities' efforts to convince the Panel that the measures in question were taken in the face of great scientific uncertainty collapse in the face of the fact that the European Communities is not faced with competing risk assessments of the stark contrast implied by the European Communities – in fact, as the evidence demonstrates, the European Communities is not faced with competing risk assessments at all – regardless of whether we are talking about pending applications or the member State national measures.

(viii) Article 2.3

4.874 The application of the approval procedure is subject to Articles 2, 5 and Annex C of the *SPS Agreement*. The European Communities' arguments ignore the case law on the relationship between Articles 5.5 and 2.3.

(ix) Annex C(1)(a)

4.875 In essence, the European Communities denies the existence of a *moratorium* and argues that it is justified in refraining from making a decision because scientific understanding may evolve and unforeseen risks may arise in the future. To accept this argument would render illusory the protection accorded by Annex C(1)(a). As a factual matter, apart from the fact that the *moratorium* is the primary cause of the delays, there is no insufficiency of scientific evidence so as to justify the delay in completing the approval procedures in question. While there may be circumstances in which a precautionary approach in selection of the risk management measure is warranted, such circumstances do not exist in this case and, in any event, a precautionary approach cannot override the requirements of Annex C.

4.876 The European Communities is really arguing that the *product-specific marketing bans* are justified under Article 5.7. However, the European Communities has not claimed the protection of Article 5.7, let alone demonstrated that its requirements have been satisfied. The European Communities appears to assume that Article 5.7 does not apply to the operation of inspection, control and approval procedures. This assumption is invalid. As Canada has already demonstrated, the European Communities' measures are subject, not only to Annex C, but also the requirements of Articles 2 and 5. If, as it now appears, the European Communities is attempting to justify the *product-specific marketing bans* on the basis of insufficiency of scientific evidence, the European Communities must claim the protection of Article 5.7 and demonstrate that the *product-specific marketing bans* meet the requirements of that provision. The European Communities has failed to do so.

(e) The *TBT Agreement*

4.877 The European Communities concedes that the relevant EC legislation contains technical regulations. The *product-specific marketing bans* arising from the *moratorium* are mis-applications of that legislation. The "application" of technical regulations is subject to both Article 2.1 and 2.2 of the *TBT Agreement*.

4.878 The European Communities' argument that the phrase "in respect of technical regulations" limits the scope of Article 2.1 of the *TBT Agreement* to situations where the products in question are both subject to technical regulations is untenable. There is nothing in those words to support the narrow scope proposed by the European Communities. Nor is the Biosafety Protocol relevant to a determination of "likeness". The test of "likeness" is fundamentally an examination of the competitive relationships between the products in the market place. Even if it is possible, in principle, for international legal instruments to constitute evidence for or against "likeness", the Biosafety Protocol does not provide any guidance in this respect.

4.879 The European Communities' assertion that only the European Communities' approvals legislation for biotech products is capable of being a technical regulation is not correct. Canada has showed that the *member State national measures* are also technical regulations. Furthermore, the European Communities' contention that the "Complainants have not established that any *application* of the EC legislation … is more trade restrictive than necessary" is without merit.

4.880 Canada is not contesting the European Communities' legislation as such. Rather, it is the *moratorium*, which converts the legislation's conditional marketing ban into a permanent and unconditional marketing ban, and the resulting misapplication of the technical regulation, that Canada is challenging. It is this misapplication of the technical regulation that Canada is challenging as being more trade-restrictive than necessary, contrary to Article 2.2 of the *TBT Agreement*. Thus, the central issue before the Panel is not whether the delays in the approval of specific applications are more trade-restrictive than necessary, but whether denying the approval of specific product applications on a systemic basis – essentially the misapplication of the EC legislation – is more trade-restrictive than necessary.

4.881 The European Communities also claims that Article 2.2 does not require the measure in question to "fulfil a legitimate objective". This argument finds no textual support in Article 2.2. On the contrary, the language of Article 2.2 requires a direct causal relationship between the measure and the achievement of the objective. The European Communities' interpretive approach would make it virtually impossible to gauge the necessity of a given measure.

4.882 It is simply astounding that the European Communities, at this late stage in the proceedings, still cannot inform the Panel what the EC member States' respective appropriate levels of protection were, or how those levels of protection differ from that found in the European Communities' legislation.

4.883 The European Communities asserts that "a conformity assessment procedure does not exist where there is room for the exercise of discretion, or the weighing of complex and to some extent conflicting considerations." This argument is without merit. There is no language in the definition of "conformity assessment procedure" to support the European Communities' characterization. The definition includes a broad, and non-exhaustive, list of activities, many of which include the exercise of discretion. It seems plain that if, as the European Communities concedes, these instruments are technical regulations, then the approval procedures laid down to ensure that the substantive requirements set out therein are met must be conformity assessment procedures.

4.884 The European Communities argues that, because "release into the environment" has a character of irreversibility, the delays in approvals do not violate Article 5.1.2 of the *TBT Agreement*. However, the irreversibility of the negative impact of a given product is only one consideration to take into account when determining whether the application of the conformity assessment procedure is more strict than necessary.

4.885 Although the phrases "as expeditiously as possible" and "without undue delay" use different words, their import is the same. Control, inspection and approval procedures under Annex C of the *SPS Agreement* and conformity assessment procedures under the *TBT Agreement* are intended to achieve basically the same object. In terms of their ordinary meaning, the phrases mean essentially the same thing. The European Communities has not advanced a different or competing interpretation of these phrases. Canada has demonstrated that the *product-specific marketing bans* amount to violations of Article 5.2.1 of the *TBT Agreement*. It is now for the European Communities to rebut Canada's *prima facie* case. To date, it has failed to do so.

(f) Interpretive issues relating to GATT 1994

4.886 The European Communities makes several claims relating to Article XX of the GATT 1994. None of these claims are supported by the facts, the text of the WTO Agreements, the jurisprudence or logic. The European Communities claims that Article XX of the GATT 1994 would be available to justify a violation of one of the provisions of the *TBT Agreement* or the *SPS Agreement*. This claim is completely untenable as a matter of treaty interpretation, and the European Communities offers no cogent argument in support. In regard to GATT 1994, the European Communities has not made out a *prima facie* case for justifying any of the violations of Article III:4 and Article XI:1 (in the case of Greece) of the GATT 1994 arising from the *product-specific marketing bans* or the member State national bans. Clearly, it is the European Communities, as the party invoking Article XX, who bears the initial burden of demonstrating that the requirements of Article XX have been met. Just as clearly, the European Communities has failed to discharge this burden.

(g) "Mixed" acts

4.887 The European Communities has argued that determining which agreement applies to the measures in question is an important threshold issue. However, the European Communities' bifurcation of the measures in dispute into SPS and non-SPS components is merely an attempt to distract the Panel from focusing on the underlying issues in this case, that is whether the *moratorium*, the *product-specific marketing bans*, the delay in processing biotech products, or the *EC member State national measures* are justified in the circumstances. The European Communities' efforts to characterize these measures as falling, in part, outside the scope of the *SPS Agreement* should be rejected. However, even if one were to accept for the purposes of argument that the measures in question involve the assessment of non-SPS risks, the measures are not justifiable under either the *SPS Agreement* or the *TBT Agreement*. Regardless of whether the measures in dispute are applied to protect against exclusively SPS risks or a mix of SPS and non-SPS risks, the conclusion is the same – the European Communities' own risk assessments have concluded that there is no justification for these measures or the delay in processing biotech applications.

(h) "Mixed" delay

4.888 The European Communities argues that the reasons for the delay arise from the assessment of risks that fall within the *SPS Agreement* and risks that fall outside of the *SPS Agreement*. Assuming that the approval procedures can be split into different components, the fact that the entirety of these procedures may not be covered by the *SPS Agreement* does not mean that the entire measure falls out

of the scope of that *Agreement*. Measures taken for SPS reasons are subject to the *SPS Agreement* regardless of whether or not the measures are also be subject to the *TBT Agreement* or GATT 1994. Otherwise a WTO Member would be able to avoid its obligation under Annex C(1)(a) by claiming that the delay arose for non-SPS reasons. Where a procedure falls both under the *SPS Agreement* and the *TBT Agreement* and a Member challenges delay in that administrative procedure under both *Agreements*, the assessment of whether Annex C(1)(a) of the *SPS Agreement* and Article 5.1.2 of the *TBT Agreement* have been violated should be done in parallel. In this case, the measures in question have given rise to violations under both Annex C(1)(a) and Article 5.1.2.

(i) Mootness

4.889 Whether a claim is moot depends on the particular circumstances of the discontinuation or modification of the measure, viewed in light of the resolution of the overall dispute. The jurisprudence of both the International Court of Justice (ICJ) and the WTO confirm this view. On numerous occasions, *GATT* and WTO panels have exercised their discretion and have delivered rulings on measures that had ceased to exist or had been modified after the establishment of a panel. Canada submits that the question of mootness is not relevant to Canada's claims related to the *moratorium* because the *moratorium* has not ceased to exist and the product applications listed in Canada's panel request remain unresolved. In addition, none of the EC member State national measures listed in Canada's panel request have been withdrawn.

3. Canada's claims

(a) Moratorium

4.890 The European Communities denies the existence of the *moratorium*, asserts that it is not a measure, argues, in the alternative, that it no longer exists, that it is of a "mixed" nature and, that it is justified as a provisional measure under Article 5.7 of the *SPS Agreement*.

4.891 Essentially, the European Communities argues that no *moratorium* exists, and that the complaints arise from a series of coincidental delays. According to the European Communities, this case should be viewed exclusively through the lens of Annex C of the *SPS Agreement*, and the sole legal question is whether the delays in this procedure are "undue". While the complaining parties have advanced claims under Annex C of the *SPS Agreement*, to characterize this dispute as merely concerning procedural delays is to demonstrate a misunderstanding of its essence.

4.892 First, the evidence shows that the *moratorium* is more than a series of isolated procedural delays. Second, the European Communities' arguments rest on the faulty premise that the operation of the approval procedures for biotech products is insulated from "political" decision-making. Third, the European Communities attempts to deflect analysis of the hard questions about the necessity of effectively suspending an approval system for six years in order to adopt legislative amendments and whether this effective suspension is consistent with the European Communities' WTO obligations. In this case, the suspension of the approval regime for biotech products, and the resulting delay in the completion of those approval procedures, is not justified. Finally, the European Communities seeks to blame the victim.

4.893 The European Communities argues that, because it is not "possible to identify with any precision the precise acts and omissions" that constitute the *moratorium*, the *moratorium* cannot be a measure for the purposes of the *SPS Agreement*. Evidently, the European Communities has not asked its own officials what they meant when they used the term "*moratorium*". In any event, the meaning is abundantly clear from the context in which it was used.

4.894 The European Communities argues that the limited processing of some product applications necessarily implies that there is no *moratorium*. This self-serving interpretation of "*moratorium*" should be rejected. Canada has never argued that the *moratorium* has resulted in the complete shutdown of all aspects of the approval procedures for biotech products. It is at critical junctures in the approval procedure that the relevant EC body effectively has decided not to decide, thereby putting off making decisions on product applications. It is the effective "decision not to decide" that is the source of the *moratorium*.

4.895 The European Communities argues that if the Panel were to conclude that the *moratorium* is a measure, it would have to determine to what extent the *moratorium* comes within the scope of the *SPS Agreement*. The European Communities largely shifts the onus onto the Panel to develop the European Communities' arguments in this regard. However, the European Communities has admitted that the approval procedures for biotech products are, at least in part, SPS measures. Given that the approval procedures are – at least in part – SPS measures, the suspension of the completion of these procedures on the purported basis that the procedures were not adequate to protect against the risks assessed and managed under these procedures, should be considered an SPS measure. Consequently, even on the European Communities' terms, the *moratorium* is, at least in part, an SPS measure.

4.896 The European Communities has failed to advance any detailed argument in response to Canada's claims that the moratorium violates Articles 2.2, 2.3, 5.1, 5.5 and 5.6. Instead, the European Communities asserts that only Article 8 and Annex C apply. This argument ignores the text of Article 2.2 and the fact that SPS measures can be both procedural and substantive in nature. In relation to the *moratorium*, the European Communities asserts vaguely that "the measure would have to be considered to be of a provisional nature applied for reasons of insufficiency of scientific evidence." In this regard, the European Communities appears to rely on the Panel to divine the European Communities' arguments.

(b) The product-specific marketing bans

(i) Oilseed Rape Ms1xRf1 and MsxRf2

4.897 As Canada explained in its Second Written Submission, the European Communities' assertion that for all intents and purposes these products are approved is disingenuous. This is demonstrated by the European Communities' own official documents. In its Second Written Submission, the European Communities fails to advance any argument to refute Canada's claims regarding the *product-specific marketing bans* in relation to these two products.

(ii) Oilseed Rape Ms8/Rf3

4.898 In paragraph 168 of its Second Written Submission, the European Communities fails to mention a number of significant facts, and actually provides evidence that supports Canada's original contention that the product application was not put to a vote. Despite the existence of a positive SCP opinion, despite a delay of 15 months between that opinion and the submission by the Commission of a proposal for approving the product, and despite the readiness of the applicant to meet the extralegal requirements set out in the so-called "Common Position" on revisions to Directive 90/220 and to submit additional information that met those requirements, the Regulatory Committee never actually voted on the product application.

4.899 In relation to paragraph 169, the European Communities fails to point out that the notifier's attempts to comply with the "interim approach" were actually rebuffed by Belgium because of concerns that accepting the applicant's efforts would lead to the lifting of the *moratorium*. Even after

the Belgian scientific experts recommended approval of the revised post-marketing monitoring plan and proposed agricultural guidelines for Ms8xRf3, the Belgian government reiterated its position that this was not to be interpreted as favouring the lifting of the *moratorium*. In short, there is no question that the *moratorium* was being maintained and was having a direct and observable effect on the processing of the application for Ms8xRf3.

4.900 The European Communities also fails to say that the submission of further information by the notifier was necessary, not because of inadequacies relating to the existing legal requirements, but because the application did not meet requirements that had yet to be defined, clarified or given legal effect. Even Belgium recognized that it would be "improper government practice" to require applicants to meet ever-changing requirements.

4.901 In paragraph 172, the European Communities' assertions concerning "significant new risk information", specifically the UK Farm Scale Evaluation ("FSE") and the impact of the herbicide regime associated with the Ms8xRf3 on farmland biodiversity, are specious for several reasons. First, seed approval legislation is distinct from the pesticide approval legislation. In no other instance are the potential impacts on farmland biodiversity by the associated herbicide regime used as a rationalization for not approving a seed. Second, the European Communities has selectively used concerns about farmland biodiversity to block biotech crops while ignoring other issues that may have an impact on farmland biodiversity. Third, and most startling, EC member States have actually authorized the use of the herbicide formulation in question for general use as well as for specific use on genetically modified herbicide-tolerant crops.

4.902 By conditioning biotech product approval on an assessment of risks arising from associated pesticide use, Belgium side-steps the European Communities' own existing pesticide legislation and imposes new barriers to the approval of herbicide-tolerant biotech products, barriers that are not imposed in comparable situations involving herbicide-tolerant non-biotech crops. This demonstrates that Belgium's attempt to use concerns about herbicide use as a rationale for blocking the approval of Ms8xRf3 is arbitrary and unjustified.

4.903 Regarding the FSE, it is important to be clear about its conclusions. The FSE clearly stated that the potential impact on farmland biodiversity was not caused by the biotech product, *per* se, but by the weed management regime used by the farmer. Belgium's refusal to recommend the approval of Ms8xRf3 due to of the FSE is really because the herbicide associated with the crop is <u>too effective</u> in controlling weeds!

4.904 In addition, the UK authorities recognized that many other factors contribute to changes in farmland biodiversity, from the presence of uncropped fields, margins or strips to the type of crop cultivated. The Belgian Competent Authority appears to ignore these conclusions and similar ones of its own scientific experts and seizes upon only one factor that could impact on farmland biodiversity, the use of the herbicide, to the exclusion of all other factors. This is all the more surprising given that one principal criterion for approval of plant protection products is their efficacy. The failure to place the concerns about farmland biodiversity into a broader context demonstrates that Belgium's actions are arbitrary and unjustified.

4.905 The European Communities' assertion that the use of non-selective herbicides, including glufosinate-ammonium, creates unique or unacceptable environmental risks is without merit. Several EC member States have authorized the use of glufosinate-ammonium in accordance with the requirements for plant protection products set out in Directive 91/414/EEC. Incredibly, the Belgian pesticide regulatory authorities have already authorized glufosinate-ammonium for use with genetically modified herbicide tolerant oilseed rape, including Ms8xRf3. Thus, in an act of

extraordinary inconsistency, the Belgium competent authority under Directive 2001/18 refuses to recommend the approval for cultivation of oilseed rape Ms8xRf3 on the basis of concerns relating to the use of a herbicide that its own government agencies have already approved!

(iii) Oilseed Rape GT73

4.906 Now that the European Communities has provided what appears to be complete documentation, any remaining uncertainty about time line calculations can be removed. That documentation shows that the Dutch Competent Authority required at least forty-two months to conduct the initial assessment, instead of the ninety days set out in the legislation. The European Communities' assertion that "this period of time was entirely dedicated to resolving scientific and technical issues" disguises the fact that it took the Competent Authority over three and one half years to issue the initial assessment. It is not reasonable simply to attribute this to "resolving scientific and technical issues". The "slippage in the timetable" caused by the issue of confidentiality should not be attributed to the applicant where the "slippage" arises from an applicant seeking to ensure the fulfilment of the European Communities' obligations, both under the *SPS Agreement* and domestic law, relating to the protection of legitimate commercial interests.

4.907 The movement of the application from the Netherlands to the Community-level in January 2003 does not negate the existence of the *moratorium*. To the contrary, the continued excessive delays arising with each procedural step support a finding that the *moratorium* continues to be maintained. As to the objections lodged by EC member States, Annex II to this submission demonstrates that the objections were without scientific merit. The European Communities' assertions misrepresent or gloss over a number of salient facts, including the failure by the European Communities to respect its own time limits, the apparent disregard by the EC member States for EFSA's opinion at the Regulatory Committee stage, and the failure of Germany to act in a manner consistent with its own previous statements with respect to the conditions necessary to lift the *moratorium*. In short, the repeated, unjustified delays created by the EC member States demonstrate beyond question that the European Communities has violated its obligations under Annex C of the *SPS Agreement* or, alternatively, Article 5 of the *TBT Agreement*, as well as providing clear and compelling evidence that a *moratorium* on the approval of biotech products has been put in place and continues to exist.

(c) The EC member State national measures

4.908 The European Communities' asserts that the complaining parties have not engaged on the facts; in fact, it is the European Communities that has been remarkably reticent in examining the facts and scientific evidence relating to the *EC member State national measures*. This is reflected in the limited space allotted in the European Communities' submissions to an examination of the facts and science surrounding these measures. The table appended to the European Communities' second written submission is completely unsupported by any arguments or references to specific exhibits. Most of the facts and science relating to these measures comes from the complaining parties.

4.909 Nowhere in its submissions does the European Communities disclose that it has already requested the EC member States to lift their bans, nor does it put into evidence any of its correspondence with those member States in this regard, even though new evidence shows that the Commission favours a repeal of the bans.

4.910 The European Communities also repeats its assertion that "[a]ll the Complainants originally stated that member State measures are provisional measures". This assertion is as incorrect now as it was when it was first made. To the contrary, Canada has noted that, despite the requirements of the

European Communities' own legislation, and despite the numerous and uncontradicted risk assessments declaring these products to be safe, the bans have been maintained, thus belying the notion that these measures are of a temporary nature.

4.911 *France's* decision to extend its bans until October 2006 was not taken in an informational vacuum. On 13 February 2004, the French government received expert scientific advice from its own scientists that importing and marketing oilseed rape seeds derived from Topas 19/2 for processing and animal feed purposes hold no greater risks than importing and marketing conventionally bred oilseed rape seeds. Despite this advice, France extended its ban on oilseed rape seeds derived from Topas 19/2 until October 2006, when the original authorization for this product expires.

4.912 In regard to the cultivation of oilseed rape that has been genetically modified for herbicide tolerance, the French scientific experts found no direct risks to the environment. Any concerns were limited to potential indirect environmental and agronomic management issues arising from the use of the herbicide. As Canada has already demonstrated, however, any concerns held by France with respect to oilseed rape seeds derived from Ms1xRf1 because of the indirect impacts associated with the herbicide glufosinate-ammonium are belied by the fact that France has already authorized the herbicide in question for uses relevant to biotech oilseed rape cultivation, including total weed elimination.

4.913 Regarding the European Communities reference to "different levels of protection sought by different legislators", Canada notes that the European Communities has yet to actually identify these allegedly different levels of protection or the specific products to which they apply, and has yet to identify the specific "legislators" to which it is referring. To assert, as the European Communities does, the national bans are justified on the simple grounds that some mysterious legislator somewhere has in mind an unspecified level of protection, one that is allegedly higher than that intended to be achieved by the Community legislation, is to make a mockery of the rigorous requirements found in the *SPS Agreement* with respect to basing SPS measures on scientific evidence and a risk assessment.

S. THIRD WRITTEN SUBMISSION OF ARGENTINA

1. Introduction

4.914 Argentina's further comments concern, in particular, the information submitted by the European Communities on 30 September 2004 (last set of 5 CD ROMs). In addition, having reserved its rights to develop arguments related to the *TBT Agreement*, Argentina would like to put forward certain comments in this regard as well.

4.915 Argentina wishes to reaffirm that the information provided by the European Communities did not match the positive scientific opinions already issued by the European Communities' scientific committees, which favoured approval of the stalled agricultural biotech products. Moreover, this additional information tends to confirm the information submitted by the European Communities at an earlier stage of this process, in the sense that the European Communities has prevented the applications for agricultural biotech products from reaching final approval, despite the positive scientific opinions. As if this were not enough, the European Communities has itself explicitly acknowledged that this additional information is not relevant to the case. In this respect, Argentina would like to focus on the European Communities' acknowledgement that the relevant information has already been provided. However, taking into consideration the relevant information submitted by the European Communities, Argentina would reply to the additional documentation submitted by the European Communities as follows.

2. Arguments

(a) The *de facto* moratorium

(i) The existence of a de facto moratorium

4.916 Although the European Communities has repeatedly acknowledged the existence of a *de facto* moratorium, it also insists on distorting this fact by referring to issues such as the alleged need for a precise definition of a *de facto* moratorium or the alleged need for specific identification of acts or omissions within the European Communities or the need for a "plan or course of action" or a "decision not to decide".

The "Inter-Service Consultation" phase

4.917 Argentina affirms again that the European Communities has admitted the existence of a *de facto* moratorium. Apart from the declarations and statements made by EC officials, we have demonstrated that the scientific evidence supporting approval of the agricultural biotech products has not been deferred or postponed for mere procedural reasons. From the information on the CD ROMs, it is evident that the European Communities and/or its member States tried to refute or ignore the positive scientific opinions of its Scientific Committees, in order to stall the approval or marketing of agricultural biotech products.

4.918 As we have shown, there are relevant stages within the proceedings, with no legal basis in the approval procedures but with political relevance for stalling the procedure and demonstrate that the European Communities was treating agricultural biotech products "in baskets".

4.919 The "Inter-Service Consultation phase" effectively prevented all the applications – with positive scientific opinions in 1998 – from moving forward: within the Regulatory Committee draft stage, and beginning on 4 September 1998 for all these products, the applications for Falcon GS40 Oilseed rape, MS8xRF3 Oilseed rape, and A5/15 Fodder beet were stalled. Only Bt 531 cotton and RRC 1445 cotton (of particular interest to Argentina) were able to reach the Regulatory Committee voting stage in that year. In respect of these two products, this phase took place twice in September 1998 and May 1999 after there was a lack of a qualified majority vote in February 1999.

4.920 In conclusion, these applications for approval of agricultural biotech products had the following in common: all of them were submitted under Directive 90/220, all of them received a positive scientific opinion within the European Communities before 2000, and all of them underwent an additional stage that was not included in the European Communities' approval legislation, namely, the "Inter-Service Consultation" phase, which is capable of stalling the procedure and reveals the *de facto* moratorium.

4.921 These applications were put to the vote in the Regulatory Committee, where the positive scientific opinions were ignored by those EC member States who voted negatively without any scientific evidence that could override the positive opinions. It is evident that in 1998-1999 the European Communities was revealing its intention not to have any further agricultural biotech products approved. This was confirmed by the "Common Position" and the declarations of several member States, which revealed the position towards agricultural biotech products within the European Communities.

The "Common Position" and the declaration by various member States

4.922 In 1998 the approvals and rejections of applications stopped because the EC legislation was considered inappropriate. In June 1999 the EU Council of Environmental Ministers drew up a document called the "Common Position" for the reform of Directive 90/220. This document stated there would be no approvals until there was new legislation. The Declaration by Denmark, Greece, France, Italy and Luxembourg stated their intention of not allowing more biotech approvals. This position was reiterated in July 2000 during an informal Environment Council meeting in Paris. In Argentina's view, the "Common Position" reveals the European Communities' intention not to approve any more agricultural biotech products.

Regarding the "Interim approach"

4.923 The European Communities' consideration of a change in the legislation created uncertainty about the approvals. As a consequence, several applicants offered to fulfil the requirements contained in the "Common Position", since they had no other choice. Afterwards, in July 2000, the Commission proposed the so-called "Interim approach". This came after a long period of time without approvals and was the result of the applicants' concerns – not of any initiative by the European Communities, as the European Communities asserts.

4.924 Under the "Interim approach" there were neither approvals nor rejections. Moreover, the entry into force of Directive 2001/18 brought the "Interim approach" stage to a close.

4.925 Argentina recalls again what it has previously asserted with regard to what the European Communities calls "progress" in the approval proceedings. This has actually entailed neither approvals nor rejections of applications. The "Interim approach" became just another expression of the *de facto* moratorium.

Further applications receive positive scientific opinions before the entry into force of Directive 2001/18

4.926 While all the applications with a positive scientific opinion dated 1998 were stalled, new applications were in position to be approved thanks to the positive opinion of the Scientific Committees: both Phoe6/Ac Oilseed rape and Bt11 maize received a positive opinion on 30 November 2000 and were to be resubmitted under Directive 2001/18. Both applications were stalled for two years. The same can be argued with reference to the potato, though within a shorter time-frame, since the positive scientific opinion was issued in July 2002.

4.927 In February 2001, six member States reaffirmed their commitment to suspending approvals, on the grounds that the new procedures were inadequate.

4.928 By the end of October 2001, the majority of member States essentially agreed that the moratorium should not be lifted until the full traceability and labelling provisions had entered into force. At an informal meeting of the Environment Council, eight member States effectively rejected the Commission's plan to consider new authorizations, by demanding that the new regulations be in force first. In December 2001, Belgium declared once again that the *de facto* moratorium would have to be maintained until there was proper legislation on traceability and labelling.

4.929 Consequently, the European Communities was clearly announcing its intention to maintain the *de facto* moratorium, even if Directive 2001/18 was to enter into force. This refutes the European

Communities' allegation that any delays should have ended with the entry into force of Directive 2001/18.

4.930 Since 2000 new applications under Directive 90/220 received positive scientific opinions before Directive 2001/18 came in force (October 2002). These applications did not go through any "Inter-Service Consultation" phase (except NK603 maize at a late stage), but they were stalled, some before reaching the Regulatory Committee stage, some within that stage due to the negative vote of certain member States which ignored the positive scientific opinions. In any case, these applications were stalled until Directive 2001/18 came in force and had them all resubmitted with new requirements.

4.931 Additionally, some products received positive scientific opinions under Regulation 258/97, starting a little earlier (September 1999). These products, it will be recalled, did not go through any "Inter-Service Consultation" phase, but were also stalled, both before reaching the Regulatory Committee stage and within that stage.

4.932 In this connection, Argentina cites the situation of GA21 maize: Maize GA 21 C/GB/97/M3/2 (withdrawn in July 2001 due to the decision to discontinue the application, on 21-03-2001) and C/ES/98/01 received a positive scientific opinion from the SCP under Directive 90/220 in September 2000. The application did not reach the Regulatory Committee stage and had to be resubmitted in January 2003 under Directive 2001/18. It was finally withdrawn in September 2003.

4.933 As demonstrated, further applications received positive scientific opinions, favouring their approval, but were stalled within their procedures and some had to be withdrawn.

(ii) Conclusion

4.934 In Argentina's opinion, this element of intent, of deliberate action, which – through the "Common Position", the Declaration of Denmark, Greece, France, Italy and Luxembourg, and the additional "Inter-Service Consultation" phases – is reflected in the approval proceedings, shows that the *de facto* moratorium constitutes a measure and that it is not the mere outcome of a situation that has existed since 1998. From 1998 on there were no more approvals of agricultural biotech products because the European Communities decided that there should be no more approvals of agricultural biotech products. This intention within the European Communities was expressed, made effective, and reiterated over time by several member States.

4.935 After considering the European Communities' reasons for the absence of approvals of new agricultural biotech products between 1998 and the present – insufficiency of Directive 90/220 and the need for replacement by Directive 2001/18, the need for further legislation on traceability, labelling, monitoring, liability, coexistence, etc. – Argentina concludes that they do not release the European Communities from its WTO obligations. None of these reasons should prevent the approval of agricultural biotech products that have received a positive scientific opinion within the European Communities.

4.936 The European Communities referred to the need for even newer legislation on traceability, labelling, monitoring, liability and coexistence. None of this new legislation deals with risk assessment – which the positive scientific opinions by the Scientific Committees do address – so the European Communities cannot disregard the risk assessment undertaken and suspend all approvals without infringing the *SPS Agreement*.

4.937 Argentina not only maintains that the *de facto* moratorium is a current existing measure – and it certainly was at the time that the terms of reference of this Panel were established – but also reiterates that the WTO Agreement is meant to deal with *de facto* measures as well, including any actions or omissions of WTO Members. Otherwise, WTO Members could circumvent their WTO obligations by merely issuing informal measures, which have not been set forth in positive legislation.

(b) The "suspension of processing and failure to consider individual applications for specific products of particular interest to Argentina"

(i) General comments

4.938 Having received the final information from the European Communities relating to the products of interest of Argentina, we realize that the European Communities has not refuted the information, but rather confirmed Argentina's allegations and, consequently, does not overturn the positive scientific opinions from the EC Scientific Committees. Starting from the positive scientific opinions issued by the European Communities itself, and given the resulting non-approval due to the European Communities' deliberate actions aimed at having no agricultural biotech products approved, we once more state that this claim goes far beyond a mere question of delay – as the European Communities would have us believe.

4.939 As Argentina has stated before, since the *de facto* moratorium affects all applications, these relevant additional stages also apply to the products of interest of Argentina, namely, Bt-531 cotton, RRC 1445 cotton, NK 603 maize, GA 21 maize and Soy Lines A2704-12 and A5547-127. In this respect, Argentina reaffirms its arguments contained in its Written Rebuttal.

(ii) Specific products

4.940 In this section, Argentina will refer to the information provided by the European Communities on the last five CD ROMs on 30-09-2004. However, it is useful to recall that the "suspension and failure to consider" has been argued by Argentina starting from when the applications submitted under Directive 90/220 and under Regulation 258/97 were stalled.

4.941 Argentina will once again go through the applications relating to the agricultural biotech products of interest, analysing the documents provided by the European Communities, and demonstrating once again that the additional information does not overturn the positive scientific opinions of the EC Scientific Committees. In fact, all the information demonstrates that the European Communities and/or some of its member States put forward arguments or concerns of a non-scientific nature.

Bt 531 cotton

The proceedings were stalled

4.942 As regards the relevant stages identified by Argentina in its Rebuttal, the additional information submitted by the European Communities confirms that the approval proceedings for Bt 531 cotton under Directive 90/220 (and later Directive 2001/18) were stalled.

Comments on the information provided on the CD ROMs

4.943 Regarding the specific documents submitted by the European Communities relating to Bt 531 cotton under Directive 90/220 and Directive 2001/18, Argentina affirms its position that the positive

scientific opinion by the Scientific Committee on Plants dated 14 July 1998 is the relevant document to be taken into account. The following does not refute this SCP opinion: the launching of the "Inter-Service Consultation" on the draft Commission Decision (4 September 1998); is non-scientific in nature and did not refute the positive scientific opinion; the launching of the vote in the Regulatory Committee (26 November 1998); the Danish request to extend the deadline for a vote to review additional information (30 November 1998); the letter by the *Commissie Genetische Modificatie* (NL) (3 December 1998); the COM note to the effect that the deadline for voting had been extended (4 December 1998); the Belgian request to postpone the vote (10-12-1998); the UK request to postpone the vote (21 December 1998); the note to the effect that the deadline had been extended (23 December 1998); the Opinion of the *Commission du Génie Biomoléculaire* (13 January 1999); the note on the lack of a qualified majority (22 February 1999); the launching of the "Inter-Service Consultation" phase (7 May 1999); the letter (25 July 2001) (as well as the translations (18 February2002)). The European Communities was unable to invoke any scientific evidence capable of refuting the positive scientific opinion dated 14 July 1998.

4.944 Any EC concerns regarding further information on certain issues had been properly answered as of February 2002, but the process remained stalled thanks to the "Inter-Service Consultation" phase that had been in force since May 1999 and continued until Directive 2001/18 came into force in October 2002, requiring all applications to be updated at member State level. For these reasons, Argentina does not accept the European Communities' allegation that it was due to the applicant that the approval procedure did not proceed. From the Regulatory Committee voting stage and the "Inter-Service Consultation" phase the approval procedure for Bt 531 cotton was stalled because of the European Communities, not because of any action or omission on the part of the applicant.

4.945 Additionally, we observe that although it came into force in October 2003, Directive 2001/18 was published in the Official Journal in April 2001. Since the applicant had to submit information under the new legislation, Argentina cannot accept the European Communities' statement concerning "29 months" to fulfil the requirements.

4.946 Argentina will now turn to the last documents at member State level. The following documents does not refute the SCP opinion of July 1998: the letter from the lead CA (1 August 2003); and the NCB letter (2 October 2003).

4.947 In Argentina's opinion, it has been proved that the application for Bt 531 cotton had to pass through several procedural stages not included in the European Communities' legislation, and that reveals a clear intention within the European Communities not to allow the final approval of this agricultural biotech product.

RRC 1445 cotton

The proceedings were stalled

4.948 As to the relevant stages identified by Argentina in its Rebuttal, the additional information submitted by the European Communities has confirmed that the approval proceedings for RRC 1445 cotton under Directive 90/220 (and later Directive 2001/18) were stalled.

Comments on the information provided on the CD ROMs

4.949 Regarding the specific documents submitted by the European Communities relating to RRC 1445 cotton under Directive 90/220 and Directive 2001/18, Argentina reaffirms its position that the positive scientific opinion by the Scientific Committee on Plants dated 14 July 1998 is the relevant

document to be taken into account. The following does not refute the SCP opinion: the launching of the "Inter-Service Consultation" on the draft Commission Decision (4 September 1998); the launching of the vote in the Reg. Comm. (26 November 1998); Denmark's request for an extension of the deadline for a vote to review additional information received by Monsanto (30 November 1998); the letter from the *Commissie Genetische Modificatie* (3 December 1998); the COM note extending the deadline for the vote (4 December 1998); the Belgian request to postpone the vote (10 December 1998); the statement by Austria (13 December 1998); the UK request to postpone the vote and discuss further information recently submitted (21 December 1998); the COM note extending deadline (23 December 1998); the Opinion of the *Commission du Génie Biomoléculaire* (13 January 1999); the COM note concerning a further extension of the deadline for a vote at the request of the lead CA – 26 January 1999 – was procedural in nature and did not rebut the positive scientific opinion of July 1998; the UK response to the European Communities (10 February 1999); the note on the lack of a qualified majority (22 February 1999); the launching of the "Inter-Service Consultation" phase on the draft Council Decision (7 May 1999).

4.950 In the light of the above and according to the European Communities' information, from the launching of the "Inter-Service Consultation" phase in May 1999 to the update under Directive 2001/18 in January 2003, the applicant received no request for further information or clarification, so the European Communities cannot even suggest that the process was ongoing. Additionally, the European Communities was unable to invoke any scientific evidence capable of refuting the positive scientific opinion dated 14 July 1998.

4.951 Argentina will now refer to the last documents at member State level: the following documents do not refute the positive scientific opinion of July 1998: the letter from the lead CA (1 August 2003); the NCB letter (2 October 2003).

NK 603 maize

The proceeding was stalled

4.952 As previously stated, the applications for NK 603 maize were initiated in 2000 under Directive 90/220 (later Directive 2001/18), and in 2001 under Regulation 258/97. In both proceedings, the application received a positive scientific opinion in November 2003. Although NK 603 maize was finally approved after the initiation of this WTO proceeding, this should not impair the ability of the Panel to deliver a finding on the claim relating to this specific product.

Comments on the information provided on the CD ROMs

4.953 The NK 603 maize application under Directive 90/220 was originally submitted in August 2000 and later had to be resubmitted under Directive 2001/18. In this connection, Argentina will refer to information provided by the European Communities on the CD ROMs. NK 603 maize received a positive scientific opinion from EFSA dated 25 November 2003, which is the relevant document to be taken into account. The following does not refute the EFSA opinion: the documents and stages prior to the positive scientific opinion (25 November 2003); the launching of the "Inter-Service Consultation" on the draft Commission Decision (8 December 2003); the lack of a qualified majority in the Regulatory Committee (18 February 2004) – does not reflect the positive scientific opinion and is rather procedural in nature; it demonstrates that some member States continue to vote negatively despite the scientific evidence; the transmission of the proposal to the Council (26 March 2004); the position of Denmark (4 June 2004).

4.954 Regarding the specific documents submitted by the European Communities relating to NK 603 maize under Regulation 258/97 (originally submitted under this Regulation in April 2001), a positive scientific opinion was received from EFSA, dated 25 November 2003 which is the relevant document to be taken into account. The draft decision presented to the Regulatory Committee (no qualified majority) – 30 April 2004 – was procedural in nature.

GA 21 maize

The proceeding was stalled

4.955 Although the application for GA 21 maize was withdrawn in September 2003 under the a Directive 90/220 (later Directive 2001/18), Argentina considers this withdrawal to be evidence of a *de facto* moratorium proceeding and of the "suspension and failure to consider". The application made no progress in the proceedings and was withdrawn.

Comments on the information provided on the CD ROMs

4.956 Concerning the specific documents submitted by the European Communities relating to GA 21 maize under Directive 90/220 and Directive 2001/18, Argentina reaffirms its position that the positive scientific opinion by the Scientific Committee on Plants dated 22 September 2000 is the relevant document to be taken into account.

4.957 The positive opinion dated 22 September 2000 was followed by: the letter (19 January 2001); the Spanish letter (21 March 2001); the letter (decision to discontinue UK notification) (21 March 2001); the undertakings to fulfil the requirements of Directive 2001/18 (21 September 2001); the updates and commitments (18 March 2002); the new SNIF and updated risk assessment (15 January 2003). These documents are either of a non-scientific nature or are specifically refuted by the scientific arguments submitted by Argentina. The application was finally withdrawn (15 September 2003).

(c) "Undue delay"

4.958 With respect to "undue delay", after analysing the information and chronologies submitted by the European Communities, Argentina affirms and demonstrates that the delays that occurred during the proceedings were not on the part of the applicants, but on the part of the European Communities and/or its member States. We do not accept the European Communities' allegation in this respect.

4.959 Concerning Bt 531 cotton, there were no delays on the part of the applicant following the issuance of the positive scientific opinion (July 1998). The alleged objections in the Regulatory Committee were scientifically contested by Argentina, inasmuch as they do not match the positive opinion of the Scientific Committee. Additionally, we do not accept the delay of 29 months plus 7 months attributed to the applicant either, since, as previously stated, there are no EC documents specifically requesting information that might suggest delay on the part of the applicant. As to the European Communities' assertion regarding the need to have the monitoring plan completed, the monitoring plan was originally presented in December 1996 with the applicant's first notification, and that this monitoring plan received a positive scientific opinion in July 1998. Thus, we cannot accept a vague and general assertion that the monitoring plan was incomplete.

4.960 In connection with the European Communities' statements concerning RRC 1445 cotton, we consider them to be irrelevant as well. The outcome of the written procedure in the Regulatory

Committee that the European Communities mentions has already been scientifically addressed by Argentina.

4.961 As regards the monitoring plan to be completed, Argentina agrees with the European Communities that this monitoring plan was requested under Directive 2001/18. For the same reason, we also stress that this plan was presented by the applicant on January 2003, and that the European Communities' requests for additional information were made in August and October.

4.962 With reference to the case of NK 603 maize under Directive 90/220 and Directive 2001/18, as well as under Regulation 258/97, Argentina reiterates that these two proceedings were started in August 2000 and April 2001 respectively, and that there had been no further progress as of August 2003. For the above-mentioned reasons, Argentina considers that the specific agricultural biotech products of particular interest were affected by "undue delay" in their approval procedures following their submission to the European Communities.

(d) *TBT Agreement*

4.963 As stated at the outset of this Supplementary Rebuttal, Argentina would like to elaborate further on its alternative arguments relating to the *TBT Agreement*.

(i) Technical regulation

Article 2.1 of the *TBT Agreement*

4.964 The European Communities has not explained in any detail the supposedly proper interpretation to be given to the words "in respect of technical regulations" contained in Article 2.1 of the *TBT Agreement*. However, it can be inferred that the European Communities considers this phrase to refer to less favourable treatment within the limited scope of a single regulation, without explaining the reasons why.

4.965 However, there is no basis for considering that likeness should properly be understood "as relating to products within the field of application of the technical regulation", as the European Communities asserts. If this were the case, it would be very easy for Members to circumvent their WTO obligations. Moreover, the only practical result of such an interpretation would be that simply by applying different legislation to products that are actually "like" a Member could avoid scrutiny under WTO rules and, thus, engage in "less favourable treatment" without any legal consequences.

4.966 Argentina considers that Article 2.1 of the *TBT Agreement* basically develops obligations similar to those of Article III.4 of the GATT 1994. Thus, the phrase "in respect of technical regulations" simply reflects the difference in scope between Article 2.1 of the *TBT Agreement* and Article III.4 of the GATT 1994, which applies the same disciplines but to a much broader range of measures.

Article 2.2 of the *TBT Agreement*

4.967 With reference to this part of the European Communities' rebuttal, Argentina would first like to point out that it has challenged, in the alternative, the application of the EC legislation under the *TBT Agreement*. In this respect, as Argentina has made clear throughout its presentations in these proceedings, the European Communities' legislation *per se* has not been challenged, only the application of that legislation.

4.968 The European Communities affirms that "… the prohibition on marketing, pending authorization is the very essence of the GMO legislation – not an application of it …". Contrary to this assertion by the European Communities, Argentina considers that the "very essence of the GMO legislation" is not "the prohibition on marketing pending authorization" but assessing the suitability of products in order to approve or reject them for release into the environment or for consumption as food or feed.

4.969 It should also be pointed out that the concept of "application" includes not only the act of approval (or rejection) but also the failure to approve (or reject), as in the case before the Panel.

4.970 The European Communities also repeats its recurrent allegation that what the complaining parties are actually claiming is a delay that is more restrictive than necessary. Argentina has already made its claim clear enough in this regard. Argentina wonders whether it is possible to consider that, for example, in the cases of Bt 531 cotton and RRC 1445 cotton, the passage of six years after a positive assessment by the competent scientific committee with no approval or rejection can somehow be regarded as "the provisional absence of a final decision". Argentina considers the answer to this is obviously no.

4.971 Moreover, WTO Members are being adversely affected by this EC infringement of Article 2.2 of the *TBT Agreement*, since according to that Article "*Members shall ensure that technical regulations are not … applied with … the effect of creating unnecessary obstacles to international trade …* ". It seems reasonable to infer that, although the article refers to the way in which Members apply technical regulations, it also refers to non-compliance of those regulations (in the present case, the European Communities' approval system).

4.972 The European Communities also asserts that there is no obligation to conduct a risk assessment under Article 2.2 of the *TBT Agreement*. However, probably as a second thought, immediately after this assertion the European Communities makes clear that "In any event, the European Communities is currently in the process of assessing the risks in order to authorize these products". It seems that the European Communities is acting in this way 'just in case', which to some extent reveals the inconsistency of its own arguments.

4.973 The European Communities' argument has no basis in the text of Article 2.2 of the *TBT Agreement* because this article establishes that "… *In assessing such risk, relevant elements of consideration are, inter alia: available scientific and technical information* …".

4.974 The European Communities is therefore bound to make an 'assessment' because Article 2.2 of the *TBT Agreement* refers to this obligation. Moreover, in assessing such risk, 'available scientific and technical information' constitutes 'relevant elements' of consideration. These "relevant elements" of consideration are the positive scientific opinions of the European Communities' scientific committees. The European Communities also challenges the assessment of its own Scientific Committees by asserting that "The European Communities fundamentally disagrees that it has been demonstrated that there is no risk associated with the relevant products" although, three paragraphs earlier it asserts that "EC GMO legislation is not a matter before this Panel". The Scientific Committees being so relevant to the European Communities' approval legislation, it is difficult to see how they can be challenged without challenging the relevant legislation.

4.975 Moreover, the European Communities does not explain why it is wrong to break the provision down into three components. The European Communities' assertion that "whether or not the objective is actually fulfilled in fact is irrelevant provided that the measure contributes or is capable of contributing to that objective", is not explained either.

4.976 However, in Argentina's view, the phrase "technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create" in Article 2.2 of the *TBT Agreement* must be considered to entail a meaning. If the objective is not achieved, the application of the respective technical regulation becomes inconsistent with that article.

4.977 It must be pointed out that the European Communities is definitely "avoiding risk assessment" since it has not taken the positive scientific opinions into account, and is "making decisions not based on a risk assessment", for similar reasons.

4.978 The European Communities' assertion to the effect that "Those opinions (EC Scientific Committee opinions) may or may not be sufficient for the Commission or the Council, and may at the same time be insufficient for the member States" only reveals the lack of a basis for the European Communities' arguments since there is no scientific evidence that might jeopardize the opinions of those Committees.

4.979 Finally, the European Communities alleges that "Article 2.2 of the *TBT Agreement* does not even use the precise words 'risk assessment'". However, as that article is worded "*In assessing such risks*", it is difficult to see how a Member can 'assess a risk' other than by carrying out an assessment of it (the risk). It is important to note that this article stipulates that " … *In assessing such risks, relevant elements of consideration are, inter alia: available scientific and technical information* … ".

4.980 However, as already explained, the European Communities has insisted and confirmed that it "is currently in the process of assessing the risks in order to decide whether to authorize these products". What would be the reason for undertaking such an assessment if there was absolutely no obligation to do so under Article 2.2 of the *TBT Agreement*?

(ii) Conformity assessment procedure

Article 5.1.1 of the *TBT Agreement*

4.981 It has been shown that the application of the European Communities' legislation is inconsistent with this provision since agricultural biotech products receive less favourable treatment than non-biotech products.

Article 5.1.2 of the *TBT Agreement*

4.982 The European Communities only refers to "release into the environment" and does not explain the situation of products which have received positive opinions from the EC Scientific Committees to the effect that they do not entail any risks for the environment. In other words, the European Communities simply denies any inconsistency with this article on its part.

Article 5.2.1 of the *TBT Agreement*

4.983 The European Communities simply refers to the meaning of "as expeditiously as possible", and asserts that Argentina has not proved inconsistency in the context of the specific product applications. The paragraph affirming that the complaining parties have not proved it sounds strange since there have been no approvals or rejections at all since 1998. Nor has there been any scientific evidence to refute the opinions of the EC Scientific Committees. Moreover, Argentina has awarded an argument elsewhere and the European Communities has not developed a competing argument.

T. THIRD WRITTEN SUBMISSION OF THE EUROPEAN COMMUNITIES

1. Introduction

4.984 The European Communities welcomes the course that the Panel has followed in this dispute after the Second Written Submissions. Rightly, the proceedings have come to focus on certain delays that are alleged to have occurred in individual product applications; and on the question whether such delays were justified.

4.985 At the same time, it has become clearer what the dispute is not about: The dispute is not about a general moratorium, but about individual delays. Furthermore, neither the Panel nor the experts consulted in this dispute are required to decide whether genetically modified organisms (GMOs) *per se* present a risk or not. Nor are they required to decide whether specific GMOs should or should not be authorized in the European Communities: those decisions will in any event have to be made by the authorities of the European Communities on the basis of the relevant legislation, whatever the outcome of this dispute may be. Rather, the experts have the important, but more limited, task to assist the Panel in understanding the scientific background of a number of requests for additional information or objections that have caused delays in the processing of individual product applications.

4.986 The Complaining parties have come to realize that they can only prove their case if they demonstrate instances of 'undue delay' for each individual product application. In their Second Written Submissions they had still relied almost exclusively on the existence of an ominous 'general moratorium'. Manifestly, the assertion of such a moratorium (whatever the exact definition of such a non-measure may be) was to serve one main purpose, namely to relieve the complaining parties of their burden of proof with respect to specific problems that the complaining parties allege to have occurred during various product applications. To the extent they have at all addressed individual product applications their allegations are sketchy or manifestly unfounded. Supposedly it is with this third written submission that the complaining parties now intend to finally address the issue of delay in a proper way.

4.987 The European Communities put all relevant facts 'on the table' in its First Written Submission. Since the complaining parties have not so far come back to the facts and the legal arguments presented by the European Communities, there is little that the European Communities can add to its previous Submissions at this stage. In light of the course the proceedings have taken, however, the European Communities would like to take the opportunity to address a few key issues it considers pertinent at this stage of the proceedings.

4.988 First, it would like to point out that the complaining parties have not met the onus of proving their case. The European Communities then wishes to draw the Panel's attention to the role of panels and expert advice under the DSU with a view to assisting the Panel in making its factual findings. Finally, the European Communities will sketch certain implications that the principle of procedural fairness has on the Panel's selection of potential questions to experts in the complaining parties' third written submissions.

2. The burden of proof

4.989 As the European Communities explained in detail in its Second Written Submission[83], it is for the complaining parties to establish a *prima facie* case. The failure of the complaining parties to

[83] Paras. 10 et seq.; paras. 248 et seq.

address each and every delay in its Second Written Submission is particularly regrettable in view of the fact that the European Communities presented detailed chronologies and additional documentation since the very beginning of this procedure. Documents subsequently made available by the European Communities merely serve to support the facts known to the Panel, without adding any substantive new facts. On the basis of this information, the European Communities has entirely refuted the complaining parties' original contention that the procedures have been "stalled". It has demonstrated that all notifications have been continuously processed and that, to the extent that delays have occurred, these delays occurred for legitimate reasons.

4.990 Since the European Communities has, thus, refuted the contention that procedures have been "stalled", it is for the complaining parties to present a *prima facie* case of undue delay with respect to each individual product application. The complaining parties have not taken this opportunity in their Second Written Submissions.

4.991 Instead of presenting detailed facts and arguments which would warrant the conclusion that 'undue delays' occurred, the complaining parties' discussion of individual product applications is mostly reduced to a particular *legal* argument, which runs like a red thread through their Submissions: that the European Communities is under a WTO obligation to authorize a product application, once an advisory scientific committee has issued a 'favourable' scientific opinion. The European Communities has demonstrated that this legal argument is simplistic and erroneous as a matter of law.[84] In any event, a legal argument – persuasive or not – is never a substitute for a rigorous presentation of the facts that are necessary for the Panel to reach its conclusions.

4.992 The failure on the part of the complaining parties to present a *prima facie* case with regard to each individual product application cannot be 'compensated' by reference to additional information that may be contained in expert opinions. The Panel must not make the case for the complaining parties. In *Japan – Agricultural Products II*, the Appellate Body confirmed this fundamental rule of evidence valid also in WTO proceedings:

> "Article 13 of the DSU and Article 11.2 of the *SPS Agreement* suggest that panels have a significant investigative authority. However, this authority cannot be used by a panel to rule in favour of a complaining party which has not established a *prima facie* case of inconsistency based on specific legal claims asserted by it. A panel is entitled to seek information and advice from experts and from any other relevant source it chooses, pursuant to Article 13 of the DSU and, in an SPS case, Article 11.2 of the *SPS Agreement*, to help it to understand and evaluate the evidence submitted and the arguments made by the parties, but not to make the case for a complaining party."[85]

4.993 Hence, the Panel can only base its findings on expert advice to the extent that complaining parties have asserted all such facts necessary to substantiate their claims. The Appellate Body in *Japan – Agricultural Products II* overruled the panel on the ground that it based itself on information not expressly asserted by the complaining party:

> "In the present case, the Panel was correct to seek information and advice from experts to help it to understand and evaluate the evidence submitted and the

[84] The procedure requires the *regulator* (other than the scientific body) to take account of various non-SPS concerns and the Community legislation which sets this procedure is not at issue in this case. *See* second written submission of the European Communities, paras. 27 et seq.

[85] Appellate Body Report, *Japan – Agricultural Products II*, para. 129.

> arguments made by the United States and Japan with regard to the alleged violation of Article 5.6. The Panel erred, however, when it used that expert information and advice as the basis for a finding of inconsistency with Article 5.6, since the United States did not establish a *prima facie* case of inconsistency with Article 5.6 based on claims relating to the 'determination of sorption levels'".[86]

4.994 The European Communities welcomes the fact that the Panel took the opportunity to seek extensive background information and technical advice from experts. At the same time, it invites the Panel to be mindful of the fact that such expert advice does not alter the burden of proof. It is entirely on the complaining parties to present a *prima facie* case of inconsistency with WTO law; and to refute any such evidence presented by the European Communities to the contrary.

3. The role of the Panel

4.995 The present dispute has arrived at a very delicate junction. The Panel has used its right pursuant to Article 13 of the DSU and Article 11.2 of the *SPS Agreement* to consult several experts on certain aspects of GMOs. The Panel has sought expert advice both with a view to receiving general background information and to clarifying specific questions of science regarding individual product applications. As a result, the Panel will need to evaluate extensive scientific evidence to reach its finding. To assist the Panel in this task, the European Communities wishes to draw the Panel's attention to the particular role of panels and experts under the DSU.

4.996 The role of panels in WTO dispute settlement is set by Article 11 of the DSU. It provides that a panel must make an "objective assessment" of the facts. Consequently, the standard of review to be applied by panels is neither 'total deference' to a factual determination by a Member's authority nor a *de novo* review of such a determination, allowing the panel complete freedom to come to a different view than the competent authority.[87] As the Appellate Body noted, a panel is not tasked to "substitute [its] own conclusions for those of the competent authorities."[88]

4.997 A distinguished, former chairman of the Appellate Body wrote on this issue: "the panel should accord a considerable degree of discretion to national authorities in the determination and assessment of facts." In particular, a panel cannot "displace the national authority" by rejecting findings made by such an authority on the grounds that it considers other findings more warranted. Finally, a panel is bound to "respect the parameters of the national authority's own investigation."[89]

4.998 In *US – Cotton Yarn*, the Appellate Body had the occasion to further elaborate on and clarify the line that is to be drawn between permissible "objective assessment" and prohibited *"de novo* review":

> "In our view, a *panel* reviewing the due diligence exercised by a Member […] has to put itself in the place of that Member at the time it makes its determination. Consequently, a panel must not consider evidence which did not exist *at that point in time*. A Member cannot, of course, be faulted for not having taken into account what it could not have known when making its determination. If a panel were to examine such evidence, the panel would, in effect, be conducting a *de novo* review and it

[86] Appellate Body Report, *Japan – Agricultural Products II*, para. 130.
[87] Appellate Body Report, *EC – Hormones*, para. 117.
[88] Appellate Body Report, *US – Lamb*, para. 106.
[89] C.-D. Ehlermann, N. Lockhart, "Standard of Review in WTO Law", 7 *Journal of International Economic Law* (2004) 491, at 502.

> would be doing so without having had the benefit of the views of the interested parties. The panel would be assessing the due diligence of a Member in reaching its conclusions and making its projections with the benefit of hindsight and would, in effect, be reinvestigating the market situation and substituting its own judgement for that of the Member. In our view, this would be inconsistent with the standard of a panel's review under Article 11 of the DSU."[90]

4.999 The Appellate Body's ruling in *US – Cotton Yarn* is of perfect relevance for delimitating the panel's standard of review in the present case. The obligation "to put itself in the place of that Member at the time it makes its determination" has several consequences for the present Panel. Thus, the Panel must look at the state of scientific information and data existing at the time of the measure in question (in this case, the alleged "delay") rather than, from an *ex post* perspective, at the current state of scientific knowledge.[91] On this basis, all answers by the experts to questions which relate to specific products as well as to those that aim at giving the Panel a scientific background to the dispute need to take into account this *décalage* in time between the current scientific knowledge and the scientific knowledge at the time of the alleged "delay".

4.1000 Moreover, the requirement of an "objective assessment of the facts" largely depends on the concrete question at issue and the provisions of WTO law on which a claim is based. As the same distinguished commentator put it, "[c]ertainly, panels perform an 'objective assessment'; but the scope and intensity of the panel's assessment is not the same for every issue, in every dispute."[92] For the *SPS Agreement,* the Appellate Body stated in *EC – Hormones*:

> "The standard of review appropriately applicable in proceedings under the *SPS Agreement*, of course, must reflect the balance established in that Agreement between the jurisdictional competences conceded by the Members to the WTO and the jurisdictional competences retained by the Members for themselves. To adopt a standard of review not clearly rooted in the text of the *SPS Agreement* itself may well amount to changing that finely drawn balance; and neither a panel not the Appellate Body is authorized to do that."[93]

4.1001 Hence, in the present case, the Panel must take account of the carefully struck balance between jurisdictional competence of the WTO and the sovereignty of its Members as reflected in the relevant covered agreement. This balance, in turn, is expressed differently in different provisions of the covered agreement. In the case of the *SPS Agreement,* an Article 5.2 claim may warrant a relatively strict review of the examination undertaken by a Member's competent authority. By contrast, the more general wording of Article 1(a) of Annex C of the *SPS Agreement* ("without undue delay") indicates a more deferential standard of review.

4.1002 The latter provision is central to the present dispute. The "fine balance" drawn by the *SPS Agreement* is reflected in the notion of "undue delay". When considering the issue of "undue delay", the Panel is not required (or permitted) to engage in a *de novo* review of individual product applications. Rather, the Panel merely needs to look at the applications to satisfy itself that such delays that may have occurred were based on a reasonable justification. In other words, the Panel is

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[90] Appellate Body Report, *US – Cotton Yarn*, para. 78 (emphasis original).

[91] *See* also C.-D. Ehlermann, N. Lockhart, cited above, at 502: "This constraint influences the temporal scope of the panel's factual review. To remain in the 'place' of the national authority, the panel is not entitled to examine new facts that were not, or could not, have been included in the national authority's investigation."

[92] C.-D. Ehlermann, N. Lockhart, cited above, at 496.

[93] Appellate Body Report, *EC – Hormones*, para. 115.

not asked to determine whether a prudent government, in the abstract, *should* have behaved or not in a certain manner thus causing delay. It merely needs to find whether, in the concrete case and in light of the factual information and the legal arguments before the relevant authorities, that behaviour which in the end caused a delay *could* justifiably have been adopted.

4.1003 In this context, the European Communities notes that some questions to the experts[94] could be interpreted as coming close to a (prohibited) *de novo* review of product applications. For example, in the General Questions section, the Panel repeatedly asked whether "[o]n the basis of the information before the Panel, [*there is*] any scientific evidence to support the hypothesis that" certain risks may ensue from GMOs. The European Communities does not dispute the right of the Panel to request such *background* information that it considers useful for its understanding of the current scientific debate on GMOs. However, when making its findings, the Panel must be mindful of the proper standard of review. In line with the Appellate Body holding in *US – Cotton Yarn*, the relevant point in time is the time of the adoption of the measure alleged to be WTO inconsistent. For example, to decide whether a request for information was justified, it will be necessary to inquire in the state of scientific knowledge or uncertainty at the time the information was requested.[95]

4. The function of expert advice

4.1004 The proceedings have moved to the stage of expert consultation. In deciding to consult experts pursuant to Article 13 of the DSU and Article 11.2 of the *SPS Agreement*, the Panel has acknowledged the importance of certain scientific questions for resolving the present dispute.

4.1005 The European Communities notes that many of the questions invite the experts to respond "on the basis of the information before the Panel" or "given the information before the Panel".[96] As the European Communities has previously noted, the experts should also be requested to provide the Panel with other information of which they may be aware even if it is not "before the Panel". The European Communities, therefore, welcomes the fact that the Panel has invited the experts to do this in its letters to the experts.

4.1006 As the European Communities has previously argued[97], it is not open to the Panel to ignore the various scientific positions (in addition to the views expressed by the European Communities' own scientific Committees) that have evolved on risk assessment and risk management issues in the international scientific community. To understand the background of this dispute, the Panel must be aware of the various risks that were debated in the scientific world during the relevant period of time. The "General Questions" to the experts demonstrate that the Panel shares this view.

4.1007 Moreover, scientific expertise is essential to assist the Panel in determining whether certain delays that may have occurred were "undue". In this context, the Panel may need to decide whether, for example, the time needed to develop a monitoring plan was excessive, whether certain concerns by the Belgian Biosafety Council were legitimate and reasonable in light of a field study, or whether at the time of a delay, there was a degree of scientific uncertainty about a particular issue. The Panel has understood this second function of expert advice by asking several detailed questions regarding individual product applications.

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[94] Questions to Experts of 12 October 2004.

[95] The European Communities previously expressed this concern in its comments of 24 September 2004 on the draft questions to experts, cf. Explanation Nr. 2 regarding draft Question 1.

[96] *See* for example point 7 of Annex D to the letter of 23 September.

[97] Final Position of the European Communities on the Need to Seek Scientific or Technical Expert Advice, 21 July 2004; Letter of 27 July 2004 to the Chairman of the Panel.

4.1008 By contrast, neither the Panel nor the experts consulted in this dispute are called upon to decide whether GMOs *per se* present a risk or not. Expert advice under the DSU and the *SPS Agreement* does not have the purpose of resolving scientific controversies. Rather, expert advice is provided for assisting the Panel in its limited task of making findings in the dispute between the parties.

4.1009 It is implicit in the function of expert advice to "assist" the Panel that the power to make legal findings, as such, remains a prerogative of the Panel. Pursuant to Article 13.2 of the DSU, expert opinions serve to clarify "a factual issue concerning a scientific or other technical matter". Experts enable panels to fully understand any scientific and technical facts of a case. By contrast, expert opinions do not relieve the Panel of its duty to make an independent *legal* assessment of those facts.

4.1010 A final point on the role of expertise in the present dispute seems pertinent to the European Communities. Expert advice on GMOs is limited to clarifying certain questions relating to scientific risks (i.e. risk assessment in the narrow sense).[98] By contrast, expert advice cannot offer the Panel much indication as to whether certain conduct was reasonably justified from a risk management or risk communication perspective. Just as scientific opinions do not conclude the risk assessment process[99], scientific expert advice in WTO proceedings does not conclude the Panel's assessment whether certain measures could reasonably and justifiably be undertaken. Instead, the Panel will need to reconstruct a process of complex interaction with multiple actors – risk assessment bodies, risk managers or regulators – to evaluate the WTO consistency of the European Communities' actions. Expert advice can only assist the Panel in fulfilling part of this task. The ultimate, overall assessment remains the prerogative and the duty of the Panel.

5. Procedural fairness and the admission of additional questions

4.1011 The principle of procedural fairness requires that each party be able to comment on factual assertions and legal arguments put forward by the opposing party. As the flip side of the same coin, the principle of procedural fairness equally requires that each party present factual evidence as early as possible. This side of the principle is reflected in Appendix 3 to the DSU, which requires a party to present the facts of the case in its first written submission. Each party can, thus, legitimately expect the opposing party to prepare its submissions in accordance with the principles of sound administration of justice.

4.1012 The European Communities notes that the Panel, in its timetable circulated on 28 October 2004, afforded the parties an opportunity to suggest additional questions for the experts at this already exceptional third round of submissions. The complaining parties had extensive opportunity to comment and to suggest questions during the consultation on the draft questions in September. Indeed, the complaining parties, at the time, insisted on obtaining more time in order to review allegedly new information submitted by the European Communities.

4.1013 To the extent that the complaining parties, for reasons of strategy or negligence, failed to previously comment on the European Communities' Submissions and to propose the relevant questions, the European Communities respectfully requests that the Panel refrain from considering such questions now.[100]

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[98] Second written submission of the European Communities, paras. 21 et seq.

[99] Second written submission of the European Communities, para. 31.

[100] It may not be entirely coincidental that the complaining parties asked the Panel for an opportunity to submit third written submissions on 10 August 2004, i.e. right after the Panel's decision to consult experts.

4.1014 Such a selective approach would be in line with the Panel's previous practice in this dispute. The Panel has been very selective, even restrictive, in choosing from the parties' proposals such questions that would be addressed to the experts, rejecting a number of questions proposed by the European Communities. In exercising its discretion with regard to the selection of questions, the Panel has the opportunity to take into consideration the fundamental principles of procedural fairness outlined above.

4.1015 The European Communities reserves its right to suggest additional questions concerning any *new* facts and arguments presented in the complaining parties' third written submissions. For the rest, the European Communities considers it a question of procedural fairness not to re-address, in the disguise of questions to experts, any "old" issues that have already been on the table since its First Written Submission.

4.1016 The principle of procedural fairness raises another issue in this context. According to the timetable, the European Communities will be provided the opportunity to comment on any questions suggested by the complaining parties on 17 November. The European Communities notes that it will have merely four working days to comment on a potentially, large number of scientific questions. In view of the extensive time available to the complaining parties to prepare such questions, the European Communities doubts whether four days will offer sufficient time to study the questions in the appropriate detail and to provide well-founded comments. The European Communities, thus, respectfully invites the Panel to reconsider its timetable in this respect.

U. SECOND ORAL STATEMENT OF THE UNITED STATES ON THE MEETING WITH EXPERTS AND ADDITIONAL SCIENTIFIC EVIDENCE

1. Introduction

4.1017 As the United States has repeatedly explained, the central issue in this case is that the European Communities adopted a moratorium on biotech approvals. Under that moratorium, the European Communities allowed some products to make some progress through the lengthy European Communities' approval procedures, but allowed no product to reach the point of final decision.

4.1018 The central, dispositive legal issues in this dispute – whether the European Communities adopted a moratorium, and whether that moratorium is consistent with the WTO Agreement – do not turn on any scientific issues. However, the United States does believe that the answers to certain scientific questions provide further confirmation of the fact that the European Communities adopted a moratorium. In particular, when an application is delayed until an applicant responds to a scientific question that is not required as a matter of science for completion of a risk assessment, the application has been unduly delayed. Moreover, this evidence must then be added to all of the other evidence confirming the existence of the moratorium.

4.1019 In its third written submission, the United States provided over 20 examples where the questions by member States and EC regulators were not required for assessing risks. Time constraints do not allow us to address each of those examples, but – as the United States addressed in its comments on the experts' responses – the experts' comments confirm that questions were not scientifically justified. In addition, in their testimony last week, the experts did not alter their conclusions on these issues. In short, the scientific issues, and the consultations with the experts, has further confirmed the existence of the moratorium and undue delay in the processing of biotech applications.

2. Evaluating whether particular questions were scientifically justified

4.1020 As the United States has repeatedly explained, the resolution of this dispute does not turn on an examination of each and every member State objection. However, in the event the Panel makes findings on the member State objections examined by the scientists, the United States has three general comments on the issue of whether or not particular member State questions were required for assessing the risk of a product, and on how the Panel should evaluate the experts' views on this subject.

4.1021 First, as a matter of legal interpretation of the *SPS Agreement*, certain objection must be considered as resulting in "undue delay" under Annex C. In particular, where a member fails to make a decision on a product until the applicant answers a question that is so vague and general as to be unanswerable must be considered "undue delay." An example of such an unanswerable question would be "does the product have any adverse impact on any aspect of the environment," where the regulator does not specify what impacts are of concern and what impacts would be considered adverse. In essence, such a question means that the regulator is putting an impossible burden on the applicant to prove the negative – in this example, to prove that there are no adverse impacts on any aspect of the environment. That burden is compounded by the fact that the regulator gives the applicant no guidance. Such types of questions necessarily result in endless delay, which in turn must be considered "undue." Otherwise, a WTO Member could block all product approvals, indefinitely, by posing such vague and general questions. The views of the scientific experts may, however, be helpful in determining whether or not a question is so vague and indeterminate as to be unanswerable.

4.1022 Second, in deciding whether a question contributes to undue delay, or was legitimately posed to assist in assessing risks, the entire factual context of this dispute must be considered. In particular, in examining the objections, the fact that EC political-level officials and member States had announced a moratorium must always be kept in mind. In fact, unnecessary information requests often came from the same member States which had announced the moratorium. The United States submits that the Panel is entitled to employ its common-sense understanding of the entire situation in examining the facts of this case. Indeed, viewing all facts in context is simply part of making "an objective assessment of the matter before it," as provided under Article 11 of the DSU.

4.1023 Third, and relatedly, the fact that an expert is of the view that there was a plausible scientific rationale for a question does not necessarily inform the Panel that the member State asking the question shared that rationale. In many cases, the objection did not specify why additional information was needed, and the experts were left to speculate on the reasoning behind a question. Where the record provides no specific rationale for the question, the experts and the Panel are left to speculate. The experts, and very properly so, were not instructed to examine the member State objections in light of the entire factual context. In contrast, however, we submit that the Panel's objective assessment of the facts should take account of the European Communities' many announcements that it had imposed a moratorium on biotech approvals.

3. The European Communities' comments on the experts' responses

4.1024 I will now turn to the European Communities' comments on the experts' responses. Those comments, although impressive in length, have very little, if any, relevance to dispositive legal issues. Three sections of the European Communities' comments appear to be addressed to the moratorium and undue delay.

4.1025 Part V of the European Communities' comments addresses the experts' responses to the Panel's product specific questions. Time constraints do not allow us to present views on each and

every member State objection that the Panel has considered up to now in this dispute. However, I will make the following general points.

4.1026 Where one or more expert responded that a particular member State request for information was needed for a risk assessment of the products, the European Communities, understandably, supports those views. However, even if the European Communities and the experts' characterization of such member State objections are accurate, the fact that some objections by EC regulators were not unwarranted is still consistent with the existence of the moratorium. The complaining parties have never claimed that each and every member State objection or request for information was unwarranted or resulted in undue delay.

4.1027 Where one or more expert responded that a particular member State request for information was not needed for the assessment of risks, the European Communities, understandably, takes issue with those views. And, I would like to point out that the experts believed that a substantial number of different types of questions, when considered in light of the totality of information available, were unnecessary for conducting a safety assessment. Those types included:

- questions related to the safety of the antibiotic resistance marker genes in these products;
- requests for additional molecular characterization data;
- requests for quantitative, event specific detection methods;
- requests for detailed information on environmental effects when the application sought approval only for import and processing, and not for planting;
- vague and open-ended requests for information on environmental effects;
- requests for chronic toxicity studies;
- requests for additional whole-food studies; and
- requests for studies on the composition of food produced from animals that consumed biotech feed.

4.1028 At the experts' session, the European Communities directly challenged the experts on these issues. In the view of the United States, the experts were persuasive in defending their positions. Should the Panel decide it needs to make findings on those member State objections, based on all the evidence and explanation the United States has provided in its own submissions, the United States supports the views of the experts with regard to scientifically unjustified questions. Findings that such objections were not justified amount to "undue delay" under Annex C of the *SPS Agreement*, and such findings serve as further confirmation of the existence of the moratorium.

4.1029 Parts III and IV of the European Communities' comments on the expert responses address "general and methodological issues" and the Panel's general questions. The theme of these comments are "complexity," "scientific uncertainty," and "evolving science". The European Communities' elaboration on these themes is wildly overstated, which I will turn to shortly. But regardless of their accuracy or inaccuracy – the discussion of such broad themes has little or no role in the resolution of this case. To the extent such themes inform the evaluation of particular member State objections, the

experts and parties have incorporated those themes in their comments on the particular objections. And, to the extent those themes do not relate to individual member State objections, they touch on no issue in this case.

4.1030 The European Communities' general comments appear to be aimed toward the development of an argument that the moratorium falls within article 5.7 of the *SPS Agreement*. The European Communities' general discussion of themes such as "uncertainty," however, does not help the European Communities in the development of any argument under Article 5.7. In fact, Japan – the responding party in the *Japan – Apples* – similarly relied on a general theme of uncertainty, and the Appellate Body firmly rejected it:

> "The application of Article 5.7 is triggered not by the existence of scientific uncertainty, but rather by the insufficiency of scientific evidence. The text of Article 5.7 is clear: it refers to 'cases where relevant scientific evidence is insufficient', not to 'scientific uncertainty'. The two concepts are not interchangeable. Therefore, we are unable to endorse Japan's approach of interpreting Article 5.7 through the prism of 'scientific uncertainty'".[101]

The Panel should do the same here with respect to the European Communities' suggestion.

4.1031 As I noted, the European Communities' discussion of uncertainties and risks associated with biotech products is wildly overstated. The United States addressed this matter comprehensively in Section II.A of its second written submission. I won't repeat that discussion here, except to note that the European Communities' contentions are inconsistent with its own public statements regarding biotech products. For example, the EC Scientific Steering Committee stated that "published review of data do not indicate the GM crops presently in cultivation pose any more risks for humans, animals, and the environment than do their conventional counterparts."

4.1032 In addition, the experts' responses do not support the European Communities' presentation on risks and uncertainties of biotech products. Regarding the potential for these products to present any human health effects, the advice from the experts – both in their written testimony, and during the discussions last week--identified no scientific issues that could justify the European Communities' inability to determine whether the products met its level of protection. Rather, the advice confirmed that the totality of the information presented was generally sufficient to allow the European Communities to evaluate any potential adverse human health effects, even if in the abstract a scientist might have preferred more detailed molecular characterization, or more precise information on a particular point.

4.1033 Furthermore, while the experts believed that issues relating to the evaluation of environmental effects were frequently more complex than those for food safety, the experts also presented various ways to analyse and resolve the issues the European Communities raised. For example, on issues relating to potential effects on non-target organisms, one expert confirmed that although the evaluation of potential effects on non-target organisms can be challenging because it is not possible to study all of the various species, systems, and biogeochemical cycles, several different methodologies to do so are available. The expert (Dr. Andow) mentioned two approaches, one using general environmental indicator species and the other focusing on those non-target organisms that would be expected to be exposed in the agricultural environment where the crops would be grown. The fact that these methods have been available since 1999 calls into question the European Communities' post-hoc justifications.

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[101] Appellate Body Report, *Japan – Apples*, para. 184.

4. Advice from IO's on definitions

4.1034 The European Communities asserts that their interpretations are "effectively confirmed" by various organizations' advice. However, the European Communities provides little or no explanation for its conclusion. In some cases, the European Communities has selectively relied on the advice provided, generally failing to acknowledge the advice regarding how such terms are typically construed and applied. For example, although the European Communities relies on the IPPC's definition of a pest, they do not address the fact that ISPM 11, which was also cited by the IPPC, directly contradicts many of the arguments presented in its first written submission.

4.1035 For other terms, the European Communities relies on artificial, and largely irrelevant, distinctions to support its claim. For example, the European Communities argues that the definition suggested for the term "additive" confirms that the GMO itself is not an additive. This argument is entirely beside the point. Whether the plant itself is an "additive" – a point the United States has never contested – in no way resolves the question of whether the genetic insert or construct in the product is properly considered as an "additive" within the meaning of the *SPS Agreement*. Applesauce that contains food colouring is not itself considered to be a food additive, but it is indisputable that the food colouring contained in the applesauce falls within the definition of an additive in food. And any measure applied to protect human health from risks arising from the food colouring in the applesauce would accordingly be considered an SPS measure.

4.1036 The European Communities raises this same argument with respect to "contaminants," "toxin," and "disease." Whether the organizations' advice confirms that the biotech products are not themselves contaminants or toxins, is utterly irrelevant to whether either the genetic inserts or the substances produced by the inserts are contaminants or toxins. Nor would advice that biotech products are not "diseases" resolve whether measures taken to address any risks that might be presented by the antibiotic marker genes could properly be characterized as a measure taken to address "risks arising from ... disease-causing organisms."

5. Experts' advice and safeguard measures

4.1037 Our discussion of the experts' advice on the safeguard measures is mostly a legal one, so we will present our views on that in our opening statement on legal issues.

V. SECOND ORAL STATEMENT OF CANADA ON THE MEETING WITH EXPERTS AND ADDITIONAL SCIENTIFIC EVIDENCE

1. Comments on the meeting with experts

(a) Introduction

4.1038 Canada has only a few comments to make concerning the discussion with the experts on 17 and 18 February 2005. Due to time constraints, Canada will not address in detail the European Communities' voluminous Comments on the Scientific and Technical Advice to the Panel. However, we would like to note that the European Communities' Comments express many of their own views on the Panel's Questions. Many of the European Communities' assertions appear to rely on scientific evidence dating back many years that was not previously in the record. If this information is or was truly relevant, it is indeed unfortunate that it was not put before the EC Scientific Committees assessing the safety of these products, referred to in the European Communities' Second Written Submission, or indeed, included in its remarkably slim Supplementary Rebuttal Submission.

4.1039 As a result, our comments now will focus on last week's discussion with the experts.

4.1040 As a preliminary point though, I would like to make the observation that the European Communities, throughout this proceeding, has attempted to remove biotechnology from the context of modern agriculture in order to exaggerate risks and scientific uncertainty. Canada, on the other hand, has sought to put biotechnology squarely back into its proper context.

(b) Herbicide Tolerant Crops

4.1041 Drs. Snow, Squire and Andow agreed that, in principle, the ecological effects of herbicide tolerant cropping are similar regardless of whether the HT crop was developed through transgenesis or mutagenesis. So apparently apples are in fact apples after all and not pears. All experts agreed that the potential ecological and agronomic effects depended on the type of herbicide to which the crop was tolerant and not the crop itself.

4.1042 Dr. Snow explained that the key issue is whether the herbicide is used to control weeds in general, but where this is not the case (for example, as with glufosinate-ammonium) then the possible negative effects associated with a loss of the benefit of that herbicide should be minimal. In other words, volunteers and weeds tolerant to glufosinate-ammonium could be controlled using the same methods used to control conventional oilseed rape – that is to say, a different herbicide or tillage.

4.1043 Dr. Andow agreed, pointing out that glyphosate-tolerant plants present a different type of problem because of the wide use of glyphosate generally and the fact that it is one of the safer herbicides on the market. There is obviously a concern about loss of use of that particular herbicide. Dr. Andow confirmed Dr. Snow's advice that there are weeds resistant to imidazolinone, and that there are no reported weeds resistant to glufosinate-ammonium. So, any problems with the development of weed resistance to glufosinate-ammonium HT crops would be no different, and perhaps even less, than resistance to the imi-HT crops.

4.1044 Dr. Snow indicated that she thought there was a problem in Canada with the control of multiple herbicide resistant weeds, but didn't have up-to-date information on this. Considering that over 80 per cent of oilseed rape grown in Canada is HT, it would be folly to expect that there are absolutely no problems. However, all published evidence indicates that HT oilseed rape can be controlled using the same methods as controlling ordinary oilseed rape. The Hall article (Exhibit EC-37), Senior article (Exhibit CDA-194) and the Bright Study (Exhibit CDA-188) all support this conclusion. To describe this as "an extremely difficult problem to manage" is yet another unwarranted exaggeration by the European Communities.

4.1045 Several experts indicated that gene flow amongst oilseed rape is a concern in the European Communities. However, the experts distinguished between the genuine environmental and agronomic concerns and those related to labelling thresholds and co-existence. Dr. Snow indicated that she would not classify the mere presence of a transgene as a problem unless it had adverse biological consequences. Drs. Squire and Snow stated that if the herbicide to which the crops were tolerant was not used for weed control, then no problems should be expected. Now this is entirely consistent with the SCP opinions regarding risks associated with Ms1/Rf1 and Ms8/Rf3 dating as far back as to 1998.

4.1046 As the experts pointed out, gene flow also gives rise to concerns related to so-called "co-existence". But, as the Commission itself has stated and I quote"[i]t is important to make a clear distinction between the economic aspects of co-existence and the environmental and health aspects dealt with under Directive 2001/18". (Here I refer you to Exhibit CDA-165.) Now the experts make this distinction. The European Communities does not. The purely economic aspects of co-existence

arise because of the European Communities' self-imposed arbitrary thresholds for labelling and traceability. The European Communities has attempted to disguise these concerns as environmental harm. Now the experts have unmasked this disguise and confirmed that herbicide tolerant crops that do not cause injury to plant and plant products or environmental hazards, where the herbicide to which the crop is tolerant is not used extensively to control weeds.

(c) Seed Spillage

4.1047 In relation to seed spillage, Dr. Squire cites three studies concerning the in-land transport of recently harvested seeds from the farm to a processing facility. He states that spillage occurs frequently along motorways and fields, but that the seeds eventually die out. He also confirms that seed spillage is a small pollen source compared to the crops themselves. He also agreed with the EFSA opinion regarding the potential for seed spillage and the necessity of a monitoring plan. This is the EFSA opinion in relation to GT73.

4.1048 Dr. Andow in his written opinion agrees that environmental harm from seed spillage is negligible if not nil. He states at paragraph 62.01 that and I quote "it would require escape during importation and/or processing and several years of multiplication at levels similar to the multiplication during oilseed rape production and the growing of these large quantities on a landscape". He concludes that even if such a scenario were possible "there would be many, many possible ways to manage this risk".

4.1049 Both Drs. Squire and Snow confirm that the real issue is not environmental harm but perhaps a concern about meeting thresholds for labelling.

(d) Molecular Characterization

4.1050 Dr. Healy puts molecular characterization into its proper context. Although important, it is but one tool used in conducting a safety assessment. Dr. Snape, during the expert hearing, reversed his written advice in relation to oilseed rape Ms8/Rf3, indicating that the information provided by the notifier on molecular characterization was comprehensive and of a high standard and that no more information was necessary to do the safety assessment.

4.1051 In the light of the modification of his original advice, Canada submits that Dr. Snape's written opinion should be given little weight, if any. Dr. Healy's compelling, well-organized advice should be accepted by this Panel without qualification. Dr. Healy confirmed that one needs to examine the totality of information in order to conduct the safety assessment. Dr. Healy also confirmed that it is possible to conduct a safety assessment without a comprehensive molecular characterization. Although a full molecular characterization of products developed through mutagenesis may not be possible, nonetheless a safety assessment would be possible. Dr. Healy also indicated that although it is possible to conduct a complete molecular characterization for biotech crops, it is not always clear how to interpret this data, given natural variations in plants.

(e) Biogeochemical Cycles

4.1052 Dr. Snow responded to this question very concisely. She has not heard of a problem with biotech crops affecting biogeochemical processes. She confirmed that the differences in impact on biogeochemical cycles as between biotech and non-biotech crops would not be significant.

4.1053 Every form of agriculture has the potential to affect biogeochemical processes. As Dr. Andow has indicated, there are literally hundreds of these processes occurring in the soil.

Tellingly, the European Communities appears to show little concern for this issue in relation to other agricultural practices.

(f) Pest Status

4.1054 Dr. Snow confirmed that the assessment of pest status under ISPM No. 11 is related to whether the weed is more difficult to control, not the economic harm to farmers arising from thresholds established for marketing purposes.

(g) Scale-up Effects

4.1055 Scale-up effects was a recurring theme in the experts' advice. Dr. Andow confirmed that changes brought about by biotech crops would be subtle at most if at all. He indicated that any subtle changes could cause a more serious impact if the scale and rapidity of use increased dramatically. This is an inherent risk in any form of monoculture, and as the experts stated, these issues are not limited only to biotech crops. In addition, Dr. Andow stated that any effects from scaling up, can be managed through the adaptation of agronomic practice.

4.1056 Dr. Squire stated that the impacts of current agricultural practices on biodiversity have not been asked before in relation to any other form of agriculture. He said that it is legitimate to ask these questions, but he acknowledged that it would be impossible to gain a better understanding of these impacts without large scale cultivation.

4.1057 Dr. Squire was clear – he said "it's incumbent on us to scrutinize other practices like we do for GMHT. We need consistency – it's not consistent right now."

4.1058 That Mr. Chair is part of the central theme of Canada's case.

(h) Differences in Risks

4.1059 I will now make a few brief comments on mutagenesis and other methods of introducing genetic variation into plants such as radiation and chemically-induced mutagenesis; somaclonal variation; and even conventional selective breeding. Drs. Andow, Healy, Snape and Nutti all agreed that all methods of introducing genetic variation have potential to produce unexpected or unintended effects. The likelihood of changes to the genome varies with the method of genetic modification. This has been discussed in the recent report of the National Academies on the safety of genetically engineered foods. The report placed different methods on a continuum, with selection breeding from within a homogeneous population having the least likelihood of causing unintended changes and mutagenesis techniques the most likelihood. Significantly, the various recombinant DNA techniques fell at different points between these extremes.

(i) Conclusion

4.1060 Under present time constraints, we have not been able to address every issue discussed last week. However, we would be happy to answer any questions the Panel may have.

2. Comments on additional evidence submitted by other parties

4.1061 At the meeting with the experts on 17-18 February 2005, the Panel sought the parties' views on the status of certain documents referenced by the European Communities in its comments on the

experts' replies, but not submitted by the European Communities as exhibits within the deadline set by the Panel.

4.1062 Canada recalls that on 14 February 2005, the European Communities submitted a list of the documents cited to by the European Communities in its comments on the experts' replies, and a CD-ROM that supposedly contained all of the documents on the list. The list included approximately 360 separate documents. Canada also notes that the European Communities' submission of these documents was already some two weeks late.

4.1063 In reviewing the documents on the CD-ROM, it became evident that in at least one case (an article by M.J. Crawley, et al.) the document indicated on the European Communities' list is not the same as the document on the CD-ROM. Canada has been unable to determine whether there are more "substitutions" of this nature.

4.1064 More importantly, the CD-ROM received by Canada actually contains less than half of the documents found on the European Communities' list. In fact, Canada estimates that approximately 170 documents found on the European Communities' list are neither on the CD-ROM, nor among the exhibits already filed by any of the parties.

4.1065 In Canada's view, with the exception of official WTO documents, documents that have not been submitted by the parties as exhibits are not part of the record. Furthermore, no weight should be given to factual assertions or arguments that purport to derive their authority from such documents. There are a number of good reasons that support this view.

4.1066 I refer you to paragraph 12 of the Panel's Working Procedures in this regard. Paragraph 12 reflects standard DSU practice. Its purpose is two-fold. It enables the panel to make an objective assessment of the facts of the case, in accordance with Article 11 of the DSU. It also ensures that the parties have available to them and can consider in a timely manner all of the evidence upon which an opposing party relies.

4.1067 If it were the case that a party could simply refer to evidence in its submissions but not provide that evidence to the Panel and the other parties, opposing parties would be forced to track down that evidence in order to be able to protect their rights. This would impose an extraordinary burden on all parties – including, or perhaps particularly, on developing country parties – and would encourage the proliferation of improper litigation techniques. It would also severely hamper the functioning of panels, and likely have a significant negative effect on the ability of the Secretariat to assist panels in their work.

4.1068 Furthermore, in disputes such as this one, where the Panel has sought scientific expert advice, and the documents in question are extremely technical in nature, it is important for the experts to have full access to all documents on which the parties seek to rely. This is necessary in order to afford the experts an adequate opportunity to prepare for the meeting with the parties, and to assist the Panel as effectively as possible.

4.1069 In short, this is a basic issue of both procedural fairness and efficiency.

4.1070 The question arises whether, at this very late stage in the proceedings, the European Communities should nevertheless be given a last opportunity to submit these documents. In Canada's view, to allow the European Communities to benefit from its own repeated failure to meet the Panel's deadlines would threaten the integrity of the Working Procedures and render Paragraph 12 meaningless. The European Communities has had ample opportunity to submit these documents.

There can be no good reason why the European Communities was unable to produce on a timely basis documents that would have had to be in its possession in order for the European Communities to be able to rely on them when preparing its comments.

4.1071 In addition to plainly being at odds with the Working Procedures, allowing the European Communities to submit these documents at this late stage in the proceedings would significantly undermine the objective of the meeting with the experts and the second meeting of the parties. Moreover, both meetings involve considerable commitments of time and resources by the other parties, the Panel and the experts. Allowing the European Communities to submit these documents now would require the Panel to delay the proceedings further in order to allow the other parties and the experts an adequate opportunity to review and comment on the alleged significance of the documents in question, and then to afford the parties an opportunity to comment on whatever further replies are submitted by the experts.

4.1072 On a final note, as Canada has observed previously in these proceedings, the European Communities' pattern of failing to respond in a timely manner to the Panel's instructions is troubling. To reward the European Communities for its own repeated failures by allowing it to file the missing documents at this stage is to impose the consequences of those failures on the Panel, the other parties, and the experts.

W. SECOND ORAL STATEMENT OF ARGENTINA ON THE MEETING WITH EXPERTS AND ADDITIONAL SCIENTIFIC EVIDENCE

1. Comments on the expert meeting (17-18 February)

4.1073 We respectfully remind the Panel that we did not request this technical advice to be necessary for this case. Argentina considers that this WTO case is of a legal nature, rather than of a scientific one. Nevertheless, after the meetings on 17 and 18 February 2005, we consider the following issues to be relevant for the present case:

(a) Mere information vs. scientific evidence

(i) The relevance of scientific evidence

4.1074 In the current dispute, the European Communities has made every effort to submit more and more information, whether it was relevant or not. This led to a hard work that only confirmed that our initially submitted scientific evidence remained unrefuted.

4.1075 Argentina recalls the Panel's Follow-up Question 4[102], related to the distinction between what regulators "need to know" vs. what is "nice to know", as Dr. Snow had correctly pointed out in her responses.[103] When answering this Follow-up Question 4, Dr. Squire correctly asserted that:

> "If we get what we need to know, we are there."[104]

[102] Follow-up Question 4 from the Panel to Experts, dated 17 February 2005, referring to "General questions", "Safeguard measures" and "Comparison of biotech products to other type of products" (*"Dr. Snow commented that it is not always clear where to make the distinction between what regulators «need to know» vs. what is «nice to know». (…)"*).

[103] Dr. Allison Snow "Responses to Scientific Questions from the Panel", "B. Scientific uncertainty during 1998-2003", second paragraph; 5 January 2005.

[104] Response by Dr. Squire to Follow-up Question 4 from the Panel, on Friday, 18 February 2005.

4.1076 This statement confirms the importance of identifying the necessary scientific evidence in order to make a decision. In this respect, we believe the point has been made that not any kind of additional scientific information is capable of refuting solid scientific evidence. We submitted scientific evidence, while the European Communities submitted a huge amount of information, but not evidence capable of matching the evidence submitted by Argentina.

(ii) Scientific evidence and hypothetical statements

4.1077 We appreciate the fact that Dr. Andow clarified his initially ambiguous answers, during the meetings of experts. Specifically, we appreciate the clarifications referred to his use of hypothetical statements.[105] We believe that the clarification proved to be very useful in order to make our points that there is actually no scientific evidence that can justify the European Communities' measures towards agricultural biotech products since October 1998.

4.1078 In this sense, Argentina highlights the important answer by Dr. Andow in the sense that he certainly agrees[106] with the following statement made by Argentina:

> "The absence of information does not imply the presence of effects".[107]

4.1079 We believe that the European Communities has had more than enough scientific evidence at hand in order to take a valid sanitary or phytosanitary measure and approve the agricultural biotech products, but instead the European Communities has tried to ignore this evidence in this WTO case with a huge amount of information, collected through several publications and extracted from opinions, supposed to refute solid evidence with "uncertainties".

4.1080 As the experts pointed out, there will always be a degree of new scientific findings that will complete or refine the previous knowledge. But this gap of knowledge cannot be used as an excuse for ignoring scientific evidence and applying a sanitary or phytosanitary measure without any supporting scientific evidence. As examples, Argentina welcomes that, during the meetings of experts, two important matters have been finally clarified for us all, disregarding the European Communities' arguments. With regard to horizontal gene transfer, we thank the clarification made by Dr. Squire, which confirmed Argentina's point.[108] Being so, we cannot accept the European Communities' assertion[109] as a valid scientific statement. With regard to the impact of agricultural

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[105] When answering the Questions from Argentina referring to "General questions", "Safeguard measures" and "Comparison of biotech products to other type of products" on Thursday 17 February, Dr. Andow explained that, when making his responses to the Questions from the Panel, he had taken the task "not to weigh the evidence, but to say whether it existed".

[106] Dr. Andow answered to this statement by Argentina submitted in Question 13 (advanced as question 10, referring to "General questions", "Safeguard measures" and "Comparison of biotech products to other type of products"), with the words: *"Certainly. I agree."*

[107] Response by Dr. Andow to Question 13 from Argentina (advanced as question 10, referring to "General questions", "Safeguard measures" and "Comparison of biotech products to other type of products"), in connection with Dr. Andow's paragraph 07.06 in his Response to Questions by the Panel.

[108] Question 32 from Argentina to Dr. Squire, dated 18 February 2005, referring to "Product Specific Questions". In his response, Dr. Squire stated: *"The issue of unlikely refers to the frequency… considering frequency, it is extremely low, time-dependant… whether evolution or agricultural practice is uncertain… There are studies in place… I am not qualified… In general, I agree with the tone of this question."*

[109] *See* Comments by the European Communities on the Scientific and Technical Advice to the Panel, 28 January 2005, paragraph 95, in which the European Communities refers to *"circumstantial evidence… during evolution and confirms the likelihood of the scenario."* Besides, the European Communities immediately says *"However, in terms of risk analysis, the risk has not been properly quantified and is probably very low."*

practice, the known impact of agricultural biotech products is marginal. In this sense, Argentina highlights the fact that even the European Communities had to finally admit this.[110]

(iii) The excuse of waiting for more information to appear

4.1081 It has been made clear that there is no sense in neither approving nor rejecting the approval of agricultural biotech products, just because the European Communities claims that it is waiting for new information to appear, for new technologies to develop, or for new methods and techniques to be discovered, when there is solid scientific evidence at hand.

4.1082 Argentina has carefully read the information submitted by the European Communities, and has found no matching evidence that could refute the positive scientific opinions by the European Communities' scientific committees. The alleged "uncertainties" or "hypothetical risks" do not refute the scientific evidence, and thus cannot justify what the European Communities did towards its WTO obligations.

(iv) The twisted view of the biotechnology – Relevance of science

4.1083 Argentina welcomes the appropriate clarifications by the experts in their responses and during the meetings, for example the use of the concept "contamination". The malicious use of terms has distorted the view in which these products are considered and the way in which they should be treated. Particularly, we would appreciate if the European Communities would restrain itself from using concepts like, "cancer"[111], "may induce dramatic unintended changes"[112], "infestation … to cause contamination"[113], among others.

4.1084 The experts' conclusion is contrary to European Communities' assumption that all agricultural biotech products should be treated as a whole, regardless from the "case-by-case" analysis which Argentina firmly believes should be strictly applied for deciding upon approvals or rejections of agricultural biotech products. The European Communities has continuously invoked this approach as well, but it actually does not apply it since October 1998. Even at these later stages of this WTO proceeding, the European Communities states that agricultural biotech products deserve to be considered as a whole.[114]

4.1085 In this sense, we quote Dr. Snow:

> "… Furthermore, it is not logical to group all GM crops into a single category and conclude that they are either inherently safe or inherently dangerous (*see*

[110] Comments by the European Communities on the Scientific and Technical Advice to the Panel, 28 January 2005, paragraph 238.
[111] *Ibid*.
[112] Comments by the European Communities on the Scientific and Technical Advice to the Panel, 28 January 2005, paragraph 55.
[113] Comments by the European Communities on the Scientific and Technical Advice to the Panel, 28 January 2005, paragraph 191.
[114] Comments by the European Communities on the Scientific and Technical Advice to the Panel, 28 January 2005, paragraph 45, last sentence, in which the European Communities refers to the products in general (not "case-by-case"), regarding possible effects on human health.

> Question 103 below). It is important to evaluate new GM crops on a case-by-case basis in each country where the crop will be grown, …"[115]

(b) Agricultural biotech products and "non-biotech" products

4.1086 Considering the food safety assessment, it has been proved that agricultural biotech products with a positive scientific opinion by the EC Scientific Committees have shown no differences with their "non-biotech" counterparts. Dr. Nutti has been very clear in this matter and has always remained within her field of expertise and referring to the Codex guidelines. We also recall the point made clear on Friday 18 February, regarding the feed safety, in the sense that the given products -crops- proven to be safe for humans, are expected to be safe for animals as well.

4.1087 Considering the no lesser important environmental issue, Argentina had the three experts on this matter to confront their opinions[116], and the result was that they agreed in two decisive statements. Both Dr. Snow[117] and Dr. Andow[118] agreed with the following statement by Dr. Squire, when referring to whether "contamination" risk is greater than for non-GM varieties:

> "… there is no reason to suppose that biotech crops confer different degrees of impurity compared with crops produced from, say, induced mutagenesis."[119]

4.1088 Additionally, both Dr. Squire[120] and Dr. Andow[121] did agree with the following statement of Dr. Snow, when referring to whether any of the biotech products at issue in this dispute poses a substantially greater risk as regards the direct or indirect consequences of unintentional "contamination":

> "Another way to answer this question is to focus on the characteristics of biotech crops -their phenotypes- rather than the mere presence of transgenes. This is more appropriate if the goal is to avoid direct or indirect harms to human, plant or animal health, or the environment. (…)"[122]

4.1089 Argentina observes as well that Dr. Andow agreed with two important statements by Dr. Snow, used by the Panel to put Follow-up Questions 6 and 7 to the experts:

4.1090 On one hand, Dr. Andow did agree when he was asked:

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[115] Dr. Allison Snow "Responses to Scientific Questions from the Panel", "A. Which environmental concerns about GM crops are really «science-based»", second paragraph; 5 January 2005.

[116] Questions from Argentina to Experts, dated 17 February 2005, referring to "Comparison of biotech products to other type of products".

[117] When asked to clarify by Dr. Snow, Dr. Squire stated *"A lot of crops have impurities; some can be ignored, some can be managed."* Consequently, Dr. Snow answered*: "Being so, I agree, because it is related to gene flow, and that is common to GMOs and to non-GMOs."*

[118] After the answer of Dr. Snow, Dr. Andow replied: *"If it refers to gene flow, I agree. It will depend on the goal, on the impurity management."*

[119] Dr. Squire "Measures affecting the approval and marketing of biotech products", "Notes on ecological and environmental standards", Issue 3, response to the Panel's Question 103.

[120] Dr. Squire answered: *"In the context of this question, I agree. In Europe, maybe the presence is not wanted, although there is no effect."*

[121] Dr. Andow responded: *"I agree."*

[122] Dr. Allison Snow "Responses to Scientific Questions from the Panel", "Comparable novel non-biotech products (such as plant products produced by selective breeding, cross-breeding and induced mutagenesis), answer 103, second paragraph; 5 January 2005.

> "Dr. Snow indicated that the process of inserting genes can have unintended consequences such as abnormal growth or development, but it is unlikely that these effects will be ecologically significant in commercially-produced biotech crops or that they would be more risky than the types of side-effects that arise routinely from conventional breeding".[123]

4.1091 On the other hand, he did also agree when asked:

> "Dr. Snow stated that there is no reason to expect different effects on the genetic diversity of wild relatives to arise from the gene flow from biotech as compared to non-biotech crops."[124]

4.1092 This said, we consider that it has been confirmed by the experts that agricultural biotech products with a positive scientific opinion by the EC Scientific Committees do not require a different treatment from the "non-biotech" products, as regards the food and feed safety issue and from the environmental point of view.

2. Comments on "additional scientific evidence"

4.1093 Argentina believes that there is no more evidence needed to be submitted in these proceedings, particularly after the outcome of the expert meeting. Putting it in a different way, the scientific evidence submitted by Argentina – the EC Scientific Committees positive opinions – was not matched by the mere information presented by the European Communities.

X. SECOND ORAL STATEMENT OF THE EUROPEAN COMMUNITIES ON THE MEETING WITH EXPERTS AND ADDITIONAL SCIENTIFIC EVIDENCE

1. Comments on the meeting with experts

4.1094 We had the benefit of hearing directly from the six independent scientific experts appointed by the Panel. The dominant themes that emerge from the experts' advice cannot be ignored by the Panel. We heard that the underlying scientific issues are complex and difficult – two words which were used repeatedly over the two days. We were told that the level of scientific understanding is evolving and that knowledge today is very different from ten years ago, and that five years ago the debate could not even have been held. We were told that each product has to be treated on its own merits. We were told that there are no established international standards to determine levels of ecological safety. We were told that each environment is unique and that you cannot simply transfer experience from one region, such as might be found in the United States, to another, such as might be found in the European Communities. And we were told that comparing GM products with non-GM products was like comparing apples and pears.

4.1095 The complaining parties would have the Panel ignore all of that. They would have the Panel decide against the plain facts and the views of the scientific experts. They would have the Panel decide that the EU should have simply applied the American or Canadian or Argentine experience to its own very different geographic and biological reality; and that even in the face of the insufficiency

[123] Follow-up Question 6 from the Panel to Experts, dated 17 February 2005, referring to "General questions", "Safeguard measures" and "Comparison of biotech products to other type of products". Dr. Andow answered: *"I would agree."*

[124] Follow-up Question 7 from the Panel to Experts, dated 17 February 2005, referring to "General questions", "Safeguard measures" and "Comparison of biotech products to other type of products". Dr. Andow answered: *"I would agree. There is no sense in «biotech vs. non-biotech»."*

of the science none of the delays or the measures adopted were justified. The complaining parties would even have the Panel decide that there is no difference between "apples and pears". We submit that this would bring the WTO system and the DSU to a place it was never intended to be. It was surely not the function of the WTO to be used to allow one country (or group of countries) to impose their own system of values and their own attitude to risk and biosafety on another country or group countries.

4.1096 When Dr. Squire wished the Panel "good luck", he undoubtedly had in mind, from his perspective as a scientist, the monumental task of sorting out definitively the complex, evolving, divergent and contradictory views on the scientific issues. In reality, of course, this Panel's legal task is far more limited than that. And to that end, the scientific advice will eventually have to be placed in its proper legal context.

4.1097 The European Communities believes that the legal rules determine the relevance and significance of the scientific advice. The complaining parties, on the other hand, right from the start of this case, have made several erroneous legal assumptions – not least the claim that the European Communities adopted in 1998 and then maintained thereafter a definitive and general decision not to approve any GM products in Europe. This false assumption has seriously distorted the complaining parties' presentation and appreciation of the science.

4.1098 The scientific experts' advice was generally untainted by the legal context in which it was given. That gives it a special value. It was indeed striking to listen to the closing views of the experts. Taken together, and placed in the proper legal context, in our view, those statements clearly support the legal position of the European Communities in this case. They plainly entitle a WTO member to proceed with prudence and caution in its decision-making processes.

4.1099 In particular, the European Communities invites the Panel to take careful note of the remarkably high degree of consensus among all the experts to the effect that the science of GMOs is highly complex, continuously evolving, and still contains many open questions and uncertainties. On that basis alone, it cannot be right for the Panel to follow the simplistic and reductionist "one size fits all" approach of the complaining parties. We heard was that there is a basis for concern and prudence.

4.1100 The European Communities would like to briefly recall the tenor of some of the advice. Time and again the experts came back to the differences between food safety and environmental protection. Dr. Andow repeatedly stressed that there is a world of difference between these two subjects. Traditional food is generally assumed to be safe for consumption – so GM risk assessment for food safety, whilst still methodologically controversial, can generally start on the basis of comparison. This is simply not true of the environmental risk assessment. Consequently, the complaining parties' central assumption – that there are reliable comparators for environmental purposes – is not supported by the advice. At this time the science is not sufficiently well known. There are many respects in which the overall effect of GM products on the environment – whether negative, neutral or positive – was in 1998 and remains still today uncertain. This was eloquently illustrated by Dr. Andow's description of the far reaching consequences of what he referred to as the "European" earthworm's invasion of the forests of North America; juxtaposed to the beneficial effects of earthworms on soil structure in European agro-ecosystems.

4.1101 Another very striking closing remark made by Dr. Andow – which has been a *leitmotif* of all the expert advice – is the novelty, evolution and rate of change of scientific knowledge on highly complex issues, such as the environmental impact of changes due to the introduction of new agricultural technologies. GM products, Dr. Andow observed, have, to some extent, been swept up in

such developments. This case concerns many issues at the frontiers of science, in which the situation is dynamic and rapidly evolving. Legislators are entitled to be prudent.

4.1102 Dr. Andow also reminded us that, in this increasingly complex and evolving situation, it is legitimate (and even necessary), for assessors and legislators to take into account the way in which different issues are connected. He referred to herbicide resistant GM crops. In this respect, it may be true that one thing is the assessment of the GM product, and another thing is the assessment, done in isolation from the GM crop, of the herbicide used. However, it is now clear that it is legitimate – from a scientific point of view – to take the view that there are cross-cutting issues between the approval of an HTGM crop and the approval of the corresponding herbicide. Most notably, the use of the herbicide may affect the composition of the food or feed resulting from the HTGM crop as compared with its non-GM equivalent. Furthermore, Dr. Andow also reminded us that the newness of some of the herbicide tolerant traits, introduced into several crops in an agricultural environment where these herbicides are already present for other purposes, certainly had raised legitimate scientific questions and concerns for a decision maker. With a growing awareness of such issues comes a growing awareness of the implications of the lack of reliable comparators as regards environmental effects, and a growing awareness of the need to obtain information that is as complete as possible for conducting a full assessment. Time and again the experts advised that prudence and caution were justified.

4.1103 With regard to resistance, Dr. Andow also recalled that, over the last 50 years or so, knowledge about resistance problems had developed progressively. First with respect to insecticides; then with respect to fungicides; and more recently with respect to herbicides. For years entomologists were telling the world, with the introduction of each new insecticide, that there was no way that insect resistance problems would develop. And each time resistant insects would nevertheless emerge. So eventually, during the 1980s, scientists understandably stopped making such predictions. There is now a much greater awareness that it is possible that such problems could arise with a similar or greater impact, in the light of the level of expression of tolerance in GM plants, in the context of herbicide resistance. And glyphosate is an area of particular concern because of the way in which it is already used in the Europe, which reflects the particular agricultural structures in different regions. And Mr. Chairman, Members of the Panel, I would like to add that Glufosinate, although currently of more limited use in Europe, is nevertheless widely used as a main weed killer in orchards and vineyards, close to oilseed rape transport routes and close to major crop fields in Europe. Contrary to Canada's assertion, these are matters of significant and legitimate concern.

4.1104 Dr. Healy confirmed the need for a case-by-case approach. She urged that there be a careful assessment of all the available information. She emphasised that the quality and the quantity of the information were important for the risk assessment. She confirmed that missing information – that is, insufficient science – could legitimately give rise to safety concerns, and that generally the more data one has, the better the safety assessment can be. She indicated her view that, in a number of the applications she looked at when formulating her advice, not all the expected information was present or of sufficient quality.

4.1105 Dr Healy also echoed Dr. Andow's comments about rapidly changing science. She confirmed that scientific knowledge about molecular characterisation techniques has developed extensively over the past decade, particularly as regards the sequencing of the insertion and of the flanking regions. She observed that there has been a rapid evolution in detection methods, and that this accelerated in the late 1990s, with significant implications on the question of specificity in identifying the GMO. Her observations lend support to one of the European Communities' basic legal points: at the frontiers of science, assessors and legislators are entitled to be prudent.

4.1106 Dr. Snow rather memorably noted that learning about the concerns and issues relevant for the agro-ecosystem in the European Communities was like learning about another planet. She indicated that she had appreciated this process, and that, by placing herself in the shoes of the European Communities, she had come to understand that many of the concerns and requests for information were, indeed, valid. Picking-up on the closing remarks of Dr. Andow, and foreshadowing those of Dr. Squire, Dr. Snow indicated a shared concern about mischaracterised comparisons with regard to possible changes in agricultural practices, and their environmental implications. She also confirmed her view that many of the issues remained open as regards co-existence and traceability.

4.1107 Dr. Squire underlined how much has been learnt over the last 5 or 6 years on the scientific and technical aspects of European agro-ecosystems; he observed that the current debate could not even have been conducted a few years ago; and he expressed satisfaction that the relevant issues were now being more fully aired.

4.1108 Dr. Squire also drew the attention of the Panel to the fact that the concerns that were expressed in Europe and the research that had been done in response to them were now reflected in the international consensus reflected in the Codex standards. Accordingly, even though these standards did not exist at the time the European Communities was making many of its requests for further information these requests were compatible with what was later reflected in the standards. Dr. Nutti also confirmed that the Codex process started around 1999-2000 and it took four years to adopt the standard. So in fact, what the complaining parties would perhaps qualify as unnecessary requests, or inaction, has turned out to be the basis for international consensus, and if we have the international standards that we have today is in part thanks to the efforts made by EC authorities to know more.

4.1109 Dr Squire also reminded us that, as regards the environment, we are discussing potential impacts that, whilst not immediately catastrophic or large, did concern small changes that could certainly be significant and that incrementally, over time, could lead to very significant impacts. In the case of co-existence, he expressed the view that even very small changes could have dramatic effects for farmers' livelihoods.

4.1110 Earlier, Dr. Squire had recalled that, in some parts of Europe, and in contrast to the Americas, a very large proportion of land is in agricultural use, so that, in those areas, the "environment" is essentially constituted by agro-ecosystems. Consequently, in these regions of Europe, agricultural management, environmental, conservation and biodiversity issues are inseparable. In this situation, it is perfectly reasonable that the authorities consider that one cannot afford to obliterate a species just because it does not appear to be immediately economically useful. That is because, in complex ways, such species contribute to sustaining the environment that, in turn, supports us. The European Communities shares this view. It does not support the contention of Canada that the purpose of agriculture is to reduce biodiversity, or the apparent view of the United States that the conservation of biodiversity must be limited to specific geographical areas. By contrast, the European geographic and environmental context is materially different, so that one of the objectives of agriculture is the sustainable management of biodiversity. Unlike Canada, the European Communities does not ask the Panel to consider these matters "with respect to the whole world" (as Dr. Snow remarked) – but rather with respect to the specific characteristics of the receiving environment that European decision-makers are charged with protecting.

4.1111 Dr. Snape's comments throughout the experts' meeting often recalled the basic truth that one cannot compare "apples and pears". He made abundantly clear his view that it is perfectly acceptable from a scientific point of view for assessors and legislators to take into account the basic differences between GM and non-GM products. He confirmed the need for an extensive molecular characterisation in order to ensure sufficient knowledge for a proper risk assessment – that is, in order

to identify potential hazards – and in order to be able to assess the potential impact of the GM product.

4.1112 The European Communities has already commented on certain differences in approach between Drs. Snape and Healy. But the meeting with the experts served to clarify that, in fact, Drs. Snape and Healy agree on many issues. For instance, both of them confirmed that sophisticated methods of molecular characterisation were available by 1995. Moreover, Dr. Snape has written, and Dr. Healy explained orally last Friday, that they were surprised by the poor quality of the data submitted by applicants as regards molecular characterisation (with one exception). The European Communities considers that risk assessors are not required to operate on the basis of assumptions or guesses. They are entitled to seek complementary data. If the technology to produce such data was available at that time – as has been confirmed – and it was therefore practicable for companies to provide the data, why shouldn't the EC authorities ask for it? Why should risk assessors rely on second-best, potentially inaccurate, alternatives to carry out their work?

4.1113 Finally, with regard to food safety, Dr. Nutti accepted the general proposition that, at least where international guidelines, such as the Codex, left certain matters open for interpretation, there could be different but equally valid scientific views about how best to proceed, or about the amount of data requested. Where there are no established international standards – as in the case of environmental assessment and protection and notwithstanding the recent adoption of the Biosafety Protocol, which will hopefully lead to the emergence of such standards – Dr. Nutti's point becomes even more valid. Dr. Nutti also clearly admitted that there is a lack of international guidance as regards feed safety assessments – a matter in respect of which, in any event, Dr. Nutti made it very clear that she had not offered any advice to the Panel – and that the issue was therefore much more open than in the case of food safety.

4.1114 Perhaps we should step back and try to achieve some kind of overall perspective on the expert advice. In this respect, the European Communities would like to recall that the complaining parties launched this case on the basis that the science was sufficiently complete and that the science mandates, as the only possible approach, the immediate approval of all the relevant products by the European Communities. The complaining parties' view was that this Panel did not even need any advice from independent experts. Plainly, in the light of what the experts have now advised, the complaining parties' position is untenable. The scientific advice justifies the Communities' prudence and caution. It confirms the need to consider each product on its own merits. It confirms that the European Communities was and is justified in taking the time necessary to obtain the appropriate information – information that the applicants had simply failed to provide – and to consider all of the concerns legitimately raised by scientists, legislators and stakeholders. After the closing statements from the experts, there can be no doubt that the complaining parties' assumptions – and the legal assertions based on those assumptions – have been demonstrated to be wrong.

2. Comments on additional evidence submitted by other parties

4.1115 The European Communities has some difficulties in understanding the Panel's approach to the submission of "additional scientific and technical evidence" and/or "comments". The Panel's invitation to comment, today, on additional evidence submitted by the other parties, for us, is a welcome opportunity to clarify a number of issues.

4.1116 First, the European Communities notes the Panel's and Canada's apparent understanding that "evidence" is solely constituted of scientific papers or other forms of documented scientific expertise (such as the experts' advice) and that *comments* on such evidence do not constitute "evidence". It notes that the United States has accordingly not submitted any scientific evidence at all.

4.1117 The European Communities submitted evidence within the above meaning in its 31 January submission as well as in its 10 February submission and referred to a considerable number of scientific papers. Which leads to the second point.

4.1118 The issue arises as to when evidence within the above meaning can be considered to have been submitted to the Panel. The European Communities notes that the Panel reserved further discussion on this issue for the second meeting. As the European Communities has explained (in its letter of 14 February as well as at the expert meeting), it takes the view that where scientific expertise is publicly available, a reference to the source is enough for the purposes of submitting that evidence to the Panel. Where, on the other hand, such evidence is not publicly available, a copy of the expertise needs to be submitted to the Panel. Based on this understanding, the European Communities has submitted copies of all papers that are not yet published and has provided references to all other published papers it has relied on in its comments. In order, however, to facilitate the Panel's work it has sent, on 14 February, a CD containing copies of papers referred to in its 31 January and in its 10 February submission. The European Communities notes that Argentina has not submitted any copies of the scientific papers it has referred to in its submissions.

4.1119 Third, it is not entirely clear to the European Communities whether there is a difference between comments on additional evidence on the one hand, and comments on comments (on additional evidence) on the other. In a previous version of the timetable of these proceedings, the latter notion had featured, but terminology has changed since then. What complicates issues further is that we have been invited to comment on additional evidence as provided by the other parties today, but will have another opportunity to do so again some time after the hearing.

4.1120 The European Communities does of course have comments on the complaining parties' contentions. They were contained in our 10 February submission, which we annex to the first oral statement at the second meeting of the Panel with the Parties. The complaining parties have had them since 10 February, and the Panel will also have read them before rejecting them.

Y. SECOND ORAL STATEMENT OF THE UNITED STATES ON THE EUROPEAN COMMUNITIES' SECOND AND THIRD SUBMISSIONS

1. Introduction

4.1121 Since the first substantive meeting, hundreds of pages have been written and many, many hours have been expended by all involved. But in terms of the development of the dispositive legal issues, the complaining parties' case has only been further confirmed and remarkably little else has changed. In particular, the central defence of the European Communities – despite the overwhelming evidence to the contrary – remains that the European Communities did not impose a moratorium. The European Communities still has not even attempted to rebut the complaining parties' arguments showing that the moratorium is inconsistent with the *SPS Agreement*. And likewise, the European Communities has still not attempted to explain how its member State safeguard measures could be consistent with the *SPS Agreement*.

2. Developments since the first substantive meeting

4.1122 The European Communities' submissions have provided additional confirmation of the complaining parties' case – even though the complaining parties' first written submissions were more than sufficient and no additional confirmation was required. The confirmation has followed a consistent pattern: the European Communities has repeatedly submitted information supposedly in support of its positions, but each time the European Communities' information is both consistent with

the existence of a moratorium, and indeed provide further support for the complaining parties' contentions that the European Communities has adopted a moratorium and has failed to process applications without "undue delay."

4.1123 The first US written submission provided overwhelming evidence that the European Communities adopted and maintained a moratorium under both its deliberate release and novel food directives. EC officials and bodies from across the range of EC institutions – the Commission, the Council, the Parliament, and member States – have acknowledged the existence of the moratorium. Although no further confirmation is needed, the United States is providing one further official acknowledgment of the moratorium. The United States does so only because the European Communities in this dispute has claimed ignorance of the moratorium, and has asked the complaining parties to explain it. The exhibit, from a French Government website, asks and answer the question, "What is the *de facto* moratorium on GMOs?" The United States suggests that if the European Communities wants a definition of the moratorium, the European Communities should refer to this exhibit, which describes the moratorium, at least in the view of the Government of France.

4.1124 The first US written submission went on to explain that the moratorium was inconsistent with various provisions of the *SPS Agreement*: Articles 2.2, 2.3, 5.1, 5.5, 7, and 8 and Annexes B and C. Among other things, the United States explained that many of the product applications caught up in the moratorium had received positive risk assessments from the European Communities' own scientific committees. But then those applications failed to make further progress when the applications reached a political level – in particular, when the European Communities refused to submit the applications to a vote by member States in the European Communities' regulatory committee.

4.1125 The European Communities in its first written submission attempted to rebut the US *prima facie* case by arguing that any and all delays were the result of legitimate scientific questions, and by relying on certain exhibits to its first written submission. Those exhibits contained chronologies of the approval process for a number of products, along with only a small selection of the underlying documents cited in the chronologies.

4.1126 As the United States explained at the first substantive meeting, the European Communities' chronologies were perfectly consistent with the existence of a moratorium. The chronologies showed some questions from regulators and some responses, and some progress, but at the end of the day no decisions were made. Moreover, certain chronologies contained lengthy, unjustified gaps – of over two years – for which no explanation other than the European Communities' adoption of a moratorium were plausible.

4.1127 Also at the first meeting, the European Communities represented to the Panel that each of the member State objections and questions resulted from conflicting risk assessments, and thus that all delays were warranted to address outstanding scientific issues. When the Panel asked the European Communities to point out those risk assessments in the exhibits provided with the European Communities' first written submission, the European Communities explained that such documents were held by the member States. In other words, the European Communities had made representations to the Panel about a set of documents even though – according to the European Communities – the Commission did not even have access to those documents and would need to request them from member States.

4.1128 By late June, the European Communities provided additional documents from the dossiers, although the dossiers were still far from complete. In its second written submission, the United States explained that the partial product dossiers provided by the European Communities did not, as the

European Communities had asserted, contain competing risk assessments. And, the documents provided yet further confirmation – though none was needed – that the European Communities had subjected applications to "undue delay" and had adopted a moratorium. The United States identified additional application histories – particularly those nearing the final stage of the decision-making process – that exhibited lengthy, unwarranted delays, unrelated to any requests for additional information. In addition, a number of product histories contained specific statements from member States acknowledging the existence of the moratorium. In each case, the member States wrote that regardless of any scientific issues regarding the particular application at issue, the member State asking for more information was not going to vote for approval, unless and until the European Communities had adopted new forms of legislation.

4.1129 In August, the Panel requested that the European Communities complete the application histories that the European Communities had relied upon for its defence. As a result, an amended set of application histories was made available to the complaining parties and the Panel by the end of September.

4.1130 As pointed out in the third US written submission, once again the European Communities' additional documentation did not include the competing risk assessments claimed by the European Communities, and the documentation was fully consistent with the existence of a moratorium. And once again, upon examination, the documentation provided further evidence – although none was needed – of "undue delay" and the existence of the moratorium. The United States showed 13 examples of how underlying documents in the product chronologies confirmed the existence of unwarranted delays in processing applications. The third written submission of the United States also provided over 20 examples where the questions by EC regulators were not required for assessing risks.

4.1131 The process of consultation with experts followed. The experts' written and oral responses were consistent with the US views, and the experts noted many types of questions which were scientifically unjustified.

4.1132 In sum, the documents submitted by the European Communities and the comments from the experts are entirely consistent with a political-level moratorium under which applications were allowed to make some progress but were never allowed to reach a final decision. Moreover, the documents illustrate many instances of unwarranted delays in the form either of inactivity by the European Communities or member State officials, or in the form of unjustified requests for additional information.

3. Burden of proof

4.1133 Throughout this proceeding, the European Communities has placed great emphasis on the issue of the burden of proof – for example, the European Communities' third written submission is devoted largely to this topic. This dispute, however, presents no difficult or unusual issues regarding burdens of proof.

4.1134 The European Communities argues that the United States has not met its burden of presenting a *prima facie* case because the first written submission of the United States did not address "each and every delay" in the processing of each product covered in the US panel request. This argument is baseless. The contention of the United States and the other complaining party is that the European Communities adopted a moratorium that never allowed products to reach final approval. The United States does not contend, as the European Communities' argument implies, that the European Communities suspended all processing of applications, nor does the United States contend that each

and every one of the European Communities' delays were unwarranted. Thus, nothing in the theory of the US case requires an examination of each and every delay for each and every product.

4.1135 The European Communities also asserts that the European Communities, as opposed to the complaining parties, has provided most of the evidence in this dispute. This contention is untrue: the complaining parties have provided extensive evidence. For example, the first written submission of the United States included over 100 exhibits, including positive risk assessments by EC scientific bodies, numerous statements by EC officials acknowledging the moratorium on biotech approvals, and copies of the relevant EC laws and member State safeguard measures. What the European Communities really objects to is that the European Communities, as opposed to the complaining parties, provided the documents in the product application histories. The United States, however, did not need the application histories to prove its *prima facie* case. It was the European Communities itself that chose to rely on the application histories in the European Communities' attempt to rebut that *prima facie* case. Having chosen to rely on the product application histories, the European Communities cannot complain when the complaining parties insist that this information must be complete, and that the European Communities not be permitted to rely on excerpts of information presented by the European Communities out of context for purposes of this dispute.

4. Member State safeguards

4.1136 With regard to the member State safeguard measures, the United States has explained that, in each case, the European Communities' own scientific committees had reached positive risk assessments, and had examined and rejected the reasons put forth by the member States for adopting the measures. Accordingly, these measures also were not "based on scientific principles" and were "maintained without sufficient scientific evidence," in violation of Article 2.2. The measures also were not "based on" a risk assessment, in violation of Article 5.1. Although the European Communities has since vaguely implied that the measures fall within the scope of Article 5.7, this provision cannot apply to the member State safeguard measures. The European Communities itself has completed positive risk assessments: therefore the scientific evidence cannot be considered "insufficient."

4.1137 The European Communities continues not to provide a serious defence of the member State safeguard measures. Since the first substantive meeting, the only new development regarding the safeguard measures is that the Panel posed some questions to experts on the safeguards, and certain experts responded to those questions.

4.1138 With regard to food safety, the expert specializing in food safety found no validity to any of the rationales put forward by the member States. With regard to environmental effects, experts specializing in environmental issues wrote that certain member States in certain instances may have had scientific concerns that were not adequately addressed in the European Communities' positive risk assessments. These views of the experts on environmental issues, however, have very little significance for the resolution of this dispute, and certainly cannot suffice to bring the safeguard measures within the scope of Article 5.7.

4.1139 As the European Communities itself has stressed in its third written submission, the role of the experts is to provide views on scientific questions posed by the Panel; it is not the role of the experts to make the case for a disputing party. But the European Communities has never explained how Article 5.7 might apply to any of the member State safeguard measures. In particular, the European Communities has not described (1) why the member State believed that the relevant scientific evidence was insufficient to assess a risk, or even the specific risk that was of concern to the member State, (2) what available pertinent information might serve as the basis for the safeguard

measure, (3) whether the member State sought to obtain additional information necessary for an objective assessment of the risk; and (4) whether the member State reviewed the measure within a reasonable period of time.

4.1140 The experts provided scientific opinions on some of the elements that might be relevant to an analysis under Article 5.7 of the *SPS Agreement*, but those statements do not come close to a full analysis under Article 5.7. Moreover, even if the European Communities were to tried to build an Article 5.7 argument from the responses of the experts, the European Communities could not do so.

4.1141 First, the safeguard measures are product bans, preventing cultivation, import and processing, and the use of the products as food. The experts' responses, however, entirely support the scientific findings of the European Communities' scientific committees with respect to food safety. In addition, the experts' scientific concerns addressed cultivation, not import and processing. Thus, the experts' responses cannot serve as the basis for an argument that the safeguard measures fall under Article 5.7.

4.1142 Second, the experts' responses cannot assist the European Communities in meeting the third and fourth requirements of Article 5.7. In particular, Article 5.7 requires Members adopting a provisional measure to seek to obtain additional information necessary for an objective assessment of the risk; and to review the measure within a reasonable period of time. There is no basis for finding that the member States adopting the safeguard measures sought the additional information necessary for an objective assessment. As the Appellate Body confirmed in the *Japan – Agricultural Products II*, where a Member fails to seek additional information as required under Article 5.7, the measure cannot fall within the scope of the Article 5.7 analysis.

4.1143 Third, even where the experts speak of risks associated with cultivation, the experts were left to speculate on the actual reason the member State had for adopting the measure. The experts' speculations of the rationales of the member States cannot stand in the place of actual assertions by the European Communities concerning any purported scientific basis for its member State measures.

4.1144 Fourth, and finally, in the event the Panel would engage in further analysis of environmental issues under Article 5.7, the United States notes that the same experts who disagreed with the risk assessments of the SCP also generally found that either (1) science has advanced since the date of the imposition of the measures so that a risk assessment is now possible, and (2) that management measures are available and that there would no longer be a scientific basis for a total ban on planting. In addition, the experts noted that in some cases studies could have been started as early as 1998 to address the member States' concern. Those opinions of the experts are summarized in Part II.C of the US comments on the experts' responses.

5. Mootness

4.1145 At the first substantive meeting, the European Communities argued that this dispute is moot because the European Communities had approved a single product – a sweet corn for food use – under the Food and Feed directive. As the United States explained it its second and third written submissions, the concept of mootness is inconsistent with the text of the DSU and longstanding GATT and WTO practice. The measure to be examined in this case is the moratorium at the time of Panel establishment, which is August 2003. Nonetheless, the United States would like to point out recent developments illustrating that the moratorium is still very much alive. To be clear, whether or not the moratorium is maintained after August 2003 is not a legal issue before the Panel. But the current status of the European Communities' moratorium should be of considerable relevance to an understanding of the European Communities' motivations, and to an objective assessment of the facts.

4.1146 The United States refers the Panel to US Exhibit 148, which is an article describing the latest state of play in the political manoeuverings that lie at the heart of the moratorium. The excerpt illustrates and supports the following points.

4.1147 First, even nearly a year after the April 2004 entry into force of the new tracing and labelling and GM food and feed directives, the European Communities must still fight a political battle to reach a decision on any biotech product. This undermines the European Communities' contentions that products were delayed because of the need for the new directives to enter into force.

4.1148 Second, the application described in the article (GA21) is for food use. The product received a positive opinion from the Scientific Committee on Food three years ago, and yet the European Communities still fails to submit it to a vote of the member States in the Regulatory Committee. Since the approval is for food use, none of the environmental issues discussed at length by the European Communities in its most recent comments are relevant to the application. Yet, the political battle remains.

4.1149 Third, the European Communities continues to ban a large range of products for reasons that are openly political – openly, that is, except in the meetings in this dispute. This is why it is so important to the complaining parties, and indeed for the rules-based trading system itself, for the Panel to find that the European Communities' moratorium is not consistent with WTO rules.

Z. SECOND ORAL STATEMENT OF CANADA ON THE EUROPEAN COMMUNITIES' SECOND AND THIRD SUBMISSIONS

1. Introduction

4.1150 In these proceedings, the European Communities has consistently tried to remove biotechnology from the context of modern agriculture to exaggerate risks and scientific uncertainty. In contrast, Canada has sought to put biotechnology squarely back into its proper context. The European Communities' suggestion that its approach to biotechnology reflects a more prudent and profound concern for the environment is starkly refuted by Dr. Squire's testimony regarding general agricultural practices in the European Communities. Not only has the European Communities been "slow to learn", it has applied whatever knowledge it has learned in an arbitrary and scientifically unjustified fashion. This case is really about the arbitrary and unjustified distinctions that the European Communities has drawn between products developed through rDNA technology and products developed through the use of chemical mutagens or radiation.

2. Overview of the dispute

4.1151 Canada's principal arguments run as follows:

- The European Communities has maintained a *moratorium* on the approval of new agricultural biotech products since October 1998.

- The *moratorium* has effectively stalled indefinitely all product applications in the system, giving rise to *de facto* product specific marketing bans.

- A number of EC member States have put in place national bans on biotech products that had been approved by the European Communities prior to the institution of the *moratorium*. The member States that are maintaining these national bans are the same Member States that have expressed support for the *moratorium*.

4.1152 Canada has shown that these are distinct measures, that they are subject to the WTO Agreement, and that they are inconsistent with the *SPS Agreement*. The scientific advice given to the Panel by the experts reinforces the case that Canada has established.

4.1153 To this date, the European Communities has denied even the existence of the moratorium. It largely bases its defence on what it calls scientific complexity and uncertainty. It purports, on one hand, to rely on the advice of the experts in this regard. Where the experts do not agree with the European Communities' general theme, the European Communities seeks to discredit the experts in question, ignore their advice, and/or answer the Panel's questions itself based on what the European Communities implies is the advice of better experts. None of this has any merit.

4.1154 The European Communities argues that there are qualitative differences in the risks associated with biotech products as compared to their novel non-biotech counterparts. The evidence of the European Commission's own Directorate-General for Research demonstrates that this premise is flawed. It is also inconsistent with the repeated conclusions of the EC scientific committees and EFSA.

3. Arguments and evidence relating to the *moratorium* and the product-specific bans

(a) The moratorium

4.1155 In what follows, Canada responds to the European Communities' most recent arguments in relation to Articles 5.1, 2.2, 5.7 and 5.5. Canada has already demonstrated the ways in which the European Communities has given effect to the *moratorium* since 1998, and that the *moratorium* is a SPS measure for the purposes of the *SPS Agreement*.

(i) The European Communities has failed to base its moratorium on a risk assessment in violation of Article 5.1

4.1156 Article 5.1 requires WTO Members to base their measures on a risk assessment. The risk assessment must meet the requirements of Annex A(4) and there must be "a rational relationship between the measure and the risk assessment". The *moratorium* does not meet either requirement.

4.1157 The European Communities claims that Directive 90/220 was inadequate for assessing the environmental risks posed by biotech products, requiring amendments to that legislation. The European Communities claims that it adopted an "interim approach" while the new legislation was being developed. However, the evidence shows that the EC member States were not interested in making decisions on product applications under this approach. Furthermore, the evidence shows that the true reason for amending Directive 90/220 was to streamline the approval procedure, including a need to harmonize risk assessment criteria. A desire for harmonization does not constitute a risk assessment for the purposes of Article 5.1.

4.1158 The European Communities also asserts that an absence of appropriate risk management measures in its legislation prevented it from finalizing risk assessments. However, these risk management measures were not related to identified risks. This fundamentally undermines the European Communities' assertion that it assesses risks and applies risk management measures on a case-by-case basis. Therefore the European Communities cannot credibly argue that the need for such measures is "based on" a scientific risk assessment.

4.1159 In trying to rationalize the *moratorium* under Regulation 258/97, the European Communities points to hypothetical *unanticipated* chronic effects on human health. In essence, the European Communities asserts that the new requirements for labelling, traceability and detection methods are necessary so that long-term chronic effects of biotech products could be appropriately studied. The European Communities claims that the absence of evidence of acute toxicity is not proof of an absence of long-term chronic effects. This applies to almost any novel food and reflects the European Communities' attempt to divorce biotechnology from its proper context. The argument that long-term chronic effects need to be studied for all biotech foods, as a class, also suggests the European Communities is not assessing risks on a case-by-case basis. In any event, the European Communities fails to put forth any evidence, much less a risk assessment, to suggest that a *moratorium* was necessary until such measures were put in place. This is because no scientific justification exists.

4.1160 The *SPS Agreement* does not permit a WTO Member to suspend existing SPS approval procedures, thereby effectively banning products with pending applications, simply because it wants to update its legislation. A suspension may be warranted in some circumstances, for example, where credible scientific evidence demonstrates actual risks to human health or the environment. That is not the case here. The legislative changes, for the most part, were related to hypothetical adverse effects or to facilitate the removal of a product from the marketplace in the unlikely event of a hypothetical risk arising.

(ii) The European Communities may not rely on scientific uncertainty to justify the moratorium under Article 5.7

4.1161 The European Communities attempts to rationalize the *moratorium* and the resulting delays in processing individual applications on the basis of scientific uncertainty, claiming that the scientific evidence was insufficient to complete risk assessments and adopt appropriate risk management measures. If this is so, the European Communities must demonstrate that the *moratorium* falls within the scope of Article 5.7 and that it meets all of the requirements of that provision. The European Communities fails to do so; instead it suggests that it is for the Panel to develop the European Communities' arguments. As a matter of law, this is not sufficient to discharge the European Communities' burden.

4.1162 In any event, the *moratorium* does not meet the requirements of Article 5.7. The European Communities has not established that the "relevant scientific evidence is insufficient" to complete a risk assessment. "Sufficiency" requires the existence of an "adequate relationship between two elements". These two elements are the scientific evidence and the obligation to base SPS measures on a risk assessment. Thus, the question is whether the relevant scientific evidence is sufficient for a Member to base its SPS measures on a risk assessment. If the evidence is sufficient, then Article 5.7 may not be used as a defence.

4.1163 The European Communities cannot credibly claim that relevant scientific evidence regarding biotech products is insufficient to permit the evaluation of the likelihood of entry, establishment or spread of a pest, or the evaluation of the potential for adverse effects on human or animal health from consuming biotech products. Prior to the *moratorium*, the European Communities considered the scientific information regarding biotech products to be sufficient to permit such an evaluation. Indeed, the European Communities approved several such products, all of which remain on the EC market. Community-level scientific committees have repeatedly performed risk assessments (and have found no evidence of risk), demonstrating conclusively that there is sufficient scientific evidence to permit the European Communities to perform a risk assessment.

4.1164 Much of the "scientific uncertainty" raised by the European Communities is really the "uncertainty that theoretically always remains since science can *never* provide *absolute* certainty that a given substance will not ever have adverse [] effects". The European Communities states that, "an absence of scientific evidence does not constitute evidence of an absence of impacts or risks." This may be true if a reasonable effort is not made to conduct studies to detect plausible hazards and evaluate the risks these hazards might pose. This is obviously not the case here. A considerable amount of research on potential risks has been carried out. The European Communities is in effect seeking "absolute certainty" and then suggesting that the absence of absolute certainty makes it impossible for this Panel to do its work. It seeks to equate the lack of absolute certainty with insufficient scientific evidence, even though the Appellate Body has made it clear that these concepts are not interchangeable.

4.1165 The question here is whether relevant scientific evidence is sufficient to perform a risk assessment, not whether, at the margins, some scientific uncertainty remains. In determining whether relevant scientific evidence is sufficient one must have regard for the context. The European Communities attempts throughout its submissions to shift the focus away from the large quantity of high quality scientific information available, to the margins of scientific uncertainty. This strips biotech products of the context within which they have been developed and are to be employed, and downplays the vast experience within the European Communities and around the world with plant breeding technology, food safety assessment, and the management of herbicide and pesticide resistance, amongst other things.

4.1166 A large body of research on transgenic plants has been carried out by university and government laboratories investigating aspects of rDNA technology, and a considerable part of that research has been undertaken in the European Communities. All of this forms part of the abundance of high quality scientific evidence concerning the risks or potential risks posed by the products in question in this dispute. Dr. Squire indicated that biotech products have been subjected to an "unprecedented" degree of regulatory scrutiny. As compared to their conventional counterparts, considerably more information is known at the molecular level about the currently available biotech products. Consequently, the European Communities cannot credibly claim that relevant scientific evidence was or is insufficient then to justify the suspension of the approval procedures for biotech products. Accordingly, Article 5.7 cannot be invoked to justify the *moratorium*.

4.1167 Similarly, the European Communities cannot credibly claim that relevant scientific evidence was insufficient to perform a risk assessment in relation to specific product applications. The determination of whether relevant scientific evidence was sufficient to undertake and complete a risk assessment is linked to the issue of "undue delay" under Annex C1(a). Article 5.7 informs the determination of "undue delay" under Annex C(1)(a).

4.1168 Given the *moratorium* and its demonstrated impact on the processing of applications, the European Communities must demonstrate in each case that "relevant scientific evidence is insufficient" to complete the risk assessment in that case. This requires a determination of "sufficiency". In other words, what information is "need to know" and what information is "nice to know". As indicated by the experts, many of the requests for additional information by EC member States were not necessary to ensure the validity of the risk assessments that had been performed. So, the absence of "nice to know" information cannot justify a claim of insufficiency of scientific evidence.

4.1169 Some of the EC member State questions have been based on a presumption that the product necessarily will be cultivated on a large scale. The European Communities asserts that, because the agro-environmental impacts from large-scale cultivation cannot be predicted with absolute certainty, a

failure to approve the product is justified. However, there is no *a priori* reason why cultivation cannot be introduced on a smaller and progressive scale. A gradual introduction of a product, with appropriate monitoring plans and agricultural guidelines, has already been demonstrated to be a feasible option in the European Communities.

4.1170 In determining whether relevant scientific evidence is sufficient, it is important to consider the totality of the information submitted in support of an application. This approach is endorsed by Drs. Healy and Nutti and has been adopted by the Community-level scientific committees. In the light of the large quantity of reliable scientific evidence developed over the years, in part by the European Communities itself, and the fact that the European Communities' own independent scientific committees have been able to complete risk assessments, any claim by the European Communities that "relevant scientific evidence is insufficient" is without merit. The European Communities has failed to meet the first requirement of Article 5.7. As the requirements under Article 5.7 are cumulative, and the European Communities has not and cannot meet the first requirement, it is not necessary to address the other elements of Article 5.7.

4.1171 For these reasons, the European Communities cannot successfully invoke Article 5.7 to excuse its failure to meet the obligations under Article 5.1 or Article 2.2 of the *SPS Agreement*.

(iii) The European Communities' application of its appropriate level of protection for biotech products results in discrimination or a disguised restriction on international trade, contrary to Article 5.5 of the SPS Agreement

4.1172 It is apparent from its most recent arguments that the European Communities is seeking a level of protection for biotech products that approximates "absolute safety". The European Communities has raised almost every imaginable hypothetical risk, often relying on scientific reports that have been widely dismissed. Despite rigorous risk assessments and no evidence of harm, the European Communities strenuously maintains that risk management measures are necessary.

4.1173 Despite the broad international consensus that biotech products should be contrasted on a comparative basis with their conventional counterparts, the European Communities' approach is to assess biotech products in a vacuum. The European Communities ignores the demonstrated benefits associated with these crops and the well-established risks to human health and the environment arising from the existing practices that some of these crops can help improve. By doing so, the European Communities seriously undermines its claim to be acting on a precautionary basis in order to protect the environment.

4.1174 The European Communities' level of protection for biotech products should be contrasted with the level adopted for novel crops developed through other forms of genetic modification, such as radiation and chemically-induced mutagenesis; somaclonal variation; and even conventional selective breeding. As confirmed by the experts, biotech and non-biotech methods of genetic modification do not differ inherently with respect to the types of risks to human health or the environment that they pose.

4.1175 All methods of introducing genetic variation have potential to produce unexpected and unintended effects. The experts agreed with this. The likelihood of changes to the genome varies with the method of genetic modification. This has been discussed in the recent report of the National Academies on the safety of genetically engineered foods. The report placed different methods on a continuum, with selection breeding from within a homogeneous population having the least likelihood of causing unintended changes and mutagenesis techniques the most likelihood. Significantly, the various recombinant DNA techniques fell at different points between these extremes.

4.1176 Unintended effects do not necessarily imply hazard. The potential for hazard arises from the product, rather than the method of production. It is interesting to note that the most striking unintended effects on human health from food production have resulted from conventional breeding (*e.g.* potatoes with high levels of glyco-alkaloid). The method used in developing the product does not alter the nature of the risks.

4.1177 Despite the fact that all forms of plant genetic modification have the potential to produce unintended adverse effects, the European Communities has not imposed a *moratorium* on products from other forms of plant breeding. Indeed, although plants produced via conventional breeding methods are routinely evaluated for changes in productivity, reproductive efficiency, reactions to disease and quality characteristics, they are not assessed for safety.

4.1178 One of the most striking examples of the European Communities' selective concern about risks is the difference in its treatment of herbicide tolerant (HT) oilseed rape crops developed through mutagenesis and recombinant DNA technology. The experts agreed that HT crops, regardless of the method of production, posed similar risks. The European Communities' entire discussion in its comments on the experts' advice about the risks posed by HT crops applies equally to biotech and mutagenic crops. However, despite the fact that the likelihood of unanticipated changes to the genome are at least as likely with mutagenesis as with transgenesis, the European Communities does not require a comprehensive risk assessment for HT crops developed through mutagenesis. For mutagenic crops, unlike their biotech counterparts, there appears to be little concern with the environmental or health effects. The panoply of regulatory requirements imposed on biotech products is completely absent in the case of mutagenic crops. Above all, there is no *moratorium*.

4.1179 Given the similarity of risks and the other factors set out in Canada's First Written Submission, these differences in appropriate levels of protection are arbitrary and unjustified and give rise to discrimination or a disguised restriction on international trade in violation of Article 5.5 of the *SPS Agreement*.

(b) Product-specific marketing bans

(i) Oilseed rape GT73

4.1180 Keeping in mind that the oil produced from GT73 oilseed rape has already been approved for human consumption, Dr. Nutti's conclusions concerning the impact on human health were entirely consistent with the Dutch Competent Authority and the EFSA opinions. In terms of animal feed, the European Communities has failed to cast doubt on the EFSA 2004 opinion concerning the safety of GT73 for use as feed. The European Communities' alleged concern about the pesticide residues and related metabolites was dismissed by Dr. Nutti.

4.1181 In terms of environmental release, the alleged concern cited by EC member States appears to be related to the potential of seed spillage. The experts dismissed this concern as not being scientifically justifiable, and the studies cited by Dr. Squire are of limited applicability, given that in-land transportation of imported seeds is unlikely. In any event, if seed spillage occurs around docklands and processing facilities, these weeds can be easily controlled. Dr. Squire also agreed with the EFSA opinion that the monitoring plan proposed by the notifier was acceptable given the factors set out in the EFSA opinion. Thus, the demands for more onerous monitoring are entirely unjustified.

4.1182 Because the product-specific ban for GT73 is not supported by a risk assessment, the European Communities is violating Articles 5.1 and 2.2. Moreover, a delay of seven years in approving this product is, by any reasonable standard, "undue" and therefore violates Annex C(1)(a).

Furthermore, by imposing the ban on GT73, continuously making unjustified demands for additional information and seeking to impose onerous and unnecessary monitoring requirements, the European Communities is violating Article 5.5. The main beneficiaries are European oilseed rape producers selling their products to European Communities' crushing facilities.

(ii) Oilseed rape Ms8xRf3

4.1183 In terms of molecular characterization, Dr. Healy confirmed that the requests for additional molecular characterization were not necessary to complete the safety assessment. Dr. Snape agreed with both Dr. Healy and, importantly, with the February 2002 opinion of the Belgian Biosafety Council. The experts also confirmed that the likelihood that Ms8xRf3 would establish or spread as a weed in the absence of the application of glufosinate-ammonium was no different than for conventional varieties of oilseed rape, and that the techniques in place to control conventional oilseed rape volunteers or weeds can be applied with equal effectiveness to Ms8xRf3.

4.1184 In assessing the legitimacy of the Belgians' request for additional information on farmland biodiversity, food web integrity, etc., the Panel should bear in mind the full context in which the request was made, as well as the advice provided by Drs. Snow and Squire.

4.1185 Although the experts indicated that, technically speaking, the Belgian request was justified, when placed in context, the request should be seen as an attempt to frustrate the approval procedure. The effects of herbicide use can be managed, and herbicide-tolerant crops provide additional flexibility in terms of weed control.

4.1186 The product-specific ban for Ms8xRf3 is not "rationally connected" to the risks identified in the risk assessment, contrary to Article 5.1 and by implication Article 2.2. Moreover, a delay of nine years in approving this product is by any reasonable standard, "undue" in violation of Annex C(1)(a). In terms of Article 5.5, by imposing this ban, continuously requesting unnecessary information and seeking to impose onerous monitoring requirements and agricultural practices, the European Communities is violating Article 5.5.

(c) National bans

4.1187 Canada stands by its previous legal arguments, which are supported by considerable documentary evidence, and which demonstrate that the EC member State national bans are SPS measures, and that they are subject to, and inconsistent with, Articles 5.1, 5.5, 5.6, 2.2 and 2.3 of the *SPS Agreement*. In contrast, the European Communities has yet to develop a fully coherent legal and factual argument for each of the measures that would refute Canada's initial *prima facie* case.

4.1188 Canada has a few additional comments in the light of the advice of the scientific experts and the European Communities' written comments on those replies. In brief, the experts' advice largely reinforces Canada's arguments that the national bans are not supported by sufficient scientific evidence or a risk assessment, contrary to Articles 2.2 and 5.1 of the *SPS Agreement*. Furthermore, the expert advice supports the proposition that Article 5.7, even if it may have been applicable to these measures at the time they were adopted, did not apply by the time this Panel was established, and that it does not apply today.

4.1189 Oilseed rape Topas 19/2 was approved by the European Communities for import and processing in April 1998. It has been banned by France and Greece. The experts agreed that no scientific rationale exists for these measures given that the product was only approved for import and processing. Although Dr. Andow suggested that France could have justified its measure in 1998 –

albeit on grounds other than those actually cited by France – he concluded that France and Greece would have had sufficient data could have made a decision no later than 2001. The European Communities, in its comments on the experts' replies, misrepresents the essential question that must be answered. Indeed, France's own scientific experts did not consider herbicide-tolerant oilseed rape – when imported for processing purposes – to give rise to any more risks than conventional oilseed rape.

4.1190 The experts also agree that the "scientific evidence and other information" provided by France does not meet the definition of a risk assessment as set out in either the *SPS Agreement* or the IPPC. Although Dr. Andow suggests that the documentation does fall within Annex III of the Biosafety Protocol, in Canada's view, Annex III does not constitute an international standard for the purposes of the *SPS Agreement*, and is therefore not relevant to a determination whether the materials submitted by France meet the requirements of the *SPS Agreement*.

4.1191 Finally, based on the draft decision it has tabled in the Regulatory Committee, the European Commission shares the view that there is no scientific justification for maintaining a prohibition on the import and processing of oilseed rape Topas 19/2. The conclusion is inescapable that the French prohibition and the Greek import prohibition on Topas 19/2 is being maintained without sufficient scientific evidence, contrary to Article 2.2 of the *SPS Agreement*, is not based on a risk assessment, contrary to Article 5.1 of the *SPS Agreement*, and cannot be justified on the basis of Article 5.7 because sufficient scientific evidence exists to complete such a risk assessment.

4.1192 In relation to maize T25, according to Dr. Andow the emergence of weed resistance was the only plausible concern raised by Austria. Even then, it is not clear from the evidence that Austria was truly concerned about this potential risk. In any event, the reality, as the European Communities must recognize, is that glufosinate ammonium has been remarkably successful in terms of preventing the emergence of resistance, and herbicide resistance management strategies were well developed by the late 1990s.

4.1193 T25 has undergone an exhaustive scientific scrutiny. In each and every instance, the European Communities' own scientific experts came to the same conclusion. The European Communities' evidence cannot be considered an adequate basis to find that Austria's ban was or is consistent with either Articles 2.2 or 5.1, or justifiable under Article 5.7. Were it otherwise, the disciplines found in these provisions would be rendered largely meaningless.

4.1194 Finally, with T25 as with other products, the European Commission has tabled a draft decision asking Austria to repeal the ban prohibition on maize T25. Evidently, the Commission shares Canada view that there is no scientific evidence to justify the maintaining the measure.

4.1195 Regarding the Italian ban on maize MON809, MON810, Bt11 and T25, Canada seeks clarification from the European Communities with respect to the ban's current legal status. There is some evidence that the measure is no longer in effect, but this evidence is not conclusive. Canada therefore seeks confirmation from the European Communities (with supporting documentation) that the Italian measure has been repealed or has otherwise been rendered null and void.

4.1196 Assuming that the measure remains in effect, the absence of evidence to support a national ban in this case is, if anything, even more pronounced as compared to the other product specific bans. Dr. Nutti was the only expert who addressed the Panel's questions with respect to Italy's national ban. For each of these maize varieties, she concluded that Italy had sufficient scientific evidence available to it to complete the risk assessments, and that the information provided to the European Commission by Italy in support of its measure "did not support a temporary prohibition" of MON810, MON809,

Bt11 or T25. In its comments on Dr. Nutti's replies in relation to the Italian national ban, the European Communities offers scant scientific evidence in its efforts to discredit or contradict her opinion. It also gets some of the facts wrong. For instance, it confuses the *bla* gene, which confers antibiotic resistance to ampicillin, with the *nptII* gene. Furthermore, the *nptII* gene is not present in the final construct and, in any event, it has a 13-year history of safe use in food and feed.

4.1197 In short, as with the other EC member State national measures, the advice of the experts, and all other available scientific evidence strongly supports Canada's arguments that the Italian measure is not based on a risk assessment, contrary to Articles 5.1 and 2.2 of the *SPS Agreement*. Furthermore, it seems clear that sufficient scientific evidence exists to complete a risk assessment, and that Article 5.7 therefore is inapplicable.

4. Other issues

4.1198 Canada turns briefly to the European Communities' arguments with respect to standard of review and the definitions provided by international organizations (IOs).

4.1199 In regard to the standard of review, the European Communities makes two assertions, neither of which has any merit. First, the European Communities argues that the Panel should limit its examination of the scientific evidence and data to that existing at the time of the measure was put in place. Second, the European Communities argues that the Panel should take a deferential approach in its assessment as to whether the European Communities has violated Article 1(a) of Annex C. For each argument, the European Communities misrepresents the proper role of the Panel by misconstruing and misapplying the language of Article 11 of the DSU and the relevant jurisprudence.

4.1200 First, regarding the temporal issue, the European Communities' reliance on *US – Cotton Yarn* is misplaced; the standard of review in safeguard cases is different from the standard of review in SPS cases. To limit the inquiry to the "state of scientific information and data existing at the time the measure" arose would not enable the Panel to determine whether the measure was justifiable at the time the Panel was established, contrary to the object and purpose of the *SPS Agreement*, and inconsistent with the requirement in Article 11 of the DSU. The reference in Article 2.2 to the "maintenance" of an SPS measure would lose all meaning, contrary to the principle of effective treaty interpretation.

4.1201 Second, the European Communities' attempt to create a distinction in the application of the standard of review as between Article 5.2 and Annex C1(a) is not supported by the jurisprudence. The Panel should review the European Communities' measures based on how a reasonably diligent government would and <u>should</u> have behaved in view of the factual information at its disposal. A deferential approach to the interpretation and application of Annex C1(a) would not be consistent with the jurisprudence. In any event, there is no doubt that the European Communities has failed to meet its procedural obligation under Article 1(a) of Annex C. Accepting that 6.5 years amounts to a justifiable delay would render Annex C(1)(a) meaningless; this would be inconsistent with the principle of effective treaty interpretation.

4.1202 In regard to the definitions provided by the IOs, the European Communities asserts that the definitions support the European Communities' case. Canada disagrees. On their face, the definitions found in the materials provided by the IOs do not support the European Communities' assertions as to the meanings of the terms in question. Despite the European Communities' contentions that a GMO cannot, *a priori*, be considered as toxins, contaminants, allergens, pests, disease-causing or disease-carrying organisms, definitions of these terms, or elements of them can all be found in documents that expressly address biotechnological issues. If the European Communities' assertions were correct,

there would be little rationale for these terms to appear in glossaries and international standards documents pertaining specifically to biotechnology.

4.1203 Furthermore, and in any event, the definitions provided by the IOs are not dispositive of what the enumerated terms mean in the context of either the *SPS Agreement* or the *TBT Agreement*. This is particularly true of those enumerated terms that appear in these agreements. Terms such as these must be interpreted in accordance with the customary rules of treaty interpretation, as expressed in Articles 31 and 32 of the *Vienna Convention on the Law of Treaties*.

AA. SECOND ORAL STATEMENT OF ARGENTINA ON THE EUROPEAN COMMUNITIES' SECOND AND THIRD SUBMISSIONS

1. The *de facto* moratorium measure

(a) The measure addressed in these proceedings

4.1204 Referring to the *de facto* moratorium, which is the lack of any approvals or rejections of any new agricultural biotech product since 1998, the European Communities has failed to approve a single application until 2004. Faced with this lack of approvals or rejections, the European Communities has limited itself to deny the existence of the *de facto* moratorium or, alternatively, to assert that if such a measure exists it would not be challengeable under WTO Agreements. Argentina has demonstrated throughout these proceedings that both assertions have no basis.

4.1205 The existence of the *de facto* moratorium has been recognized by high EC officials with jurisdiction over the matter addressed in this dispute in a number of opportunities, and this evidence was put before the Panel. Hence, Argentina will not repeat references to this striking evidence.

4.1206 The *de facto* moratorium consists in a persistent conduct of the European Communities that reflects a practice. This pattern of conduct is a compound of acts and omissions that have as effect the stalling of all applications in the European Communities' approval system. The *de facto* moratorium operates at the crucial stages of the procedures under EC regulations. Although some applications have moved within the approval procedures, this movement in no case has resulted in approval or rejection. This fact lies at the heart of the concept of the *de facto* moratorium.

4.1207 The European Communities' assertion about the impossibility of challenging the *de facto* moratorium under WTO Agreements was rebutted by Argentina in these proceedings. Argentina's arguments are supported by GATT/WTO jurisprudence and they were explained in its First Written Submission.

4.1208 Argentina would like to stress that if we were to follow a narrow definition of "measure", it would result in allowing WTO Members to circumvent legal scrutiny of their measures simply by not putting them in a piece of legislation. Moreover, it would also devoid WTO law of its meaning.

4.1209 The first of these consequences (circumvention of legal scrutiny) was already referred to in Argentina's First Written Submission, and even pointed out by third parties in these proceedings. However, Argentina would like to refer to the second of these consequences (to devoid WTO law of its meaning).

4.1210 According to Argentina's point of view, from the GATT/WTO jurisprudence arises quite clearly that one central feature of WTO system is to ensure that Panels and the Appellate Body are able of scrutinizing all measures regardless the way by which WTO Members may have put them in

place. A narrow definition of "measure" would lead not only to foster the lack of transparency by the WTO Members but also to deprive panels and the Appellate Body from analysing any measure which infringes the covered Agreements. Jurisprudence was clear in interpreting GATT/WTO law in a broad sense, in order to assure that compliance with WTO law would not be circumvented simply because of the form in which a measure is imposed. Argentina deems that in the present dispute the European Communities should not use its own lack of transparency to avoid legal scrutiny of the *de facto* moratorium.

(b) Inconsistency of the *de facto* moratorium with Article 5.1 of the *SPS Agreement*

4.1211 The European Communities' legislation establishes that the assessment of biotech products must be on a "case-by-case" basis. However, the European Communities has imposed, without any scientific evidence, an across the board measure to all biotech products in the European Communities' approval system. Since this measure lacks of any basis on scientific evidence, it infringes basic obligations contained in the *SPS Agreement*. Besides, this *de facto* moratorium undermines the European Communities' assertion that it has been assessing the risks on a "case-by-case" basis.

(c) The European Communities cannot justify the *de facto* moratorium under Article 5.7 of *SPS Agreement*

4.1212 Argentina considers that the European Communities has had sufficient relevant scientific information at hand, namely the positive opinions issued by its Scientific Committees. These positive opinions constitute sufficient scientific evidence in terms of Articles 2.2 and 5.1 and have not been refuted either by the European Communities or by the experts appointed to assist the Panel.

(d) The *de facto* moratorium infringes Article 5.5 of *SPS Agreement*

4.1213 The experts have ratified that the treatment given by the European Communities to agricultural biotech products compared with "non-biotech" products is inconsistent with Article 5.5. This is because it was demonstrated that agricultural biotech products entail similar risks than those arising from "non-biotech" products.

2. The "suspension and failure to consider" is not based on scientific evidence, and therefore violates WTO obligations

4.1214 Regarding Bt 531 cotton, we believe that the EC's alleged scientific arguments remain refuted as the evidence submitted by Argentina has not been contested by other relevant scientific evidence. As regards the meetings on 17-18 February, the issue affecting Bt 531 cotton has been analysed in a broader scope, and from the responses from the experts the European Communities cannot invoke any valid or relevant scientific evidence which could refute the positive scientific evidence arising from the opinion of the EC Scientific Committee from July 1998.

4.1215 Regarding RRC 1445 cotton, Argentina considers that the meetings from 17-18 February did clarify the questions, and confirmed our argument in the sense that there is no scientific evidence within the information submitted by the European Communities that could refute the positive opinion by the EC Scientific Committee dated July 1998 which favored the approval of RRC 1445 cotton. We particularly mention the clarification made by Dr. Squire referred to the alleged possibility of horizontal gene transfer, confirming Argentina's point.

4.1216 With regard to NK-603 maize, Argentina is pleased that it has been properly addressed by the experts. We agree with Dr. Andow, when he asserted that there were no reasons to dismiss the

positive opinion from the European Communities' scientific committees in the way the European Communities tried to do in these proceedings. As regards the meetings on 17-18 February, the original extent and value of the positive opinions by the European Communities' scientific committees have been clearly established, especially when Dr. Nutti specifically addressed an issue contained in the positive assessment and which the European Communities tried to turn into an hypothetical question. Additionally, we also appreciate that the experts did recognize that monitoring is not needed when the product is intended to be only for import and not for cultivation.

4.1217 With regard to GA 21 maize, the application was withdrawn in September 2003, and Argentina states that this withdrawal precisely demonstrates the effect of the *de facto* moratorium and the "suspension or failure to consider". GA 21 maize did receive a positive scientific assessment both under Directive 90/220 and under Regulation 258/97. The European Communities did ignore for years this scientific evidence favouring approval, until the applications were withdrawn.

4.1218 Summing up, Argentina respectfully requests the Panel to find that the "suspension and failure to consider applications of products of particular interest of Argentina" are inconsistent with the European Communities' WTO obligations.

3. The "undue delay"

4.1219 Article 8 of *SPS Agreement* establishes two different obligations: the first one refers to the commitment to comply with Annex C, and the second one establishes the obligation to ensure that "their procedures are not inconsistent with the provisions of this Agreement". Given the fact that Argentina has demonstrated that Article 5.1 has been infringed, the delay in the approval of agricultural biotech products of interest to Argentina is not justified, as it is not based on scientific evidence. Therefore, there is no reason that justifies the delay. This is without prejudice of the particular infringement to paragraph a), b), c) and e) of Annex C.1 of *SPS Agreement*.

4. The member State bans are not based on scientific evidence, and therefore violate the *SPS Agreement*

4.1220 The specific products affected by the measures applied by Germany, Austria, Italy and Luxembourg had prior approval by the European Communities, based on scientific opinions issued by the European Communities' own Scientific Committees. These member State bans have ignored this scientific evidence and maintain restrictions on the entry of these products into their territories. Furthermore, some of these countries have attempted to seek protection under safeguard procedures to try to justify their measures, which has resulted in new scientific opinions issued by European Communities' scientific committees. These new opinions refuted the grounds for the state measures.

4.1221 The foregoing, as well as the experts' responses, demonstrate the lack of scientific evidence supporting the measures currently maintained by those member states, and confirm the arbitrary and unjustified distinction made with respect to the affected products. For this reason, as in the foregoing sections, we request that the Panel confirms the inconsistency with the *SPS Agreement*.

BB. SECOND ORAL STATEMENT OF THE EUROPEAN COMMUNITIES ON THE COMPLAINING PARTIES' SECOND AND THIRD SUBMISSIONS

1. Delays

4.1222 The central issue in this case is delay. The European Communities has resisted the complaining parties' attempts to present the issue of delay in an oversimplified manner, both on the

factual and the legal level. On facts, the European Communities has demonstrated that applications have not been put on hold since 1998, as the complaining parties initially claimed. It has presented detailed chronologies that show in all cases valid reasons to delay procedures, while requests for further information were pending. Scrutiny of individual delays has shown that in the overwhelming majority of cases there were valid reasons at the origin of these delays. On law, the European Communities has resisted the complaining parties' attempts to translate these individual delays into a measure which they call "moratorium". The complaining parties' presentation of their "moratorium" has gradually changed from the description of a ban, to that of a stalling of all procedures to that of individual delays arising out of the greater scheme, which is the alleged "moratorium". We are now in the grotesque situation that the complaining parties see proof of the existence of the moratorium even in individual delays which they themselves acknowledge to be warranted. The Panel has rightly focused on assessing individual delays.

(a) Burden of proof

4.1223 As regards the individual delays, it is clear that the complaining parties' initial *prima facie* claim that all procedures have been stalled has been extensively rebutted by the European Communities through the individual product histories presented in its submissions as well as in the chronologies submitted. It is for the complaining parties to rebut this evidence by putting forward arguments and evidence as to why the reasons for delays are unjustified, with the consequence of making the delay undue.

(b) Delays identified as "undue" by the complaining parties

4.1224 Falcon GS40/90, EC 62: The United States was the only complaining party to include it in its terms of reference. The only argument raised is that the Commission refused or failed to submit a draft measure to the Regulatory Committee. The European Communities has already addressed this. As for the points addressed by the Panel's questions, the United States say that the experts were confirming its claims. The European Communities fails to see which claims. In its comments on the experts' replies, the United States refers back to sections of its supplementary rebuttal where no mention is in fact made of Falcon.

4.1225 MS8xRF3, EC 63: Similarly to Falcon GS40/90, the United States, has only challenged the interim approach (and the fact that the Regulatory Committee was not consulted) as "undue delay". The European Communities has already addressed these issues. Canada, on the contrary, has analysed at some length the process. It has repeated the arguments on the failure to vote, that the European Communities addressed. It has agreed with some steps taken, such as an agreed code of good agricultural practices and a monitoring plan. It has identified a number of requests for information that it considered problematic. On these, the Panel has asked the views of the experts, whose advice has yielded a host of divergent views showing that these issues are far from settled. For instance, on the request for further molecular characterisation, the views of Dr. Healy and Dr. Snape diverge substantially. The European Communities views on the rationale for these requests is in its comments on Scientific Advice and it stands by those views, considering that such requests were justified.

4.1226 The Canadian contention that the Belgian Advisory Council "approved" Ms8xRf3 for import and processing is wrong. National bodies only provide "opinions"; "approval" or not occur at Community level. The product is, in fact, currently under evaluation by EFSA for all uses. Canada's assertion that one objection by Belgium to approval for cultivation is "that coexistence rules are not yet in force" is misleading. One of this authority's main concern was about gene transfer, both in wild relatives and in neighbouring fields. Canada also alleges that "Belgium rejects the 'interim approach'", "rebuffing" the notifier attempts to comply. Again, Canada's selective quotations are misleading. A

careful reading of the relevant minutes (EC-63) makes clear that the authority debated about whether the application should be supplemented. The conclusion was, however, positive and the application indeed proceeded. Canada also raises that Belgium has authorized glufosinate for GM crops. As can be seen, that authorization is for a different use (seed production only) for a different event (MS1xRF2).Hence the European Communities fails to see the relevance of this fact for this authorization.

4.1227 Roundup Ready Fodder beet A5/15, EC-64: A5/15 is only within the terms of reference of the United States. Its claims are all generic and refer to issues such as the Commission refusal/failure to submit a draft measure and the application of the "interim approach". The European Communities has already addressed these. The Panel has addressed a number of points through the scientific experts, and their advice on these has been rather supportive of further requests by the CAs. Thus, Dr. Andow has concurred with the Dutch request for a theoretical safety assessment, the Dutch and UK requests for additional data on molecular characterisation, and the Italian request for transfer and recombination of genes in natural conditions, as being relevant for an environmental risk assessment and not previously addressed.

4.1228 Bt Cotton (531), EC 65: Both Argentina and the United States have included 531 in their terms of reference. Their claims are that the Regulatory Committee failed to vote and the interservice consultation amounts to the moratorium. The European Communities has addressed these, highlighting that the Regulatory Committee failed to reach a vote because of Member States' objections related to issues such as ARMG, non-target effects and the monitoring plan. Argentina does not come back to it but just skims through and dismisses some documents without proper analysis, and limiting its rebuttal to saying that a monitoring plan had already been submitted and positively assessed. The United States spends some time on this, but provides no argument to counter the validity of the concerns, and only says that all information had been provided. The Panel has not reverted to its experts on the scientific justification of these concerns and the European Communities maintains that they were legitimate and scientifically sound, not previously addressed. As for the remark that the applicant was not requested to submit specific data, requests by other CAs or by the Community's committees for additional information is automatically transmitted to the applicant. This being an automatic procedure, no trace is kept of such transmission.

4.1229 Roundup Ready Cotton (RRC1445), EC 66: As for 531, Argentina and the United States do not identify specific delay and limit the claims – yet again – to issues such as the Regulatory Committee failure to vote and the interservice consultation. In its Supplementary Rebuttal the United States dismisses the scientific concerns highlighted by the European Communities as "missing the point" of an undue delay of four years. However, the Panel's experts have considered that the objections concerning the adequacy of the monitoring plan are scientifically justifiable.

4.1230 Amylogene starch potato, EC 67: The United States was the only one to include it in its terms of reference. The only argument raised is that the Commission refused or failed to submit a draft measure. The European Communities has already addressed this issue, highlighting also the concerns expressed by the SCP on this product. The European Communities notes that three out of four Panel's experts that provided an opinion on these concerns warranted their scientific validity.

4.1231 Oilseed rape Liberator, EC 68: Yet another product included only within the terms of reference of the United States, for which it has not put forward claims apart from the usual allegation that the Commission refused to submit a draft measure. Once again, the European Communities has addressed this issue. It explained that this application was subject to a number of objections related to issues such as molecular characterisation, compositional analysis and long term environmental effects. The European Communities also highlighted current issues raised by the lead CA on molecular

characterisation and post marketing monitoring plan. The Panel has not considered necessary to assess whether these concerns were scientifically justified or not. The European Communities therefore maintains that these were legitimate and scientifically sound concerns.

4.1232 Maize Bt 11, EC 69: The United States has raised a number of claims here. Apart from the Commission's alleged failure to submit a draft measure, the United States has also alleged a two years and a half delay after the SCP's opinion. The European Communities has dealt with both claims, highlighting that the applicant has still to submit the surveillance plan requested in 2000. The argument that such plan is only to be applied after commercialisation is beside the point. If it is true that it will only be applied after commercialisation, it nonetheless needs to be submitted before authorization, with all information necessary to be properly assessed. As with regard to the US claims that concerns on compositional analysis, biogeochemistry, ecological effects, weediness, are unfounded and already addressed, the European Communities contests this. The Panel has not asked to assess whether these concerns are scientifically justified or not. The European Communities, therefore, sustains that these were legitimate and scientifically sound concerns.

4.1233 Oilseed rape GT73, EC 70: On GT73, the United States claims that the Member States opposed it on the basis of the need for legislation on traceability, labelling and coexistence. Canada appears to identify an overall delay of forty-two months, plus a number of "unreasonable or [ ] unjustified questions or objections". The European Communities stands by the arguments it has put forward and notes that some concerns arisen in this application (molecular characterisation, feeding studies, monitoring plan) have been taken up in the Panel's questions to the experts, which have given a rather positive assessment of these concerns. For the others, the European Communities maintains its position that these were either legitimate and scientifically sound concerns or regulatory requirements outside the scope of this dispute (traceability and labelling).

4.1234 Bt corn Cry1F (1507), EC 74: The United States identifies here four requests for additional information which it claims are not justified and cause undue delay. The European Communities notes that none of these have been raised for another application for the same product (EC 75). The United States claims that, apart that Member States blocked it, they opposed the application for the need for legislation on traceability, labelling and coexistence. The European Communities has dealt with these claims, highlighting a number of issues identified both by the lead CAs and by other Member States with regard to molecular characterisation, allergenicity and toxicity, environmental effects, monitoring effects, sampling and detection methods. The United States claims that some of these concerns (whole food studies, safety assessment, non-target organisms, protein analysis) are unfounded. Some of these have been taken up to the experts, which gave a rather positive assessment. For the others, the European Communities maintains that these were either legitimate and sound concerns or regulatory requirements outside the scope of this dispute (traceability and labelling).

4.1235 Nk 603, C/ES/00/01, EC 76: The United States raises issues which, in its view, support an undue delay. The United States claims that the application remained at Member State level for 25 months. Acknowledging several requests for information, the United States dwells on the fact that 12 were spent by the CA to assess the information received. The US' idea that a CA is to immediately digest and process information which the applicant has taken 13 months to gather, is somewhat naive. The United States refers to delays occurring at the Community procedure. The European Communities points out that the procedure is set out in the legislation which the complaining parties have not attacked. The United States refers to two requests for information it considered to be invalid, causing in their opinion undue delays. One is an Austrian request for data and studies on subchronic, mutagenic, reproductive and ecotoxic effects. This has not been addressed by the Panel's experts. The European Communities disagrees that that request was "unfounded and unreasonable." The European Communities notes that Austria's request was broader, covering central issues

(compositional analysis, molecular characterisation), the scientific validity of which the United States has not contested. The other request is from Spain, to use PCR to screen for putative random insertions of fragments and possible transcription. This was covered by the Panel's Question 38, but no expert replied. The European Communities refers to its comments on the experts replies and which explain why this request was scientifically valid.

4.1236 Roundup Ready Corn GA (21) EC 78 and 85: The United States admonishes certain delays at the Member State level conveniently omitting that there were numerous requests for information. All the requests identified by the United States have been covered in the Panel's Questions 40 & 40bis. These have been extensively discussed by the experts and the European Communities refers to paras. 476ff of its own comments on the experts replies, in which it explains that these requests were scientifically reasonable.

4.1237 MaisGuard x Roundup Ready (MON810 x GA 21), EC 82: The United States identifies some delays that occurred at Member State level. These can be explained: one of the parents of this hybrid, GA 21, had not been assessed yet and the CA was awaiting the assessment. Whether a safety assessment for a hybrid can be put on hold while the assessment of the parental lines is awaited was not discussed by the experts. However, it would seem obvious that the hybrid cannot be assessed conclusively as long as one of its parental events' assessment is still open.

4.1238 GA 21, Food Use, EC 91: The United States raises some arguments for "undue delay" in this application. The European Communities has already replied to most of them, and notes that the United States seems to be raising a scientific issue, which has not been addressed by the experts, about a comment by the Greek CA concerning toxicity tests of the whole product, and not only the protein. It is merely an observation from Greece that no such data exist, but not a suggestion or request to perform the tests. The European Communities fails to see how that observation could caused delay whatsoever. It would seem that the United States has singled out this comment on an arbitrary basis.

4.1239 Bt Sweet Corn, EC 92: The United States and the European Communities disagree on the nature of comments and objections made. However, irregardless of whether one would call them risk assessments or not, they were based on valid and reasonable scientific reasons, a fact which the United States does not contest. The United States addresses some requests for information on compositional analysis and substantial equivalence. These requests are not covered by the Panel's questions and the European Communities disagrees with the United States on the scientific validity of these requests.

4.1240 MaisGuard (MON810) x RoundupReady (GA 21), EC 94: The United States raises two issues on EC 94. One is a delay due to the uncompleted assessment of GA 21, one of the parental lines. As discussed for EC 82 (release into the environment, same hybrid), this question was not discussed by the experts, and the comment on the necessity of hybrid's parental assessment still applies. The second issue is a request for a whole food study in mice. This was addressed by the Panel's Question 44 and discussed by the experts. The European Communities refers to its comments on the experts' replies at paras. 555ff. It maintains that such studies were necessary to assess unintended effects caused by possible additional DNA fragments, and that the request was made on valid grounds. Therefore, the delay caused by it cannot be considered "undue."

4.1241 Roundup Ready corn NK 603, Food Use, EC 96: The United States takes issue with certain procedural delays that occurred at Community level, which are due to the way the procedure is set out. The European Communities has already commented on this on previous applications. The United States also challenges certain requests for information as invalid. These have been covered by

the Panel's Questions 53 and 54. The European Communities refers to its comments on the experts' replies at paras. 615ff, in which it explains why these requests were scientifically valid.

(c) Assessment of delays under the different claims made by the complaining parties

4.1242 Annex C 1(a) of the *SPS Agreement*. As regard the individual product claims made, on a possible violation of Annex C 1(a), first, to the extent the products for which the complaining parties have alleged "undue delays" are withdrawn or have been authorized since, the claim is *sans objet*. In this respect we refer to our comments later on mootness. Second, a delay is not undue if and to the extent it has occurred for a number of reasons, of which at least one is clearly valid. This is very clear from the text, which states: "Members shall ensure with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that: (a) such procedures are undertaken and completed without undue delay". It is not any cause of delay that is prohibited but *undue* delay in the undertaking and *completion of procedures*. If the procedure cannot be completed for some reason other than the factor under consideration, there is no violation of this provision. Third, nobody contests at this stage that the scientific knowledge on possible harmful effects of GMOs is still insufficient. The experts have painted the picture of a rapidly evolving, in parts highly controversial scientific debate and it is against this background that they – without always agreeing- have confirmed the justification for, but sometimes also criticised certain requests for additional information. It is against this background that Canada and the United States are proposing to apply the requirements of Article 5.7 of the *SPS Agreement* when assessing what is undue and what not. However, Article 5.7, just like Article 5.1, does not apply to a failure to act. The European Communities agrees that the precautionary principle is to be taken into account when assessing "undueness" in paragraph 1(c) of Annex C. As the Appellate Body has made clear in *EC – Hormones:* "there is no need to assume that Article 5.7 exhausts the relevance of a precautionary principle". Fourth, there has been considerable debate on "mixed delays," i.e. delays relating to concerns that cannot be assessed under the *SPS Agreement* but need to be assessed under another agreement. Notwithstanding the European Communities' position on the scope of the *SPS Agreement*, the complaining parties' argument that: "Nothing in the text of the *SPS Agreement* suggests, as the European Communities contends, that a Member is excused from this obligation if the delay stems from a consideration outside the scope of the *SPS Agreement*." misses the true point: if a non-SPS concern is legitimately delaying completion of a mixed SPS/non-SPS approval procedure, then that procedure is not "unduly delayed" within the meaning of the *SPS Agreement*. If WTO Members are allowed to have approval procedures covering SPS and non-SPS concerns (and no-one has said they cannot), it cannot be that WTO Members are obliged to approve products which come within the scope of the *SPS Agreement* when there are non-SPS concerns outstanding. In any event, all concerns reflected in requests for additional information were scientifically valid and reasonable.

4.1243 Delays and "*de facto* moratorium". The Panel's experts have confirmed most concerns raised by CA as valid. Where they have not done so, the experts have acknowledged that the authorities' cautious approach was certainly valid or legitimate in the context of the complex and difficult scientific issues raised at the time. Faced with this, the United States abandons logical reasoning and now invites to "put this all back in context, and to use common sense", but the reality is that the examination of individual measures is logically inconsistent with the existence of an *a priori* moratorium. The complaining parties started off this case thinking that they could attack in WTO dispute settlement the fact that GMOs are what the United States has called "a controversial political issue in the EC". However, public opposition and political perceptions are not regulated by the *WTO Agreement* and are not the proper subject of dispute settlement. Nor of course is the voting behaviour or the "intransigence" of any individual political actor. If they were, panels would be constantly discussing the internal workings of WTO Members. On the contrary, it is necessary to identify a measure within the meaning of the DSU and demonstrate that that measure is contrary to a WTO

obligation. The reality is that the European Communities has adopted legislation to regulate GM products (legislation that is not itself the subject of these proceedings) and has examined the applications that it has received.

2. Mootness

4.1244 The Panel is competent to consider those measures which were in effect in August 2003, including the Member State safeguard measures. But a measure can only be in effect in August 2003 in respect of a product application that remains "live". For those products which had been withdrawn by that date a measure can no longer be considered to be in effect. The United States appears to accept that proposition.

4.1245 The same principle must apply where a measure ceases to be in effect after the Panel has been constituted, for example because the product has been withdrawn or has been approved. In such circumstances the application is *sans objet*. It is not the European Communities' position that in such circumstances the Panel is bound not to consider the measure. Consistent with international practise, including that of the International Court of Justice, there is no longer any utility in considering a measure which ceases to be in effect because there does not exist, in respect of that measure, a dispute between the Parties. In such circumstances courts decline to proceed to consider such measures. The reason relates to the absence of any remedy which can be ordered. That is particularly pertinent in the context of the WTO DSU: how is a member to implement a Panel recommendation in respect of a measure which is no longer in effect?

V. ARGUMENTS OF THE THIRD PARTIES

5.1 The arguments of the third parties, Australia, Chile, China, New Zealand and Norway are set out in their written and oral submissions to the Panel and in their answers to questions. The third parties' arguments as presented in their submissions are summarized in this section.[125]

A. THIRD PARTY ORAL STATEMENT OF AUSTRALIA

1. Introduction

5.2 As a third party to this dispute, Australia welcomes this opportunity to present its views to the Panel.

5.3 The Panel has an important and challenging task in front of it. The first written submissions of the principal parties have raised a wide range of complex factual, scientific and legal issues, which may, or may not, be pertinent to the Panel's resolution of the dispute. The issues raised include:

- the nature of risks associated with biotech products and relevant approaches to risk assessment;
- the legal characterisation of the contested measures;
- whether these measures are subject to the WTO covered agreements, and if so, which provisions are applicable;

[125] The summaries of the third parties' arguments below are based on the executive summaries submitted by the third parties where the third parties made available such summaries to the Panel.

- whether the European Communities has acted inconsistently with any of the applicable WTO provisions; and

- the relevance, if any, to the Panel's deliberations of the European Communities' extensive references to the Biosafety Protocol and to the concept of precaution as reflected in legal texts other than the WTO covered agreements.

5.4 These issues clearly have a systemic dimension as well.

5.5 Given the facts and circumstances of this dispute and the obvious care and attention taken by the complaining parties in framing their legal claims and arguments narrowly, Australia is of the view that the Panel should adopt a measured approach and limit its rulings and recommendations accordingly. Australia notes that the Panel has considerable discretion to exercise 'judicial economy' in making an objective assessment of the matter before it, and in making its recommendations and ruling.[126]

5.6 Whatever approach is adopted by the Panel in making its objective assessment, Australia has a substantial interest in the matter before the Panel, particularly in relation to the interpretation and application of the cited provisions of the covered agreement, and in any consideration by the Panel of any legal claims and arguments regarding the relationship between the WTO Agreement and any other international laws or standards that may be considered relevant.

5.7 Given these interests, which we would expect are shared by other third parties, Australia would expect the Panel to provide all third parties with the fullest possible opportunity to express views on any specific issue of law or legal interpretation considered by the Panel to be relevant to the resolution of the dispute.

5.8 Accordingly, Australia requests the Panel to ensure that all third parties are given an opportunity to respond in writing to all relevant written questions presented to the parties following this meeting, as well as to any relevant subsequent written questions that might be raised at a later stage in the proceedings.

2. Australian interests

5.9 I would like to expand on the issues of interest to Australia.

5.10 Australia has a strong interest in any assessment by the Panel of the applicability and interpretation of the provisions of the *SPS Agreement* raised by the parties (Articles 1, 2, 5, 7, 8 and 10, and Annexes B and C). Areas of particular interest to Australia, should the Panel consider these to be of any relevance to the resolution of the dispute, are the scope of the *SPS Agreement* and its applicability to the contested measures, and the relationship of Article 5.7 with other provisions of the *SPS Agreement* or with any other relevant agreements.

5.11 Australia also has a strong interest in any assessment by the Panel of the applicability and interpretation of the provisions of the *TBT Agreement* (Articles 2, 5 and 12) and of the GATT 1994 (Articles III and XI) which have been raised by the parties. Areas of particular interest to Australia, should the Panel consider these to be of any relevance to the resolution of the dispute, include the scope and application of the *TBT Agreement* in general, and of the term "like products" under the relevant TBT and GATT provisions in relation to biotech products.

[126] Appellate Body Report, *US – Wool Shirts and Blouses*, page 18.

5.12 Finally, in relation to the European Communities' extensive references to the Biosafety Protocol and to the concept of precaution as reflected in non-WTO legal texts, in Australia's view the matter before the Panel can be resolved solely by reference to the WTO covered agreements. Given the facts of this dispute, there is no need for the Panel to consider the applicability of such non-WTO legal texts. Of particular relevance is the fact that none of the three complaining parties are parties to the Biosafety Protocol.

5.13 However, should the Panel consider the Biosafety Protocol or non-WTO reflections of the concept of precaution to be of any relevance to the resolution of the dispute, Australia has a strong interest in ensuring that its views on these issues be taken into account.

3. Third party participation rights

5.14 I want to conclude by registering clearly with the Panel Australia's expectation that all third parties will be provided with the fullest possible opportunity to express views on specific issues of law or legal interpretation considered by the Panel to be relevant to the resolution of the dispute. As noted earlier, Australia expects this view is shared by other third parties.

5.15 Article 10 of the DSU requires the Panel to ensure that the interests of third parties are fully taken into account during the Panel process. At this point in the process, an extraordinarily wide range of factual, scientific and legal issues have been raised. It is also apparent that the fundamental nature of the dispute and legal claims is vigorously contested; this is most clearly indicated in paragraph 11 of the European Communities' first written submission which purports to reserve the right to provide a "a full refutation of the Complainants first written submission" for its second written submission. Given this situation, it is simply not possible for third parties to determine which of these issues will be the subject of an objective assessment by the Panel, and it would be unproductive for third parties to present views on the full range of issues on a completely speculative basis.

5.16 Against this background, Australia has therefore not presented any substantive views on the wide range of factual, scientific and legal issues raised by the principal parties. Instead, we have sought to identify issues on which Australia wishes to present its views, in the event those issues are considered by the Panel to be relevant to the resolution of the dispute. As indicated earlier, given the circumstances in this dispute, the most appropriate approach for the Panel to take into account Australian and other third party interests under the covered agreements is to provide third parties the fullest possible opportunity to provide responses to any written questions presented to the parties following this meeting, as well as to any subsequent questions that might be raised at a later stage in the proceedings. This approach is within the Panel's discretion and is fully consistent with relevant DSU provisions, such as Articles 10 and 13.[127])

B. THIRD PARTY ORAL STATEMENT OF CHILE

5.17 Chile is grateful for the opportunity to express its views in this dispute. We are motivated by a genuine interest in the discussion of this subject matter in respect of which my country, like many other developing countries, is currently developing a national policy. We also have a systemic interest in the proper interpretation and application of the provisions of the WTO agreements, in particular the *SPS Agreement*, the *TBT Agreement*, and the GATT 1994.

5.18 The purpose of this statement is to provide the Panel with certain items of information regarding the objectives of a biotech policy in a country like Chile. We recognize that the work of

[127] Appellate Body Report, *US – FSC (Article 21.5 – EC)*, para. 243.

this Panel is determined by its terms of reference, and specifically, by the legal provisions which Argentina, Canada, and the United States consider to have been violated by the measures adopted by the European Communities. However, we cannot simply disregard the possible implications of a ruling like the one that has been requested for the developing countries that are currently drawing up their policies and legislation in that area.

5.19 The development of a biotech policy is seen by Chile as a way of maintaining and enhancing the competitiveness of certain economic sectors that rely on scientific and technological innovation, such as the agricultural, forestry and aquaculture sectors. Indeed, modern biotechnology would help to improve competitiveness by fostering the protection and preservation of genetic material while at the same time paving the way to involvement in areas such as biomedicine.

5.20 All of this calls for an appropriate regulatory framework, one that would consolidate the role of public institutions with legal authority in the biotech area. At the same time, there is a need for coordination among these agencies and proper consultation with civil society, for adequate entrepreneurial institutions, and for scientific and technological capabilities and the capacity to train human resources.

5.21 For all of these reasons, Chile is highly interested in the systemic implications of the WTO consistency of product approval measures within the European Union. In particular, we are concerned by the failure to approve the release of biotech products since 1998, in spite of the existence of Community legislation in that respect (Directive 90/220, replaced by 2001/18). Likewise, we are concerned by the bans on the release of biotech products in certain EC member States that would appear to be inconsistent with Community legislation. Finally, we are interested in the relationship between the failure to approve the applications for entry with the new Community legislation on traceability and labelling of biotech products.

5.22 Mr Chairman, let me turn to the two unsolicited submissions received by the Panel from third parties that are not party to this dispute.

5.23 I begin by stressing that there is no provision under the DSU that enables panels to accept unsolicited and unwanted information. The Appellate Body has ruled on this issue in the past, but that does not constitute a precedent. On the contrary, most WTO Members expressed their opposition to this kind of submission at a special meeting of the General Council at the end of 2000. On that occasion, participants reaffirmed the intergovernmental nature of the Organization on which the participation of Members rests, particularly under the DSU. Chile and the other Members represent a national stance which, as a rule, has been developed taking account of all of the sectors and interests involved. Chile cannot negotiate – or seek the settlement of a dispute – with each one of these interests separately. Nor can the other Members negotiate with the Chilean actors separately. We assume that the national position of a Member is reflected in its submissions, arguments and defence, and that these do not represent the vision of certain sectors only.

5.24 Secondly, the rights and obligations of Members can only be modified by consensus following a formal negotiation process such as the one that has been conducted since the Doha Ministerial Declaration, in which, once again, the opinion of the majority of Members was that the participation of non-governmental third parties in WTO disputes should be rejected.

5.25 Thirdly, the developing countries already suffer from serious limitations during the dispute settlement process: for example, it is not easy for them to meet deadlines, or to deal with the formalities and other procedures, not to mention the growing complexity of the subjects submitted to

the mechanism and of the arguments of the disputing parties. Having to examine and reply to the questions raised in third-party submissions further increases the already considerable burden.

5.26 Finally, we understand that the Panel has consulted with the Parties on the possibility of requesting an expert opinion on certain issues raised in this dispute, in accordance with Article 13 of the DSU. Regardless of whatever position the disputing parties may have concerning the wisdom or appropriateness of such an expert opinion, we think that this is the only path to follow.

5.27 Chile respectfully requests the Panel to take these views into consideration when deciding on the issue raised by Argentina, Canada and the United States.

C. THIRD PARTY WRITTEN SUBMISSION OF CHINA

1. Introduction

5.28 Although this dispute raise a host of issues that are important to the operation of the *SPS Agreement*, *TBT Agreement* and GATT 1994, the application of Article 5.7 of the *SPS Agreement* and the likeness of biotech products and non-biotech products under Article III: 4 of the GATT 1994 call for close attention and analysis by the Panel.

2. China's view on Article 5.7 of the *SPS Agreement*

5.29 China believes that "insufficient scientific evidence" referred in Article 5.7 does not imply that Article 5.7 can be invoked without risk assessment, but merely that such an assessment can be made on the basis of factors, which would not fulfil the Article 5.2 risk assessment requirements. Thus, the application of Article 5.7 will depend not only upon the nature of the risk, but also the nature of the risk assessment. In order to prove "relevant scientific information is insufficient" the following two criteria must be met:

(1) There is a risk assessment for the subject goods; and

(2) Available pertinent information falls short to complete the examination of the risk factors listed in Article 5.2 of the *SPS Agreement*.

5.30 In *EC – Hormones*, the Appellate Body states that risk factors listed in Article 5.2 are not exclusive.[128] In this case, traceability could be a risk factor to be considered under Article 5.2 of the *SPS Agreement*. Before European Communities passed its Regulation 1830/2003, the available pertinent information could be insufficient to examine traceability of biotech products. Only after European Communities passed its regulation on traceability and labelling a more objective assessment of risk can be completed.

5.31 Article 5.7 requires the measure to be adopted "on the basis of available pertinent information". In China's view, "available pertinent information" includes not only scientific information, but also all information having logical relevance to this matter. The words "including" in Article 5.7 indicates that information "from the relevant international organizations" and "from SPS measures applied by other members" is not exhaustive in nature. Thus, in this case, the panel may consider background of so-called product-specific delay and the EC member State safeguard measures as a whole to determine whether European Communities or the EC member State adopted it on the basis of available pertinent information.

[128] *See* Appellate Body Report, *EC – Hormones*, para. 187.

5.32 In *Japan – Agricultural Products II*, the Appellate Body stated that the additional information sought must be germane to conducting a more objective risk assessment.[129] China believes that such additional information may not be narrowly interpreted as scientific information only. In this case, the European Communities' legislation process on biotech products could be considered as one aspect of the information collection.

5.33 The Appellate Body in *Japan – Agricultural Products II*, stated that "what constitutes a 'reasonable period of time' has to be established on a case-by-case basis and depends on the specific circumstances of each case, including the difficulty of obtaining the additional information necessary for the review and the characteristics of the provisional SPS measure".[130]

5.34 China is of the opinion that "reasonable period of time" depends on the capability of a WTO Member to obtain additional information. For instance, to obtain the same information to conducting a more objective risk assessment, a developing country with less research ability is more likely to take longer period of time than developed countries. In this case, GMO technology is at the frontiers of science, and each WTO Member, including European Communities, may not have capability to obtain additional information to conduct a more objective risk assessment at current stage. Thus, in order to obtain such additional information, longer period of time may be considered reasonable.

3. Biotech products and non-biotech products are not "like products" under Article III: 4 of the GATT 1994

5.35 China is of the opinion that biotech products are not like products of non-biotech products. In *EC – Asbestos*, the Appellate Body identified four general criteria in analysing "likeness" under Article III:4: (1) the properties, nature and quality of the products; (2) the end-uses of the products; (3) consumers' tastes and habits; and (4) the tariff classification of the products.[131] And none of them alone is determinative, all of the evidence, taken as a whole, must be weighted.[132]

5.36 First, when the panel considers the physical and natural similarity of biotech products and non-biotech products, the anti-natural character of biotech products must be given more weight in evaluation. "Genetically Modified Organism (GMO)" is defined as an organism, with the exception of human beings, in which the genetic material has been altered in a way that *does not occur naturally by mating and/or natural recombination*.[133] (emphasis added) Even the term "biotech products" is use instead of GMO, the panel shall bear in mind through its analysis that biotech product does not occur naturally by mating and/or natural recombination.

5.37 Second, in *EC – Asbestos*, the Appellate Body noted that: "Although we agree that it is certainly relevant that products have similar end-uses for a 'small number of … applications', or even for a 'given utilization', we think that a panel must also examine the other, *different* end-uses for products".[134] (emphasis original) There are some unique characters for biotech products intertwined with its end-use, such as insect-resistance, pesticide-tolerance. Those differences should not be ignored by this panel, on the contrary, this panel shall give more weight on the unique character of biotech products.

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[129] *See* Appellate Body Report, *Japan – Agricultural Products II*, para. 92.
[130] *See* Appellate Body Report, *Japan – Agricultural Products II*, para. 93.
[131] *See* Appellate Body Report, *EC – Asbestos*, para. 101.
[132] *See* Appellate Body Report, *EC – Asbestos*, para. 103.
[133] *See* Article 2 of Directive 2001/18.
[134] *See* Appellate Body Report, *EC – Asbestos*, para. 119.

5.38 Third, the consumers' tastes and preferences in Europe, which are unfavourable towards biotech products, shall be taken into consideration by this panel to conclude biotech products are not like products of non-biotech products.

5.39 Finally, because commercial applications of biotechnology came into being in 1990s, it is understandable that there is no distinction under tariff classification between biotech products and non-biotech products. However, the labelling requirements set forth in new legislations, such as Regulation 1830/2003, show a tendency to separate biotech products from non-biotech products. Therefore, no differences under tariff classification between biotech and non-biotech products shall be given little practical weight.

5.40 In sum, China believes that the factual evidence relating to each of the four criteria makes it clear that biotech products and non-biotech products must not be considered to be "like products".

D. THIRD PARTY ORAL STATEMENT OF CHINA

5.41 Mr. Chairman and members of the Panel, on behalf of China, I would like to thank you for providing the opportunity to present our views. Today, I will focus on two key issues in this dispute. The first issue is the requirement to invoke Article 5.7 of the *SPS Agreement*; the second issue is the "likeness" of biotech products and non-biotech products.

5.42 Article 5.7 permits Members to adopt provisional SPS measures where relevant scientific evidence is insufficient. China believes that "insufficient scientific evidence" referred in Article 5.7 does not imply that Article 5.7 can be invoked without risk assessment. In order to prove "relevant scientific information is insufficient" two criteria must be met: (1) There is a risk assessment for the subject goods; and (2) available pertinent information falls short to complete the examination of the risk factors listed in Article 5.2 of the *SPS Agreement*.

5.43 Article 5.2 lists seven risk factors that shall be considered. In *EC – Hormones,* the Appellate Body states that risk factors listed in Article 5.2 are not exclusive. In this case, traceability could be a risk factor to be considered under Article 5.2 of the *SPS Agreement*. Before the European Communities passed its Regulation 1830/2003, the available pertinent information could be insufficient to examine traceability of biotech products.

5.44 Pursuant to the second sentence of Article 5.7, a provisional measure may not be maintained unless the Member which adopted the measure seeks to obtain additional information necessary for a more objective assessment of risk. China believes that such additional information may not be narrowly interpreted as scientific information only. In this case, the European Communities' legislation process on biotech products could be considered as one aspect of the information collection.

5.45 Article 5.7 requires the Member to review the SPS measure within a reasonable period of time. The Appellate Body in *Japan – Agricultural Products II* stated that "what constitutes a 'reasonable period of time' has to be established on a case-by-case basis and depends on the specific circumstances of each case, including the difficulty of obtaining the additional information necessary for the review and the characteristics of the provisional SPS measure".

5.46 China believes that "reasonable period of time" depends on the capability of a WTO Member to obtain additional information. For instance, to obtain the same information to conducting a more objective risk assessment, a developing country with less research capability is more likely to take longer period of time than developed countries. In this case, GMO technology is at the frontiers of

science, and each WTO Member, including European Communities, may not have capability to obtain additional information to conduct a more objective risk assessment at current stage. Thus, in order to obtain such additional information, longer period of time may be considered reasonable.

5.47 As regard to Article III:4, China is of the opinion that biotech products are not like products of non-biotech products. In *EC – Asbestos*, the Appellate Body identified four general criteria in analysing "likeness" under Article III:4: (1) the properties, nature and quality of the products; (2) the end-uses of the products; (3) consumers' tastes and habits; and (4) the tariff classification of the products. And none of them alone is determinative, all of the evidence, taken as a whole, must be weighted.

5.48 First, when the Panel considers the properties, nature and quality of the products, the anti-natural character of biotech products must be given more weight in evaluation. "Genetically Modified Organism (GMO)" is defined as an organism, with the exception of human beings, in which the genetic material has been altered in a way that *does not occur naturally by mating and/or natural recombination.* (emphasis added) Even the term "biotech products" is use instead of GMO, the panel shall bear in mind through its analysis that biotech product does not occur naturally by mating and/or natural recombination.

5.49 Second, in *EC – Asbestos*, the Appellate Body noted that: "Although we agree that it is certainly relevant that products have similar end-uses for a 'small number of ... applications', or even for a 'given utilization', we think that a panel must also examine the other, *different* end-uses for products. There are some unique characters for biotech products intertwined with its end-use, such as insect-resistance, pesticide-tolerance. Those differences should not be ignored by this panel, on the contrary, this panel shall give more weight on the unique character of biotech products.

5.50 Third, the consumers' tastes and preferences in Europe, which are unfavourable towards biotech products, shall be taken into consideration by this panel to conclude biotech products are not like products of non-biotech products.

5.51 Finally, because commercial applications of biotechnology came into being in 1990s, it is understandable that there is no distinction under tariff classification between biotech products and non-biotech products. However, the labelling requirements set forth in new legislations, such as Regulation 1830/2003, show a tendency to separate biotech products from non-biotech products. Therefore, no differences under tariff classification between biotech and non-biotech products shall be given little practical weight.

5.52 Mr. Chairman and members of the Panel, China believes that the factual evidence relating to each of the four criteria makes it clear that biotech products and non-biotech products must not be considered "like products".

E. THIRD PARTY WRITTEN SUBMISSION OF NEW ZEALAND

1. Introduction

5.53 The Panel in this dispute is asked to determine whether certain measures adopted by the European Communities affecting the approval and marketing of biotech products[135] meet the requirements of the *SPS Agreement*. New Zealand is one of many WTO Members that has exercised

[135] New Zealand uses this term throughout the submission in the same sense as it is used by Canada. *See* first written submission of Canada, para. 27.

its right under the *SPS* Agreement to adopt measures to regulate the entry and release of new organisms, including genetically modified organisms, necessary for protection from any adverse effects of those organisms. The *SPS Agreement* guarantees to WTO Members the right to take measures for the protection of human, animal and plant life or health.[136] The complaining parties in this dispute do not contest that right.[137]

5.54 However, sanitary and phytosanitary measures adopted by WTO Members are subject to the disciplines set out in the *SPS Agreement*.[138] Those disciplines seek to ensure that such measures do not restrict trade unnecessarily. At issue in this dispute is whether the European Communities has complied with those disciplines.

5.55 As both a significant producer and exporter of agricultural products, New Zealand has a strong interest in ensuring that the delicate balance of rights and obligations set out in the WTO Agreements, especially the *SPS Agreement*, is maintained.

5.56 This dispute raises a number of specific issues regarding the interpretation of the *SPS Agreement* upon which New Zealand will comment. This submission will first argue that the European Communities' moratorium and its product-specific marketing bans[139] are "measures" within the meaning of the *SPS Agreement* and thus are subject to scrutiny for compliance with the disciplines of the *SPS Agreement*. Second, this submission will discuss the procedural requirements that Members must comply with in adopting sanitary and phytosanitary measures, particularly under Articles 7 and 8 of the *SPS Agreement*. And third this submission will comment on issues relating to the right of Members to adopt measures in accordance with the *SPS Agreement* and to determine their appropriate level of protection from risks to human, animal or plant life or health under the *SPS Agreement*.

5.57 Insofar as the European Communities' product-specific marketing bans may not be subject to the provisions of the *SPS Agreement*, the *TBT Agreement* would apply as argued in the alternative by Canada and Argentina. New Zealand has chosen not to address arguments concerning the *TBT Agreement* in this submission, but reserves the right to do so in the Third Party Session of the Panel.

5.58 Given the limited time that New Zealand has had to consider the first written submission of the European Communities[140], New Zealand reserves the right to make any further comment on it during the Third Party Session of the Panel. New Zealand will not comment on the European Communities' presentation in Part II of the European Communities' submission ("Factual Part"), including the European Communities' presentation of aspects of New Zealand's legislation or policy which are not in issue in this dispute.[141]

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[136] Article 2.1.

[137] First written submission of the United States, para. 68; first written submission of Argentina, para. 195.

[138] Article 2.1.

[139] New Zealand uses the terms "moratorium" and "product-specific marketing bans" in the same sense as they are used by Canada. *See* first written submission of Canada, para. 1. New Zealand will not address issues relating to the national measures adopted by particular EC member States.

[140] First written submission of the European Communities.

[141] This should not be read, however, as endorsing the EC representation of any aspect of New Zealand's policy or legislation.

2. Legal arguments

(a) The moratorium and product-specific marketing bans are "measures" for the purposes of the *SPS Agreement*

5.59 Annex A paragraph 1 of the *SPS Agreement* defines what are "sanitary or phytosanitary measures" and are therefore subject to the provisions of the *SPS Agreement*. What distinguishes sanitary and phytosanitary measures from other measures that affect international trade is their purpose, that is, they seek to provide protection from certain sanitary and phytosanitary risks.

5.60 Sanitary or phytosanitary measures include, *inter alia*, measures applied to protect plant life from risks arising from the entry, establishment or spread of pests, and measures applied to protect human or animal life or health from risks arising from contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs. The evidence of the complaining parties[142] shows that the European Communities' regulatory approvals processes have been adopted by the European Communities for the purpose of providing protection from one or more of these risks. Both the moratorium and the product-specific marketing bans are thus sanitary or phytosanitary measures within the meaning of the *SPS Agreement*.

5.61 An illustrative list of the types of sanitary and phytosanitary measures that a member might adopt is also provided in paragraph 1 of Annex A of the *SPS Agreement*. It is clear that this list is not exhaustive and that a measure of a type not listed, but which is adopted for one of the purposes listed, would still be a sanitary and phytosanitary measure falling within the jurisdiction of the *SPS Agreement*.

5.62 WTO jurisprudence has clarified that the term "measure" in the context of the WTO Agreements has a broad content. Accordingly it captures not just acts, but also omissions;[143] and not just legally binding or mandatory acts or policies, but non-mandatory measures.[144] The reason for interpreting the term "measure" as having such a broad content is clear. Primarily, it means that actions of a Member that affect trade, whether formal or informal, are comprehensively subject to scrutiny for consistency with their WTO obligations. A broad interpretation of "measure" is also specifically consistent with the object and purpose of the *SPS Agreement*. The *SPS Agreement* imposes disciplines on WTO Members' use of sanitary and phytosanitary measures in order to avoid unnecessarily restricting trade. A narrow interpretation of "measure" would allow WTO Members to circumvent their WTO obligations simply by resorting to less direct means than transparent, formally adopted laws or procedures.

5.63 As acknowledged by the complaining parties, the existence of the European Communities' moratorium and product-specific marketing bans has to be inferred from the actions and statements of the European Communities. That is because the European Communities has issued no written document, regulation or legislative provision establishing either the moratorium or the marketing bans. In the present dispute a narrow interpretation of the term "measures" would allow the European Communities to avoid scrutiny of its actions that impact on trade in biotech products because the Panel could look no further than the legislated approvals process that the European Communities has in place. New Zealand submits that such an interpretation and approach must be rejected. The *SPS Agreement* and WTO jurisprudence provides sufficient basis for the Panel in this dispute to

[142] First written submission of Argentina, paras. 36-63; first written submission of the United States, paras. 74-80; and first written submission of Canada, paras. 160-174.
[143] Appellate Body Report, *US – Corrosion-Resistant Steel Sunset Review*, para. 81.
[144] Panel Report, *Japan – Agricultural Products II*, para. 8.111.

consider the European Communities' moratorium and product-specific marketing bans to be "measures" and therefore must submit them to scrutiny for compliance with the European Communities' WTO obligations under the *SPS Agreement*.

(b) Procedural requirements of the *SPS Agreement*

(i) Failure to "publish promptly"

5.64 The need for transparency in the adoption and application of sanitary and phytosanitary measures is an important aspect of the protections provided by the *SPS Agreement* against undisguised restrictions on trade. Under Article 7 Members are required to meet the requirements for transparency set out in Annex B, including the requirement in paragraph 1 to "publish promptly" all sanitary or phytosanitary regulations that they adopt.

5.65 Applying Appellate Body jurisprudence regarding the interpretation of the term "sanitary or phytosanitary regulations"[145], it is clear that the European Communities' moratorium and product-specific marketing bans are subject to the requirement that they be "published promptly". As presented by the complaining parties, the European Communities has failed to publish the existence of either the moratorium or the bans, and thus has also failed to do so "promptly" as required.

(ii) Undue delay

5.66 Under Article 8 of the *SPS Agreement* WTO Members must observe the provisions of Annex C in the operation of their approval procedures associated with sanitary and phytosanitary measures, including the requirement in paragraph 1(a) of Annex C that approval procedures are "undertaken and completed without undue delay". In their submissions the complaining parties discuss the meaning of the term "undue delay" and conclude that in the context of paragraph 1(a) of Annex C it refers to "the 'unjustifiable' and 'excessive' 'hindrance' in undertaking or completing an approval procedure."[146] As the European Communities acknowledges[147], both the reason for the delay and its duration are relevant considerations in determining whether the delay is undue.

5.67 Thus whether there has been "undue delay" within the meaning of paragraph 1(a) must be determined on a case by case basis. In New Zealand's view there must be a strong presumption that "undue delay" has occurred where a Member has in fact suspended the operation of the approval procedures provided for in its own legislation without providing any justification in terms of the *SPS Agreement* for doing so. Accordingly in the present dispute the European Communities has acted with "undue delay" in undertaking or completing its approval procedures for biotech products.

(c) Substantive requirements of the *SPS Agreement*

5.68 The *SPS Agreement* imposes substantive, as well as procedural, disciplines on the use of sanitary and phytosanitary measures. Article 2.1 gives Members the right to establish measures, including for biotech products, that are necessary for the protection of human, animal or plant life or health and that are not inconsistent with the provisions of the *SPS Agreement*. Article 2.2 sets out the basic requirement that such measures must be based on scientific principles and may not be maintained without sufficient scientific evidence.

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[145] Appellate Body Report, *Japan – Agricultural Products II*, para. 105.

[146] First written submission of the United States, para. 89; first written submission of Canada, para. 239; and first written submission of Argentina, para. 315.

[147] First written submission of the European Communities, para. 479.

5.69 Successive Panels and the Appellate Body have now provided considerable guidance on the interpretation of provisions of the *SPS Agreement* that are relevant to this dispute. In considering the arguments before it the Panel should apply that guidance in order to ensure that the balance is maintained between a Member's right to adopt sanitary and phytosanitary measures on the one hand, and its obligation not to unnecessarily restrict trade on the other.

5.70 This balance is evident in the provisions of the Agreement relating to a Member's determination of its appropriate level of sanitary or phytosanitary protection. Annex A, paragraph 5, of the *SPS Agreement* defines the "appropriate level of sanitary or phytosanitary protection" as that "deemed appropriate by the Member establishing a … measure". However, Members may not adopt measures that are more trade restrictive than necessary to achieve their desired level of protection, taking into account technical and economic feasibility. The *SPS Agreement* also provides guidance as to when a measure could be considered to be more trade restrictive than necessary, namely where another significantly less trade restrictive measure is technically or economically feasible that would achieve the same level of protection.[148]

5.71 It is not necessary in this case to examine in great detail the level of protection afforded by the European Communities' legislated approvals processes. The legislative framework adopted by the European Communities must be taken to represent at least the level of protection deemed appropriate by the European Communities to manage risks arising from biotech products. If the measure actually applied is more trade restrictive than that, then the *SPS Agreement*, and basic logic, supports the conclusion that the measure applied is more trade restrictive than necessary to achieve the level of protection deemed appropriate. The European Communities' moratorium and product-specific marketing bans are measures that are clearly more trade restrictive than necessary to meet the level of protection that the European Communities itself has deemed to be appropriate in respect of biotech products. Accordingly, the moratorium and product-specific marketing bans are measures that are more trade restrictive than necessary for the protection of human, animal or plant life or health and thus are inconsistent with the provisions of the *SPS Agreement*.

F. THIRD PARTY ORAL STATEMENT OF NEW ZEALAND

5.72 Mr Chairman, Members of the Panel, New Zealand's views on the issues of concern in this dispute are set out in our Third Party Submission of 24 May 2004. In our statement today we briefly summarise those views.

5.73 As outlined in our submission, New Zealand has joined this dispute because of our systemic interests and our desire to ensure that the delicate balance of rights and obligations set out in the WTO Agreements, especially the *SPS Agreement*, is maintained.

5.74 The *SPS Agreement* guarantees to WTO Members the right to take measures for the protection of human, animal and plant life or health, including measures to regulate the import and marketing of biotech products. That right is not contested in this dispute.

5.75 However WTO Members that adopt SPS measures must comply with the disciplines of the *SPS Agreement* that are designed to ensure that SPS measures do not restrict trade unnecessarily. These disciplines include provisions requiring transparency in the adoption and application of such measures as well as provisions imposing substantive requirements that such measures must be based on scientific principles and not maintained without sufficient scientific evidence.

[148] Footnote 3, Article 5.6.

5.76 The "measure" at issue in this dispute is not the European Communities' legislated approvals process, but the actions taken by the European Communities that have in fact impacted on the approval and marketing of biotech products. These actions have been described by the complaining parties as a general moratorium on approval of biotech products, or product-specific moratoria or marketing bans. It is well established that the term "measure" in the WTO context is broad in content and thus a Panel may look beyond the formal laws and regulations of a Member to assess overall the nature and impact of a Member's actions on trade. Accordingly in New Zealand's view the Panel should find that these actions – the moratorium and product-specific bans – are "measures" adopted by the European Communities that affect trade in biotech products and are thus subject to scrutiny with the European Communities' WTO obligations.

5.77 The complaining parties have also demonstrated that the European Communities' measures are SPS measures within the meaning of the *SPS Agreement*. New Zealand's Written Submission highlighted three ways in which the complaining parties have demonstrated that the European Communities' moratorium on biotech products and its product-specific marketing bans failed to comply with the European Communities' obligations under the *SPS Agreement*.

5.78 The European Communities' measures fail to meet the clear procedural requirements of the *SPS Agreement* that SPS measures must first be "published promptly" and second that approvals processes that Members adopt must be undertaken and completed without "undue delay". These procedural requirements operate to provide protection against such measures being used to restrict trade unnecessarily. The European Communities' failure to publish the moratorium or the bans is clear.

5.79 In respect of whether there has been "undue delay" in the application of the European Communities' approvals processes, there must be a strong presumption that a delay is "undue" where a Member has in fact suspended the operation of its legislated approvals process without providing any justification in terms of the *SPS Agreement* for doing so.

5.80 The European Communities also failed to meet the substantive requirement of the *SPS Agreement* not to adopt measures that are more trade restrictive than necessary to achieve their desired level of protection. The legislative framework adopted by the European Communities for the approval and marketing of biotech products must be taken to represent at least the level of protection deemed appropriate by the European Communities to manage risks arising from biotech products. The European Communities' moratorium and product-specific marketing bans – more trade restrictive than the European Communities' legislative framework – are therefore clearly more trade restrictive than necessary to achieve the European Communities' appropriate level of protection.

5.81 In conclusion, for the reasons set out in New Zealand's written submission, the Panel should find that the European Communities' moratorium and product-specific marketing bans fail to meet the requirements of the *SPS Agreement* .

G. THIRD PARTY WRITTEN SUBMISSION OF NORWAY

1. Introduction

5.82 While recognizing the many potential benefits from GM products, Norway underlines that GMOs have been used for a relatively short time and that important effects on health and the environment remain not fully understood. The approval of GMOs and GM products raise several complex issues of a scientific and factual nature. The process of risk assessment is therefore

particularly time-consuming. A prudent approach to GMOs in WTO members' regulatory frameworks is therefore warranted.

5.83 Norway restricts its third party submission to certain legal issues concerning Bt. 176[149], MS1xRF1[150], and Topas 19/2.[151] These are three out of totally seven GMOs in relation to which national EC member State measures are contested.

2. Factual background, with emphasis on consequences of use of antibiotic resistance marker genes (ARMGs)

(a) Overview

5.84 GMOs are one of the results of modern biotechnology. They are created by a particular set of techniques which are used to genetically modify (or "genetically engineer") organisms. In short, they require a change of genetic material within an organism through genetic recombinant nucleic acid techniques. This is explained in more detail in chapter 2.1 of Norway's first written submission.

5.85 Contrary to what has been claimed, there is no "proven safety record" [152] with regard to GMOs. National and international regulatory developments demonstrate that GMOs are not a mere continuation of traditional breeding. This is shown in Chapter 2.3 of Norway's first written submission. GMOs should therefore not be treated as equivalent to non-GM products. Little is known about long-term effects of foods from transgenic crops. Moreover, little scientific agreement exists regarding their environmental impacts. New scientific evidence concerning environmental and health impacts is constantly emerging.

5.86 Among the possible environmental effects outlined by scientists are the spreading of genes through hybridisation between GM plants and closely related domesticated or wild species, population growth, spreading and invasion of GM plants into natural ecosystems, increased competition from GM plants or their hybrids with natural species, the spreading of genes through horizontal gene transfer from plants to microorganisms in the environment, development of herbicide resistant weeds, development of insects resistant to insecticides, effects on non-target organisms and secondary environmental effects as a consequence of changed agriculture practises e.g. new use of insecticides, herbicides, fertiliser's etc. [153]

[149] Subject to safeguard in Austria, Luxembourg and Germany.
[150] Subject to safeguard in France.
[151] Subject to safeguard in France and Greece.
[152] As stated in the first written submission of the United States, ref. heading preceding paragraph 27.
[153] Keeler K.H. 1985 (Exhibit NOR-77); Crawley, M.J., 1988. Meeting report: COGENE/SCOPE at Lake Como. Special combined issue: Trends Biotechnology & Trends Ecology, Evol 3. 2-3 (Exhibit NOR-78); Ellestrand N.C. 1988. Special combined issue: Trends Biotechnology & Trends Ecology, Evol 3. 30-32 (Exhibit NOR-79); Tidje J.M (and 6 others) 1989. Ecology. Vol 70, No 2 (Exhibit NOR-80); Williamson M. 1989. Special combined issue: Trends Biotechnology & Trends Ecology, Evol 3. 32-35 (Exhibit NOR-81); McNally R. 1994. The Ecologist, Vol 24, No. 6 Nov/Dec, 207-212 (Exhibit NOR-82); Doyle J.D, Stotzky G, McClung G, Hendricks C.1995. Advances in Applied Microbiology, Vol. 40, 237-287 (Exhibit NOR-83); The Royal Society of Canada. 2001. Elements of Precaution: Recommendations for the regulation of food biotechnology in Canada. An expert panel report on the future of food biotechnology prepared by the Royal Society of Canada at the request of Health Canada, Canadian Food Inspection Agency and Environment Canada (ISBN-0-920064-71-x) (Exhibit NOR-22); Snow A.A. *et al.*, 2004; "Genetically engineered organisms and the environment: Current status and recommendations" ESA position paper (Exhibit NOR-4).

5.87 Some of these hypothesises have been debated in the scientific literature and many of them have been verified by research in some species and environments. A consequence may be population decrease or extinction of species in natural ecosystems, or different type of problems for agriculture. Whether these types of effects will occur is difficult to predict a priori, and will depend on the species and genetic modification in question, the receiving environment or the farming and agro-ecosystem in use.

5.88 Among the scientific concerns that have been raised in connection with public and animal health are insufficient studies on putative effects of GM nucleic acids or food/feed on potential animal or human consumers, whether the transgene DNA sequences given in the notifications are the same as the insert sequences found in the GM plants, persistence and uptake of DNA and proteins from mammalian GIT (gastro intestinal tractus), transgenic or altered host cell proteins and production of chemicals and pharmaceuticals in plants. Some of the concerns will also be relevant for environmental risk assessments of GMOs due to the fact that the processes can take place in the environment.

5.89 These possible effects and concerns are explained in more detail in chapter 2.2 of Norway's first written submission.

5.90 A prime concern is the potential spreading of genes through horizontal gene transfer from plants to micro-organisms in the environment, particularly in respect of *antibiotic resistance marker genes (ARMGs)*

5.91 As described in Chapter 2.4 and documented by risk assessments, these effects were the main reason for prohibiting the three GMOs in Norway.

5.92 Horizontal gene transfer is unknown. This means that intentional genetic modification of for example plants could lead to unintentional genetic modification of other organisms. Today no scientists deny the occurrence of horizontal gene transfer, and different mechanisms have been described for the process. An increasing amount of genes and traits in different species that most probably have been spread through horizontal gene transfer, have been reported. The consequences of such unintentional genetic modifications on human health and the environment, including possible long-term effects, are not well known.

5.93 ARMGs are used as a selection tool during the process of modification. In most cases they remain within the plant as an intact genetic trait.[154] Resistance towards antibiotics is an increasing problem in therapeutic human and veterinary medicine. Most likely, this is a result of unwise use and spread of antibiotics in general. Two uncertainties exist: Firstly: When GM plants are digested, what possible increased spread of antibiotic resistance genes may occur through horizontal gene transfer to organisms in the environment and in the human and animal digestical tract? Secondly: What consequences may this have with regard to resistance development of pathogenic bacteria in the future?

5.94 Norway has explained the risks associated with Bt 176, MS1xRF1 and Topas 19/2 which led to their prohibition in Norway. The essence is described below:

[154] Droege M. *et al.*, 1998 (Exhibit NOR-105); Nielsen K. M. *et al.*, 2000 (Exhibit NOR-106), 2003 (Exhibit NOR-76).

(a) Maize Line Bt 176

Concerns are here related to risks associated with a possible horizontal transfer of the *amp* gene for resistance to the antibiotic ampicillin contained in the product, as well as with ecological effects of the insect toxin encoded by the *cryIA (b)* genes. A transfer of the *amp* gene to pathogenic bacteria in such a way that the gene is successfully incorporated and expressed would be highly undesirable. This is because it might impede clinical treatment. As is documented in the attached risk assessment, studies indicate that there is a risk for horizontal transfer of the *amp* gene.

(b) Oilseed rape line MS1 x RF1

Concerns are here related to the risks associated with a possible horizontal transfer of the *nptII* gene for resistance to the antibiotics neomycin and canamycin contained in the product, as well as with the consequences of gene flow from the genetically modified oilseed rape to wild plants and crops. Transfer of this gene to pathogenic bacteria could contribute to worsening the problem of development of antibiotic resistance. When the risks of this particular genetically modified oilseed rape were assessed, some results indicated a risk of horizontal transfer of the *nptII* gene. As with Bt 176, further studies were needed. A further concern was documented in the above-mentioned risk assessment. This was related to hybridisation between genetically modified oilseed rape and several wild and domesticated plant species in Norway. Introgression of the gene conferring gluphosinate-tolerance into cross-compatible species could lead to the development of gluphosinate-resistant weeds. In addition, hybridisation with other crop plants could have undesirable effects. These may include future agricultural problems connected to weed management.

(c) Oilseed rape line Topas 19/2

It contains the *npt II* gene encoding resistance to the antibiotics kanamycin and neomycin. The assessments and comments with regard to ARMGs in oilseed rape MS1xRF1 above are also applicable to oilseed rape line Topas 19/2.

3. Legal discussion

(a) Overview

5.95 Norway submits that risks related to ARMGs are not covered by the *SPS Agreement*, or by Article 2 of the *TBT Agreement*. The applicable WTO Agreement is thus the GATT. The member State measures are not in breach of Article III: 4 of the GATT 1994, and are at any rate justified under Article XX of the GATT 1994.

5.96 If the Panel nevertheless were to consider that such bans should be addressed under the *SPS Agreement*, Norway argues in the alternative that the national EC member States bans conform to Article 5.7 under the *SPS Agreement*.

(b) The *SPS Agreement* is not applicable to measures against ARMGs

5.97 The definitions in Annex A point 1 are quite precise. The application of the *SPS Agreement* will depend on the purpose of each particular measure, and more specifically which risks the measure is intended to protect against. If a particular objective is not covered by the *SPS Agreement*, a decision

which invokes this particular risk shall not be assessed under SPS, but rather under the *TBT Agreement* or the GATT 1994. Should the Panel decide that only one objective falls under the SPS, the remaining part of the decision must be assessed under the other Agreements.

5.98 The protection from risks arising from GMOs or GM products, is not mentioned *per se* in the wording of Annex A. Whether a measure falls under Annex A, point 1 will therefore be decided by the objective(s) of a measure in relation to the concrete risk(s).

5.99 The concern with ARMGs is that the antibiotic resistant trait in the GM crop or product DNA might be transferred to bacteria, particularly in the digestive tract of humans or animals. This might have negative impact on clinical and veterinary medicine, which relies heavily on antibiotics (and therefore on the absence of resistance to antibiotics). As explained by the European Communities[155], plant DNA is in itself not an organism. Even if it were, it would however not be the plant DNA that caused the disease. The disease would have to arise from other sources. Therefore, plant DNA is not covered by the definitions set out in Annex A point 1. Accordingly, the *SPS Agreement* is not applicable.

(c) Alternative argument in respect of Article 5.7 of the *SPS Agreement*

5.100 Should the Panel, nevertheless, decide to assess member States' national measures regarding any of the three GMOs under the *SPS Agreement*, Norway will argue, in the alternative, that the measures against the risks of ARMGs fully conform with the *SPS Agreement*, in particular Article 5.7 thereof.

5.101 The European Communities has convincingly shown that the national measures of member States – if they are to be assessed under the *SPS Agreement* – are "provisionally adopted".[156] This follows *inter alia* from the legal basis in internal EC law. We refer to the European Communities' first written submission for further details.[157] Since these member States' measures are provisional, any evaluation of the conformity of the bans with the *SPS Agreement* must be made under Article 5.7 and not under Article 5.1.

5.102 Norway argues that the four cumulative requirements set out in Article 5.7 are satisfied and accordingly that there is legal basis for adopting and maintaining the provisional phytosanitary measures.

5.103 Firstly, Norway argues that we are faced with a situation where "relevant scientific evidence is insufficient". Biotechnology is still in its infancy. Many of the scientific findings are inconclusive or ambiguous. GMOs are exceedingly complex to analyse. It may take years before one may find reliable evidence, which allows to conclude as to their possible harmful impact on health and/or the environment.

5.104 Secondly, the measures in question were adopted "on the basis of available pertinent information". The EC member States could collect information from open sources and they could depend on risk-assessments delivered by other member States due to internal transparency mechanisms within the EU. They could also depend on the Norwegian risk-assessment due to the same kind of mechanisms within the European Economic Area. On the whole, there exists a

[155] *Ibid*, paras. 431-432.
[156] At least Canada does not seem to contest that these are provisional measures, *see* first written submission of Canada, para. 379.
[157] First written submission of the European Communities, para. 589.

presumption that sufficient information was at hand for the EC member states to identify the risks posed by GMOs.

5.105 Thirdly and fourthly, the European Communities fulfils the requirement of seeking "to obtain the additional information necessary for a more objective assessment of risk and will review the measure within a reasonable period of time". In order to gain better insight a considerable amount of research is continuously carried out world-wide. An expert panel recently established under the European Food Safety Authority has recently assessed ARMGs, and a working group within the European Communities is currently considering the use of ARMGs in GMOs. In conclusion, the requirements under SPS Article 5.7 are thus met in relation to the three GMOs.

(d) The *TBT Agreement* is not applicable to measures against ARMGs.

5.106 Canada and Argentina argue that to the extent that the *SPS Agreement* is not applicable, the member State national measures could be reviewed under various subparagraphs of Article 2 to the *TBT Agreement.*[158] In Norway's view the arguments of Canada and Argentina do not correctly reflect the content of Article 2.2. The reason is that EC member State national measures are not "technical regulations" within the meaning of the *TBT Agreement.*[159] They do not contain general descriptions of a normative nature applicable to an undetermined number of producers. In the case in *EC – Asbestos*, the Appellate Body *inter alia* held that since the national measure "lays down "characteristics" for <u>all</u> products that might contain asbestos"[160] (underlining added), the measure was covered by Article 2.2 of the *TBT Agreement.* In our dispute, however, the national measures do not apply to <u>all</u> GMOs or even all GMOs coding for antibiotic resistance. Rather, each measure contains a single ban on one particular GMO. Each measure is addressed to one specific manufacturer or right holder and creates legal rights and obligations only upon this addressee. Therefore, they fall outside the scope of Article 2 of the *TBT Agreement*.

(e) The GATT 1994

5.107 Canada and Argentina claim that [some] of the member State national measures violate Article III: 4 of the GATT 1994.[161] These allegations are unfounded.

5.108 In order for a violation of Article III: 4 to occur, several conditions have to be fulfilled. A main requirement is that imported products are treated less favourably than domestic products. In this dispute, the national origin of the manufacturers is not a relevant issue. As shown throughout this submission, quite different concerns have led to these national measures. Indeed, most of the GMOs subject to member State national measures have in fact been notified by companies incorporated in the European Communities and belong to such companies.[162] Thus, the national measures do not distinguish on the basis of nationality. Moreover, there is no evidence that the national measures are in particular addressed at the imported GMOs. This is also the case with the Greek national measure, which according to its intended legal effects applies *erga omnes*.

5.109 Moreover, in order to be caught by Article III: 4 of the GATT 1994, the complaining parties must show that these GMOs are "like" products. Several factors will contribute to deciding whether

[158] First written submission of Canada, paras. 473-505; and First written submission of Argentina, paras. 547-592.
[159] First written submission of the European Communities, para. 642.
[160] Appellate Body Report, *EC – Asbestos*, para. 75.
[161] First written submission of Canada, para. 444; and first written submission of Argentina, paras. 338.
[162] *See* first written submission of the European Communities, paras. 632-633.

these are "like" products or not. As demonstrated in Chapter 2.3, most WTO members distinguish between GMOs and its conventional counterparts as regards regulatory regimes. This is because GMOs in fact may have different effects on health and environment than their conventional counterparts. Also, as shown in Chapters 2.4.2.2 and 2.4.3.2, international organisations are increasingly viewing products containing GMOs with genes coding for antibiotic resistance as distinct from conventional products. Also, the growing requirement for labelling of GMOs, which come as a respond to consumer demands, indicate that GMOs should not be treated as "like" products.

5.110 In conclusion, the member State measures in relation to the three GMOs are not in breach of Article III: 4 of the GATT 1994.

5.111 Even if there should be a breach, other Articles of the GATT 1994, Article XX of the GATT 1994, in particular sub-paragraph (b), provide a defence with respect to the three GMOs discussed here.

4. Concluding remarks

5.112 Norway respectfully requests the Panel to take the facts and arguments presented above fully into consideration when making its findings and recommendations.

H. THIRD PARTY ORAL STATEMENT OF NORWAY

1. Introduction

5.113 Norway has in its written submission addressed the risks associated with three particular GMOs: Bt 176[163], MS1xRF1[164], and Topas 19/2.[165] These are three out of seven GMOs in relation to which national EC member State measures are contested in the present case. Norway's focus on these three GMOs today is due to the fact that they contain *antibiotic resistance marker genes (ARMGs).* This is also the main reason why their marketing is prohibited in Norway.

5.114 In my oral intervention I will focus on two issues of legal interpretation. Firstly, I will argue that the *SPS Agreement* is not applicable to risks arising from ARMGs. And secondly I will show that these national measures are not infringing the GATT 1994. In respect of the scientific evidence relating to GMOs in general, as well as our other legal arguments, I refer to our written submission.

2. Application of the *SPS Agreement*

5.115 The complaining parties argue in the first instance that the member State national measures fall under the *SPS Agreement*. This argument is based on a simplification on how the *SPS Agreement* is to be understood. Only national measures that have certain specified objectives and which address certain specified risks are covered by the *SPS Agreement*.

5.116 It is clear from Annex A of the *SPS Agreement* that the "risks" covered must "arise" or be caused by the risk factors mentioned in point 1. Measures against other risks, no matter how serious their consequences may be, are not covered by the *SPS Agreement*, but may be covered by the *TBT Agreement* or the GATT 1994.

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[163] Subject to the safeguards in Austria, Luxembourg and Germany.
[164] Subject to the safeguard in France.
[165] Subject to the safeguards in France and Greece.

5.117 In respect to the risks posed by GMOs with ARMGs – as is the case with the 3 above-mentioned GMOs – the specific concern is that antibiotic resistance genes might be transferred to bacteria, particularly in the digestive tract of humans and animals (so-called "horizontal transfer"). If this should happen, the treatment of infections by certain antibiotics – ampicillin, kanamycin and neomycin – could be impeded both in human and veterinary medicine, because of resistance acquired by bacteria to these antibiotics.

5.118 According to Annex A point 1 litra b), an SPS measure is *inter alia* a measure whose purpose is to protect human or animal life or health from disease-causing organisms in foods, beverages or feedstuffs. Although the protection against ARMGs is a clear human and animal health concern, these risks do not fall under Annex A point 1. Firstly, the inserted DNA which contains the antibiotic resistance gene, is not an organism in itself. Secondly, the gene is not disease-causing, but may merely prevent the treatment of diseases caused by ordinary bacterial infections. Therefore, the *SPS Agreement* is not applicable to the national bans insofar as their object is to protect against the risks of antibiotic resistance.

3. Application of the GATT 1994 – Article III:4

5.119 Canada and Argentina have presented arguments alleging that the national EC member States bans infringe Article III:4 of the GATT 1994. As far as Article III:4 of the GATT 1994 is concerned, we have in our written submission argued that imported products are not treated less favourably than domestic products. The GMOs in question are prohibited, irrespective of their country of production.

5.120 Furthermore, Norway argues in its written submission that GMO-products are not "like" products, and we refer to our written submission for more details. Let me just point to para 105, which refers to the Codex decision of July 2003, whose guidelines now treat antibiotic resistance marker genes in food production, differently from foods which do not contain such genes. I would also point to the many national legislations that have enacted separate approval procedures for GMOs. This clearly demonstrates that most WTO Members consider GMOs to be something different from the original non-modified organisms. In conclusion Article III:4 is not infringed.

4. Application of the GATT 1994 – Article XX

5.121 If the Panel, nevertheless, were to conclude that Article III: 4 or Article XI: l of the GATT 1994 – in the case of Greece – have been violated, it must assess whether the national EC member States measures can be justified under Article XX. The burden of proof in this respect rests upon the European Communities.

5.122 Norway would like to note that in respect of the three GMOs with ARMGs, the policy pursued by the European Communities and its member States with regard to GMOs would seem to fall directly under Article XX of the GATT 1994, sub-paragraph (b) as measures to protect "human, animal or plant life or health". The risks that these GMOs pose, have been explained in detail in the Norwegian written submission and the documents annexed thereto.

5.123 Limiting myself to comment briefly upon the requirement of "necessity" in sub-paragraph (b), it is difficult to see that there could be reasonable – and less trade distorting – alternative measures available, in order to fulfil the established policy objective of avoiding antibiotic resistance. Labelling for instance, would clearly not achieve the declared health objectives. I should also note that no alternative measures seem to have been suggested by any of the complaining parties.

5.124 Finally, a remark regarding the requirements of the "chapeau" of Article XX of the GATT 1994. There is nothing in facts of this case that indicate that the national measures in this dispute are applied in a discriminatory way, nor that they represent a disguised restriction on international trade. These bans on certain GMOs are based on legitimate concerns, and are applied equally to all Members of the WTO.

VI. INTERIM REVIEW

6.1 Pursuant to Article 15.3 of the DSU, the findings of the final panel report shall include a discussion of the arguments made by the parties at the interim review stage. This Section of the Panel reports provides such a discussion. As is clear from Article 15.3, this Section is part of the Panel's findings.

A. BACKGROUND

6.2 The United States, Canada, Argentina and the European Communities separately requested an interim review by the Panel of certain aspects of the interim reports issued to the Parties on 7 February 2006.[166] None of the Parties requested an interim review meeting.[167] However, in accordance with the Panel's Working Procedures, all Parties had, and used, the opportunity to submit further written comments on each others' requests.[168]

6.3 On 8 May 2006, the Panel sent a letter drawing attention to the fact that certain aspects of its interim reports had been misconstrued by groups or members of civil society following the unauthorized public disclosure of the Panel's confidential interim reports.[169] For this reason, the Panel in its letter made a number of statements relating to its findings in this case.[170]

6.4 On 10 May 2006, the Panel issued its final reports to the Parties on a confidential basis.

B. STRUCTURE

6.5 The Panel first addresses the Parties' requests for changes to the interim reports (Section VI.C). The Panel notes in this regard that it did not receive comments on each of the Sections of the interim reports from each of the four Parties. The Panel has structured its treatment of the Parties' requests below in the following manner:

(a) Section VI.C.1 concerns Section VII.A of the interim reports (Procedural and Other General Matters).

(b) Section VI.C.2 concerns Section VII.C of the interim reports (Relevant EC Approval Procedures).

(c) Section VI.C.3 concerns Section VII.D of the interim reports (General EC Moratorium).

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[166] Letters of the Parties of 17 March 2006.
[167] Letters of the Parties of 7 March 2006.
[168] Letters of the Parties of 19 April 2006.
[169] *See infra*, Section VI.F.
[170] Letter of the Panel of 8 May 2006. In the interests of transparency, the text of the letter is attached to these reports as Annex K (available on-line only). The text of the letter is reproduced in Annex K is not part of the Panel's findings and is not intended to modify them in any way.

(d) Section VI.C.4 concerns Section VII.E of the interim reports (Product-Specific Measures).

(e) Section VI.C.5 concerns Section VII.F of the interim reports (EC Member State Safeguard Measures).

(f) Section VI.C.6 concerns Section VIII of the interim reports (Conclusions and Recommendations).

6.6 In addition, this Section also notes certain other changes (editing, etc.) that were not specifically requested by the Parties (Section VI.D).

6.7 Next, this Section deals with the European Communities' request for redaction from the public version of the Panel reports of portions disclosing "strictly confidential information" (Section VI.E).

6.8 Finally, the present Section addresses the public disclosure of the Panel's confidential interim reports (Section VI.F).

C. PARTIES' REQUESTS FOR CHANGES TO THE INTERIM REPORTS

1. Procedural and other general matters

6.9 The **European Communities** identified an incorrect reference to the year 2005 at paragraph 7.47.

2. Relevant EC approval procedures

(a) Comments common to Canada and Argentina

6.10 **Canada** and **Argentina** request that the hypothetical example used by the Panel at paragraphs 7.162-7.163, and footnote 132 (Canada) be qualified to avoid the possibility that its use may be misconstrued. In these paragraphs, the Panel relies on a hypothetical example (concerning food labelling) to explain its interpretive approach to the issue of mixed measures. Canada is concerned that use of the hypothetical example could be misconstrued as the Panel expressing a view on the purpose of Regulations 1829/2003 and 1830/2003, measures that were not within the Panel's terms of reference. Argentina considers that the example is not an essential part of the Panel's reasoning and could be removed without affecting the Panel's conclusions. Moreover, in Argentina's view, the Panel's reasoning finds practical application when the Panel addresses whether the EC approval procedures are SPS measures in terms of their purpose.

6.11 The **European Communities** responds that it fails to see how this example could be understood to refer to any "real life" measure such as Regulation 1829/2003 or to generally express any views on the WTO-compatibility of such a measure. Indeed, the Panel elsewhere in the report explicitly states that it does not take any view on the WTO-consistency of labelling requirements. Accordingly, the Panel need make no change to its report.

6.12 The **Panel** has removed the relevant example at paragraph 7.162 and deleted the old footnote 132.

(b) Comments by Canada

6.13 **Canada** requests that the Panel reconsider its representation, at paragraph 7.164, of Canada's position in relation to the issue of whether a requirement can constitute both an SPS measure and a non-SPS measure. Canada is concerned that the Panel's comments in footnote 127 suggest that the Panel has misapprehended Canada's position in this regard.

6.14 The **European Communities** argues that Canada fails to state clearly what it is that it requests the Panel to do. Presumably, Canada's concerns could be met if footnote 127 would be re-phrased as follows:

> "Canada had a more complex position and characterised the issue of whether a measure that addresses both SPS risks and other types of risks or policy objectives should be considered a single measure or a series of measures, as 'semantic'."

6.15 In response to Canada's comment, the **Panel** has expanded its representation of Canada's position in footnote 339.

6.16 **Canada** identified an editorial oversight at paragraph 7.337.

6.17 **Canada** also notes that at paragraph 7.411 the Panel states that "it is reasonable to assume that the requirement that the consumer be informed of the presence of a GMO irrespective of whether there is an associated health risk is at least in part imposed to prevent consumers from being misled. In other words, we consider that, at least in part, Regulation 258/97 requires the identification of the presence of a GMO in a food product in order to ensure that those consumers who have a preference for food not containing or consisting of GMOs are not misled into purchasing food containing or consisting of GMOs". Canada respectfully requests that this passage be revised to make it clear that the Panel is not making a finding that the absence of a GMO label necessarily leads to consumers being "misled". According to Canada, the presence of a GMO label may have the opposite effect and actually mislead consumers. In any event, Canada submits that whether consumers are actually being misled is a factual matter that was not addressed by any of the parties in their submissions.

6.18 The **European Communities** considers that Canada's comment on the use of the word "misled" must be dismissed. It is obvious that the Panel is merely referring to the wording used in Regulation 258/97, which in its Article 3 explicitly refers to the objective of not misleading consumers.

6.19 The **Panel** has added a footnote to paragraph 7.411 in response to Canada's comment.

(c) Comments by the European Communities

6.20 The **European Communities** argues that at paragraph 7.117 the third sentence should be deleted as it is not correct that the Council can adopt a "different" measure. The Council may adopt a modified measure, but not by qualified majority. In fact, the same rules as for legislative proposals apply here, *i.e.*, the Council can modify a Commission proposal only by unanimous vote (Article 250(1) of the *Treaty Establishing the European Community as Amended by Subsequent* Treaties (hereafter the "EC Treaty"). Furthermore, for the sake of completeness, it seems appropriate to describe what happens if the Council rejects the proposal.

6.21 The **United States** does not agree with the European Communities' suggested modifications concerning paragraphs 7.117, 7.123 and 7.136. First, the record in this dispute does not contain an

instance where the Council rejected a Commission proposal. (Instead, the Council failed to reach qualified majorities for acceptance or rejection). Thus, the Panel has no need for "sake of completeness" to address this possibility. Second, the EC comments do not cite to any prior EC submission that describes the procedures that apply when the Council rejects a Commission proposal.[171] Thus, the procedures to be followed by the Commission following a Council rejection by qualified majority would appear to be a new factual matter not previously considered by the Parties or the Panel. For these reasons, the United States submits that it is neither necessary nor appropriate to address such procedures for the first time at the interim review stage.

6.22 The **Panel** has made appropriate changes to paragraph 7.117 and its accompanying footnotes in response to this EC comment. However, the Panel agrees with the United States that it is not necessary, in the context of these proceedings, to address the procedures to be followed in the event that the Council rejects a draft measure of the Commission. The Panel has therefore refrained from adding relevant explanatory text at paragraphs 7.117, 7.123 and 7.136.

6.23 The **European Communities** submits that, for the sake of completeness in footnote 95 to paragraph 7.123 it should be explained what happens if the Council rejects the proposal.

6.24 For the reason explained in connection with the EC comment on paragraph 7.117, the **Panel** has refrained from making the requested addition to footnote 309.

6.25 The **European Communities** argues that at paragraph 7.129 the word "consent" should be replaced by the word "authorizations", since "consent" is a term which is not used in Regulation 258/97 but only in Directives 90/220 and 2001/18.

6.26 The **Panel** has made an appropriate change to paragraph 7.129 in response to this comment.

6.27 The **European Communities** submits that, at paragraph 7.136 the third sentence should be deleted as it is not correct that the Council can adopt a "different" measure. The Council may adopt a modified measure, but not by qualified majority. The same rules as for legislative proposals apply here, *i.e.*, the Council can modify a Commission proposal only by unanimous vote (Article 250(1) of the EC Treaty). Furthermore, for the sake of completeness, it seems appropriate to describe what happens if the Council rejects the proposal.

6.28 The **Panel** has made appropriate changes to paragraph 7.136 and its accompanying footnotes in response to this comment. However, for the reason explained in connection with the EC comment on paragraph 7.117, the Panel has refrained from addressing the procedures to be followed in the event that the Council rejects a draft measure of the Commission.

6.29 The **European Communities** identified a missing indefinite article in paragraph 7.152.

6.30 The **European Communities** requests that the Panel reflect, in a footnote to paragraph 7.199, the fact that in its response to Panel question No. 120 the European Communities also referred to the cover note accompanying the circulation of the so called "Dunkel Text" of 20 December 1990.

6.31 The **United States** argues that paragraph 7.199 addresses the EC arguments (properly rejected by the Panel) that the *SPS Agreement* does not cover measures meant to protect the environment. The

[171] In fact, the European Communities' comprehensive descriptions of its approval procedures set out in its prior submissions do not address this matter. *See, e.g.*, EC first written submission, pages 51-63; *see also* Exhibits EC-119 and 120 (presenting a flowchart of approval procedures under 258/97 and 90/220).

United States does not agree that the Panel should include the new footnote suggested by the EC summarizing an additional EC argument involving a cover note to the "Dunkel Text." The EC arguments regarding this matter are set forth in the EC answer to the Panel's questions (in particular, Question 120), and those answers are already appended in full to the interim report. Moreover, the EC comment does not acknowledge that the United States, in its response to the EC answer to Panel question No. 120, fully responded to the EC argument regarding the purported significance of this cover note to the "Dunkel Text". If a footnote were added that recited the EC argument, then – to maintain balance – a new footnote would be required to reference the US rebuttal of the EC argument. However, since all of this material is already appended to the report, and since (the United States submits) the EC argument is without merit, the interim report would not be improved by the addition of the footnote suggested by the European Communities.

6.32 The **Panel** has made appropriate changes to paragraph 7.199 in response to this EC comment, preferring to include the reference to the cover note in the text rather than in the footnote. For balance, the Panel also added a summary of the United States' and Canada's responses to the EC argument based on the negotiating history. Furthermore, in view of the European Communities' request for inclusion of a reference to the above-mentioned cover note and in view of the EC argument based on this note – that environmental damage is not covered by the *SPS Agreement* – the Panel found it appropriate (i) to address explicitly the cover note, which has also resulted in some restructuring (paragraphs 7.209-7.211), (ii) to clarify the example used at paragraph 7.210, and (iii) to add footnote 503 for further clarification of paragraph 7.209. In addition, the Panel has deleted the old footnote 158 which contained no text. The Panel furthermore corrected a typographical error at paragraph 7.209.

6.33 The **European Communities** argues that the first sentence of paragraph 7.236 should be deleted as it does not seem to accurately reflect the arguments made by the European Communities and suggests that the second sentence be rephrased based on the EC reply to Panel question No. 119.

6.34 The **United States** does not agree with the EC suggestion. To the contrary, the United States submits that this statement in the interim report is indeed a fair characterization of the EC's arguments regarding the term "pest."[172] The United States would not object, however, if the interim report were to include a statement, as the EC suggests, to the effect that the EC believes that the IPPC may be relevant context for interpreting the term "pest."

6.35 The **Panel** has made appropriate changes to paragraph 7.236 in response to the EC comment.

6.36 The **European Communities** requests that a statement by Dr. Squire (Annex H, paragraph 468) be added to footnote 227 to paragraph 7.281 so that the view of all experts on the relevant issue are referred to.

6.37 The **United States** does not agree with the EC suggestion that a statement from Dr. Squire should be appended to the footnote. The statement of Dr. Squire cited by the European Communities states no scientific opinion regarding the risks of ARMGs. Instead, in the context of discussing EC member State objections, Dr. Squire simply notes that there is a "perception" that ARMGs should not be used in herbicide-tolerant ("HT") crops. Moreover, Dr. Squire explains that given the vagueness of the member State objections, he is not able to evaluate their scientific merit. He accordingly summarizes his opinion by explaining "[t]his notwithstanding, and as in other instances, unless

[172] *See, e.g.*, EC second written submission, para. 51 ("Thus not any 'undesirable cross-breed', as the Panel put it in question 32, can be considered a pest. In particular a cross-breed that harms biodiversity is not a pest. Nor is cross-breed that harms micro-organisms, animals or the environment.").

criteria can be given, from both the proposer and objector as to what is a desirable or acceptable comparator, then progress with the discussion is impossible, as it became in this instance."[173]

6.38 **Canada** also disagrees with the suggested addition of Dr. Squire's comments in relation to ARMG. The EC suggestion implies that Dr. Squire was of the view that ARMG presents risks to human health or the environment, neither of which is the case. Tellingly, the European Communities quotes Dr. Squire out of context. The full quote is as follows:

> "The issue of antibiotic resistance was considered in the SCP's opinion (EC-66/At.53) and found not to pose risk, but there is now widespread perception that antibiotic resistance should not be introduced through GMHT products."

6.39 Canada submits that it is unclear whether Dr. Squire agreed with the opinion of the SCP on the risks of antibiotic resistance. If Dr. Squire disagreed with the SCP, presumably he would have stated so explicitly. Therefore, in terms of the issue discussed by the Panel in paragraph 7.274, *i.e.*, the risk of transferral of antibiotic resistance, Dr. Squire's comment is unrevealing. Dr. Squire does not discuss "scientific evidence", but only "perception". The cause of the "widespread perception" may have nothing to do with the actual risks associated with the use of ARMG and may simply reflect the unfortunate politics of agricultural biotechnology in Europe. For instance, scientists working in this field may have stopped using ARMG because of "optics", manipulated by anti-GMO advocates, and the availability of alternative means to achieve the same objective. Canada notes that although Dr. Squire initially indicated that he would do so, he did not respond to either of these two general questions on the existence of scientific evidence relating to the transfer of antibiotic resistance (Questions 1 and 2). Consequently, his views on the actual risks associated with the use of ARMG are unknown.

6.40 **Argentina** likewise does not agree with the EC proposal and requests the Panel to maintain the wording of footnote 227 as it currently stands. It is important to recall that when the Panel addressed to the experts the specific issue of "antibiotic resistance marker genes" (Annex H, General Questions 1 and 2), Dr. Squire did not provide an answer that expressed his point of view as an expert. Additionally, Argentina points out that the addition suggested by the European Communities reflects a mere "perception" (as it is literally stated by Dr. Squire) and not a statement or opinion based on scientific evidence as requested by the Panel.

6.41 The **Panel** does not consider it appropriate to add the relevant statement to footnote 437. The statement that "there is now a widespread perception that antibiotic resistance should not be introduced through GMHT products" does not shed light on the risk of transferral of ARMG or the existence or magnitude of adverse effects on human health or the environment from the presence of ARMG or their products.

6.42 The **European Communities** requests that footnote 252 to paragraph 7.316 be deleted in its entirety, arguing that Canada's description of Directive 91/414 does not properly reflect the requirements set by the legislation and the way the legislation is implemented. The European Communities submits that in any event, the Panel itself takes the view that the question of whether Directives 90/220 and 2001/18 are applied, *inter alia*, to avoid diseases to humans or animals resulting from herbicide residues in food or feedstuff ultimately can be left open. The footnote, therefore, is also not necessary.

[173] Annex H, para. 468.

6.43 **Canada** disagrees with the EC suggestion to delete footnote 252. This footnote is important context to explain the Panel's statement that "[i]t is not clear to us from reading Directives 90/220 and 2001/18 whether they are applied, *inter alia*, to avoid disease to humans or animals resulting from herbicide residues in GM plants used as food or feedstuff." In this footnote, the Panel sets out Canada's argument that the European Communities failed to acknowledge that the risks associated with the use of plant protection products, including the risks to human and animal health from herbicide residues in food and feedstuff, were addressed by other relevant EC legislation. Canada pointed out that Commission decisions and scientific committees have repeatedly confirmed that "the authorization of chemical herbicides applied to plants and the assessment of the impact of their use on human health and the environment falls within the scope of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market…and not within the scope of Directive 90/220/EEC."[174] Moreover, Canada emphasized that the herbicides used in conjunction with herbicide tolerant crops, specifically glyphosate, had received a full evaluation under Directive 91/414/EEC, including an assessment of the use of glyphosate with glyphosate tolerant crops, as early as 2001.[175] In addition, the risks to human and animal health of residues of glyphosate had been fully assessed prior to the establishment of MRLs under Directive 98/82/EC.[176] This information is important in that it reveals that many of the purported risks associated with biotech crops advanced by the European Communities are in fact risks associated with the use of plant protection products generally, and that these risks, contrary to the European Communities' selective portrayal of its own regulatory environment, have received a full assessment under other pertinent legislation. On this basis, Canada is of the view that the footnote should be retained. That being said, however, Canada suggests that the Panel clarify that MRLs are not established pursuant to Directive 91/414/EEC, but, rather, pursuant to other relevant European Community rules.[177]

6.44 The **Panel** considers that the old footnote 252 is not essential and has therefore deleted it as requested by the European Communities.

6.45 Like Canada, the **European Communities** identified an editorial oversight at paragraph 7.337.

6.46 The **European Communities** requests that the Panel delete a sentence in paragraph 7.368 which it considers does not accurately reflect its position.

6.47 The **Panel** has deleted the relevant sentence in paragraph 7.368 in response to this comment.

6.48 The **European Communities** submits that the wording "even in cases where" in paragraph 7.384 should be deleted as it implies that authorizations may be granted in either scenario, *i.e.*, where the product has been found to be safe and where the product has not been found to be safe. The latter is not possible, as market authorizations are only granted if there is no risk to human health and the environment.

6.49 **Canada** disagrees with the suggested alternative wording for paragraph 7.384. The wording "even in cases where" does not imply that authorizations may be granted in cases where the product has been found not to be safe. To the contrary, this wording highlights the fact that the labelling requirement in Directive 2001/18 is applicable regardless of the conclusion of the risk assessment or the actual risks associated with a particular biotech product. This emphasis is appropriate given the

[174] Canada's second written submission, para. 142 and footnote 163.
[175] *Ibid*., para. 183 and footnotes 194 and 195.
[176] *Ibid*., para. 185 and footnote 196.
[177] *See ibid*., para. 180.

Panel's inquiry in paragraph 7.377 and succeeding paragraphs regarding whether the imposition of a labelling requirement under these circumstances can be considered an SPS measure. Alternatively, the Panel may wish to consider replacing "even in cases where" with "regardless of the fact that".

6.50 **Argentina** does not consider the proposed amendments to paragraph 7.384 to be acceptable. Regarding the first proposed amendment, the European Communities is changing the scope and sense of the first two sentences. It is cutting off the first sentence by adding a full stop after the word "GMO", and thus linking the rest of it with the proposed amendment which Argentina considers not to be acceptable. As to the second proposed amendment, the European Communities is giving no reason for it (it only refers to the first one). Argentina notes that, the competent authorities have not granted a market authorization even when the scientific evidence showed that the release was safe. Since the European Communities' proposed description is not accurate, especially the word "therefore", Argentina respectfully requests the original wording to be maintained.

6.51 The **Panel** has made appropriate changes to paragraph 7.384 in response to this EC comment.

6.52 The **European Communities** argues, with reference to the old paragraph 7.381, that it does not agree with the Panel that the labelling requirement in Directive 2001/18 only serves the purpose of protecting human health and the environment in the way the Panel has described it. This said, the European Communities does not object to the statement that this is one possible purpose of labelling and therefore bears a rational relationship. However, as, in the European Communities' view, it is not the only purpose – the other one being consumer information – the European Communities submits that the wording should be more "open" and the last sentence should be deleted as it suggests exclusivity of purpose. Finally, the European Communities suggests to use the words "even though" instead of "even in cases where".

6.53 The **United States** submits that the European Communities has no basis for its suggestion that the Panel delete one of the most important sentences in that section of the interim report: namely, the concluding sentence to paragraph 7.381. That paragraph (and sentence) provide:

> "The preceding paragraph makes clear that there is a rational relationship between the labelling requirement in Directive 2001/18 and the purpose of protecting human health and the environment, even in cases where a product containing or consisting of a GMO has been found to be safe for human health and the environment. Accordingly, we see no reason to assume that the labelling requirement is intended to serve a purpose which is different from the purpose Directive 2001/18 says it seeks to achieve, *i.e.*, the protection of human health and the environment."

6.54 The United States contends that the European Communities' only basis for suggesting the deletion of the last sentence in paragraph 7.381 is the assertion that the labelling requirement also serves the purpose of "consumer information." However, the European Communities provides no basis for this assertion, and does not, for example, cite to any supporting provision of the Directive. Indeed, as the Panel correctly notes, the labelling requirement is an integral requirement of Directive 2001/18, and the very first article of that directive states that its objective is "to protect human health and the environment." Thus, the European Communities has provided no basis in the record for its suggested change to paragraph 7.381.

6.55 **Canada** also disagrees with the European Communities' proposed deletion of the last sentence of paragraph 7.381. The Panel's conclusion that there is "no reason to assume that the labelling requirement is intended to serve a purpose which is different from the purpose Directive 2001/18 says it seeks to achieve, *i.e.*, the protection of human health and the environment"

is a sound one given the text of Directive 2001/18 and the European Communities' own submissions in this case. The Panel rightly points out that the only stated purpose of the Directive, other than approximation of member State laws, is to protect human health and the environment. Moreover, the European Communities did not refer to "consumer information" as an objective of Directive 90/220 or 2001/18 in its description of its legislative framework set out in its first written submission, paragraphs 155 to 163, or in its explanation of the flaws in Directive 90/220 that it claims needed to be rectified by Directive 2001/18.[178] The European Communities' position has been that the new labelling requirements in Directive 2001/18 were intended to strengthen post-marketing surveillance, and not for "consumer information" purposes. Consequently, the suggested change does not reflect the position taken by the European Communities in these proceedings and should be disregarded.

6.56 **Argentina** considers that the first phrase of paragraph 7.381 should remain unchanged. First, as the European Communities indicates, the Panel does not state in paragraph 7.380 that protecting human health and environment "is the only" purpose. The Panel explicitly stated that the purposes in Article 20 of Directive 2001/18 referred *inter alia* to situations described in paragraph 7.380, and correctly describes to what extent the identification and labelling of GMOs contributes to some of the purposes of Article 20. Second, both the described purposes of Article 20 in paragraph 7.380, and the wording of Article 20 itself (especially paragraphs 2 and 3) explicitly refer to foreseen situations of risks to human health and the environment. Consequently, Argentina considers that the wording proposed by the European Communities ("can be") diminishes the real extent of these situations, foreseen in Directive 2001/18/EC, and which are provided for with a specific procedure. The wording proposed by the European Communities could be understood as envisaged for situations "merely happening" to deal with human health and environment, and would not express the clear purpose stated in Directive 2001/18 referring to the sense of labelling.

6.57 Argentina submits, in addition, that from paragraph 7.379 the Panel seeks to identify the rationale of labelling as set out in Directive 2001/18, and uses, among other provisions, Article 20. The Panel did find a rationale and found it to be related with the purpose of protecting human health and the environment. The European Communities states that there is another purpose, namely consumer information. Argentina considers, as it believes the Panel to have done, that the purpose of informing both the consumer and the authorities is not exhaustive in itself but also aimed towards a proper handling of the information on the labelled product. Argentina acknowledges that there might be a purpose for information related to what the Panel correctly recognized as "nice to know", or for avoiding confusion about the product, but Argentina considers - and believes that the European Communities would agree with this - that the purpose of informing does serve another purpose, a more important one than the answering to what is "nice to know" or avoiding confusion, directed to the better management of risks should these occur and therefore related to what one "needs to know", as the Panel said. Argentina considers that this far more important purpose than the one of mere information with no subsequent purpose of action, should not be diminished.

6.58 Finally, Argentina argues that the Panel sought to find the rationale for labelling in order to determine whether it relates to the protection against the risks established in the *SPS Agreement*. The Panel found the rationale precisely "besides" the purpose of consumer information (assuming *arguendo* the statement of the European Communities is correct in putting at the same level of importance consumer information and information provided for risk management) and "within" the same information (in order to make a further use of it -information is of no great value unless one uses it for a purpose - for risk management, as correctly established in paragraph 7.380). Therefore, Argentina considers that it is proper to say that there clearly "is" a rational relationship between the

[178] EC reply to Panel question No. 92.

labelling requirement and the purpose of protecting human health and the environment, and requests that the original wording by the Panel be maintained.

6.59 The **Panel** has made appropriate changes to paragraph 7.389 in response to this EC comment. The Panel also found it appropriate to make further changes, or additions, in response to the EC comment at paragraphs 7.385-7.389 and 7.391.

6.60 Regarding the EC assertion that the labelling requirement in Directive 2001/18 serves two purposes – the protection of human health and the environment, on the one hand, and consumer information, on the other hand – we note that the European Communities, in its comments on the interim reports, does not put forward a single argument to substantiate its assertion. Nor does it identify any evidence on the record which would support the conclusion that consumer information is one purpose for which the labelling requirement in Directive 2001/18 is applied.[179] We point out in this regard that in its first written submission the European Communities described the EC legislation concerning the approval of biotech products in some detail, including Directive 2001/18. The European Communities stated that Directive 2001/18 pursues the related but distinct objectives of "protecting human health and the environment". Consumer information was not mentioned as an objective of the Directive or of the labelling requirement contained therein.[180]

6.61 We further note that whereas Regulation 258/97 explicitly refers to the concept of "consumer information" in the context of labelling[181], neither the preamble nor the main text of Directive 2001/18 do. This is consistent with the fact that Directive 2001/18 is concerned with the deliberate release of GMOs into the environment and not with food containing or derived from GMOs, Indeed, Directive 2001/18 refers, not to final consumers of GMOs[182], but to "users" of GMOs (such as crop farmers, or livestock farmers using GMOs for animal feed)[183]. We also note that, unlike Regulation 1829/2003 (on genetically modified food and feed) and Regulation 1830/2003 (concerning the traceability and labelling of GMOs and the traceability of food and feed produced from GMOs), Directive 2001/18 does not refer to such concepts as "informed choice" of consumers, or users, or "freedom of choice" of consumers, or users, in connection with its labelling provisions.[184] The preamble to Directive 2001/18 merely states that labelling to indicate the presence in a product of a GMO serves to "ensure that the presence of GMOs in products containing, or consisting of, genetically modified organisms is appropriately identified".[185] This leaves unanswered the question of why appropriate identification is sought. We therefore consider that the preamble to

[179] It is worth noting that in its first written submission the European Communities described the EC legislation concerning the approval of biotech products in some detail, including Directive 2001/18. The European Communities stated that Directive 2001/18 pursues the related but distinct objectives of "protecting human health and the environment". Consumer information was not mentioned as an objective of the Directive or of the labelling requirement contained therein. EC first written submission, paras. 142-143.

[180] EC first written submission, paras. 142-143.

[181] Article 8(1) of Regulation 258/97.

[182] In contrast, Article 8(1) of Regulation 258/97 concerning novel foods and food ingredients refers to the "final consumer" of a novel food or food ingredient.

[183] Articles 19(3)(f) and 20(2) of Directive 2001/18.

[184] The preamble to Regulation 1829/2003 (on genetically modified food and feed) states that labelling of biotech products enables the "consumer", or "user", to make an "informed choice" and precludes "potential misleading of consumers" as regards methods of production (17th, 20th and 21st preambular paragraphs of the Regulation). Along similar lines, the preamble to Regulation 1830/2003 (concerning the traceability and labelling of GMOs and the traceability of food and feed produced from GMOs) states that accurate labelling of biotech products enables operators and consumers to "exercise their freedom of choice in an effective manner" (4th preambular para. of the Regulation).

[185] 40th preambular para. of Directive 2001/18.

Directive 2001/18 does not assist in determining whether the labelling requirement serves the additional purpose of consumer information.

6.62 Even if we were to accept, *arguendo*, that the relevant labelling requirement in Directive 2001/18 could help processors of raw materials (*e.g.*, rape seeds) to provide information and assurances to the final consumer about their food products (*e.g.*, highly refined rape seed oils produced from non-GM rape seeds) and in particular about their method of production[186] – for instance by reducing the likelihood of accidental and unintentional use of GM raw materials (*e.g.*, GM rape seeds) – the fact remains that neither the preamble nor the main text of Directive 2001/18 contains any reference to "consumer information" as an objective of the Directive in general or its labelling requirement in particular.[187]

6.63 We also find relevant in this connection the provisions of Article 26 of Directive 2001/18, which applies to GMOs subject to containment measures (contained use) or to GMOs to be made available for research and development activities. Like the GMOs which are for placing on the market, the GMOs covered by Article 26 are subject to a requirement whereby the presence of GMOs must be indicated on a label or in accompanying documentation using the words "This product contains genetically modified organisms". Given that the GMOs at issue in Article 26 are not released into the environment for the purpose of placing on the market, *i.e.*, for making available to third parties such as consumers we are of the view that the labelling requirement contained in Article 26 is not imposed for the purpose of "consumer information", that is to say, for the purpose of enabling consumers to make an informed choice and preventing potential misleading of consumers.

6.64 We recall that the requirement to identify the presence of a GMO is exactly the same in the case of contained use or release at the research stage (Article 26) and release for the purpose of placing on the market. This circumstance, coupled with the fact that the labelling requirement applicable in the situations envisaged in Article 26 is not, in our view, applied for "consumer information" purposes, and that there is no indication in Directive 2001/18 that the labelling requirement applicable to GMOs which are for placing on the market is imposed, at least in part, for "consumer information" purposes, raises further doubt in our minds about the validity of the unsubstantiated EC assertion that the latter labelling requirement is partly imposed for the purpose of "consumer information".

6.65 Canada and Argentina submitted the Commission's 1996 Report on the Review of Directive 90/220/EEC in the context of the Commission's Communication on Biotechnology and the White Paper.[188] This Report was not submitted by the United States or the European Communities, but the European Communities referred to its content in very general terms in a response to a question from the Panel.[189] We note that the Report contains the following two paragraphs:

> "The issue of labelling of products under Directive 90/220/EEC has been the subject of controversy. Some Member State Authorities object to the placing on the market of a product whose labelling will not indicate that it is genetically modified. The

[186] We note that some foods derived from GMOs – *e.g.*, highly refined rape seed oils in which neither DNA nor protein of GMO origin is detectable – are not subject to mandatory labelling under Regulation 258/97.

[187] It is also useful to recall in this context that Directive 2001/18 applies to various kinds of products containing, or consisting of, GMOs, including products not intended for human consumption, such as products for industrial use (*e.g.*, products for use as lubricants).

[188] Exhibits CDA-119 and ARG-53.

[189] EC response to Panel question No. 92(a). We note once more that the European Communities, in its comments on the interim reports, did not substantiate its assertion regarding the purpose of consumer information, and in particular pointed to no document in the record which would support its assertion.

> current provisions of the Directive do not allow the imposition of such labelling in the absence of any link to risk assessment. Specific provisions on labelling are, however, foreseen in product legislation.
>
> It will be essential to address this issue in order to take into account the need to inform consumers and to comply with the international obligations of the Community. The issue of labelling will be considered when preparing the amendment of Directive 90/220/EEC and the final provisions of other relevant product legislation will be taken into account."[190]

6.66 In the second of the two above-quoted paragraphs the Commission refers to the need for consumer information, although without explaining why consumers need to be informed.[191] Even if it were assumed that the Commission saw a need for "informing consumers" to ensure that consumers could make an informed choice and to preclude potential misleading of consumers as regards methods of production, it is important, in our view, to bear in mind the following elements. *First*, the Commission is not the Community legislator. Directive 2001/18 was adopted by the European Parliament and Council.[192] The views of the Commission do not necessarily reflect the views of the European Parliament and Council. Indeed, the Report of the Commission specifically mentions that controversy surrounded the issue of labelling and that member States took divergent views on the need for labelling to indicate the presence in a product of a GMO. *Secondly*, even disregarding the fact that the Commission is not the Community legislator, we note that the Commission Report is dated December 1996 and that Directive 2001/18 was not adopted until March 2001. In our view, it cannot simply be assumed that a statement made by the Commission more than four years before the date of adoption of Directive 2001/18 accurately reflects the purpose of the provision actually enacted on labelling. *Finally*, we recall that the phrase "inform consumers" did not find its way into the final text of Directive 2001/18. Given this, we think it is entirely conceivable that a deliberate choice was made by the Community legislator not to endorse this particular rationale for requiring labelling to indicate the presence in products of a GMO.[193] Certainly, the deliberate omission of the phrase "inform consumers" cannot lightly be assumed to have no substantive meaning when the same Community legislator (consisting of the European Parliament and Council) did use the phrase "inform the final consumer" in Regulation 258/97 and included very similar phrases in Regulations 1829/2003 and 1830/2003. The deliberate omission further seems significant in view of the fact that the same Community legislator in Article 26 of Directive 2001/18 imposed an identical requirement to indicate the presence of GMOs for GMOs that are not for placing on the market. As we have said, the Article 26 labelling requirement in our view is not imposed for "consumer information" purposes. For these reasons, we consider that the link between the 1996 Report of the Commission and the 2001 Directive of the European Parliament and Council is not sufficiently close and direct to allow us to conclude, without more, that the labelling requirement in Directive 2001/18 is applied, in part, for the purpose of consumer information.

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[190] Exhibits CDA-119 and ARG-53, p. 9.

[191] We recall that Regulation 258/97 and Regulations 1829/2003 and 1830/2003 explain why consumers, or users, need to be informed.

[192] The European Communities explained that Directive 2001/18 was adopted through the so-called "co-decision" procedure which involves several rounds of reading in the European Parliament and Council and, as a last resort, a reading in a conciliation committee. The European Communities told the Panel that the draft Directive 2001/18 went through all these stages before it was finally adopted on 12 March 2001. EC first written submission, para. 158.

[193] It is worth recalling once more that the Report of the Commission itself draws attention to the fact that the issue of labelling to indicate the presence in a product of a GMO had been the subject of controversy among member States.

6.67 Additionally, we note that in response to a question from the Panel, the European Communities referred to its 1998 proposal for a European Parliament and Council Directive amending Directive 90/220.[194] Consistent with what the Commission announced in its 1996 Report, the Commission proposal states that applications for approval are to contain a proposal for labelling which shall inform the consumer of GMOs in the relevant product(s) "whenever there is evidence that the product(s) contain(s) GMOs".[195] Thus, the 1998 Commission proposal proposes labelling to inform consumers about whether products contain or consist of GMOs. It does not propose labelling to help inform consumers about whether products which do *not* contain or consist of GMOs have nonetheless been produced from GMOs (*e.g.*, highly refined rape seed oils produced from GM rape seed). Regarding the link between the 1998 Commission proposal for an amended Directive and Directive 2001/18, we are of the view that the considerations we have put forward regarding the 1996 Report are valid, *mutatis mutandis*, also in the case of the 1998 proposal for an amended Directive. In particular, it must be recalled (i) that the Commission is not the Community legislator, and (ii) that the proposed phrase "inform the consumer" does not appear in the final, adopted text of Directive 2001/18. In respect of the last point, we again highlight the fact that the Community legislator did use the phrase "inform the final consumer" in Regulation 258/97 and that it used very similar phrases in Regulations 1829/2003 and 1830/2003. As we have said, the omission of the phrase "inform the consumer" further seems significant in view of the existence of Article 26 of Directive 2001/18. Accordingly, as with the 1996 Report of the Commission, we are of the view that the link between the 1996 Report of the Commission and the 2001 Directive of the European Parliament and Council is not sufficiently close and direct to allow us to conclude, without more, that the labelling requirement in Directive 2001/18 is applied, in part, for the purpose of consumer information.

6.68 In the light of the above elements and considerations, we are not convinced by, and therefore are unable to accept, the European Communities' unsubstantiated assertion in its comments on the old paragraph 7.381 of the interim reports that the relevant labelling requirement in Directive 2001/18 is applied, in part, for the purpose of consumer information.

6.69 The **European Communities** suggests a change to the wording of paragraph 7.383 to clarify what "otherwise" refers to.

6.70 **Canada** argues that the Panel should reject the European Communities' suggestion to change "otherwise" to "that there is no such rational relationship" in the second sentence. The suggested modification changes the meaning of the sentence, which Canada understands to be that nothing in the record suggests that the labelling requirement in Directive 2001/18 is related to any purpose other than protecting human health and the environment.

6.71 **Argentina** also does not consider this change to be appropriate. Regarding the replacement of the word "is", the suggestion by the European Communities undermines even more the findings of the Panel: for paragraph 7.381 the European Communities proposed "can be", and now it proposes "may be" for paragraph 7.383, which provides for an even lower level of certainty. Such a change would alter the Panel's reasoning to such an extent as to create confusion as to whether the objectives derived from Directive 2001/18 should be considered as "SPS-purposes" or not. The Panel has correctly found a clear and easy rationale, which links the labelling requirement in Directive 2001/18 with the purpose of protecting human health and environment. The European Communities is trying

[194] EC reply to Panel question No. 92(a). The European Communities did not submit this proposal, but in a footnote to its reply provided a reference to the Official Journal of the European Communities, where the proposal may be found.

[195] Article 11(2)(e) of the proposal.

to find an "open door" out of the *SPS Agreement*, even when the specific purpose of protecting human health and the environment was found and stated. For these reasons, Argentina considers that the word "is" should remain unchanged.

6.72 About the replacement of the word "otherwise", Argentina does not consider it acceptable either, because it also undermines the level of certainty. Should the EC proposal be accepted, the resulting text would suggest that the rational relationship of the labelling requirement with an SPS-purpose was found by the Panel simply "by exclusion". Consequently, Argentina considers that the original word "otherwise" should remain, because it clearly establishes that there is nothing which might lead the Panel to depart from its finding (and not that the Panel came to that finding because it had no other choice).

6.73 The **Panel** has made certain changes to paragraph 7.391 in response to the EC comment on the old paragraph 7.381. This change obviates the need for the change requested by the European Communities in relation to the old paragraph 7.383.

3. General EC moratorium

(a) Comments common to the United States, Canada and Argentina

6.74 The **Complaining Parties** individually request that the Panel issue a recommendation that the European Communities bring its general moratorium into conformity with its obligations under the *SPS Agreement*. The Complaining Parties assert that the Panel's analysis of this issue did not take account of all relevant factors and that the general moratorium which the Panel found to have existed in August 2003 did not cease to exist after August 2003. The Complaining Parties submit that the factors cited by the Panel as justifying the need for it to make findings in this case also justify the need for a recommendation. Furthermore, the Complaining Parties contend that the failure to make such a recommendation could be prejudicial to their interest as complaining parties. They argue that in the absence of a recommendation with regard to the general moratorium, the European Communities (should it fail to come into compliance) may try to argue that the Complaining Parties should be denied recourse to Article 21.5 of the DSU, and should be required to bring an entirely new case to examine a modified general moratorium. Canada notes that, in contrast, with regard to the product-specific measures and member State safeguard measures, Canada would (should the European Communities fail to come into compliance) have recourse to Article 21.5 of the DSU. According to Canada, this procedural bifurcation of the dispute would make it harder for the Parties to reach a positive resolution of the overall dispute. The Complaining Parties additionally argue that if the Panel were to add a recommendation to its finding that the general moratorium is inconsistent with the *SPS Agreement*, it would not add to the obligations, or diminish the rights, of the European Communities in any way. Canada points out in this regard that the Panel could recommend that the European Communities bring its measures into conformity with its WTO obligations "to the extent that it has not already done so".

6.75 The **European Communities** opposes the Complaining Parties' propositions, which, in its view, are unfounded and must be dismissed. More specifically, the European Communities notes that Canada accuses the Panel of having made a selective and limited assessment of the developments that have taken place after its establishment. The European Communities submits that what Canada is attacking, in reality, is that on the basis of the Panel's characterization of the measure, one fact – namely that of approvals being adopted – mattered more than any other for the question of a continued existence of the measure. Thus, fundamentally, Canada is challenging the Panel's characterization of the measure as a general "moratorium" affecting all decisions on biotech products. If that was not the measure that Canada intended to challenge, it should have made it clear in its

request for the establishment of a Panel and its submissions to the Panel. What Canada or the other Complaining Parties cannot seriously claim is that a situation in which decisions on GMO applications are adopted under the relevant legislation would be consistent with the continued existence of a general "moratorium".

6.76 The European Communities further notes that notably Argentina alleges that the Panel lacks jurisdiction to find that the supposed measure has ceased to exist. The European Communities points out that the question of whether a panel has jurisdiction to find whether the measure before it has ceased to exist, in practice, has not, generally speaking, been an issue in past disputes, since the parties, in most cases, actually agreed that the measure had ceased to exist. This said, in the case *US – Certain EC Products* the parties did disagree on the continued existence of the March 3 measure and the panel naturally assumed jurisdiction to rule that that measure had expired (while refusing to assume jurisdiction over the legally distinct measure of April 19th). More generally, however, the European Communities submits that the Panel has jurisdiction because it is its task to secure a positive solution to the dispute according to Article 3.7 of the DSU. It follows necessarily that the Panel cannot simply ignore subsequent developments that affect the existence of the measure identified in its terms of reference. If it did otherwise, it would leave open the fundamental question underlying these disputes and, as a result, the Panel would fail to produce a report that actually helps all the Parties to come closer to a final and positive solution.

6.77 In relation to the issue of whether there is a need for a recommendation, the European Communities observes at the outset that the Appellate Body's ruling in *US – Certain EC Products* regarding measures that have ceased to exist does not leave any open question. If a measure has been found to have ceased, no recommendation is to be made.[196] The European Communities notes that in contrast, the general gist of the Complaining Parties' arguments on this issue is to move all issues relating to subsequent developments regarding a challenged measure to the implementation stage and to treat them there as a question of whether or not a Member has brought itself into full conformity with its obligations. This approach ignores a panel's duty to secure a positive solution to the dispute, which obliges it not to refuse to rule on issues it has the ability to rule on. Furthermore, in basing their arguments on due process and on the necessity of preventing "moving target" situations, the Complaining Parties overlook that these considerations also apply to the responding party. Indeed, in trying to secure a positive solution to the dispute a panel needs to take into account either side's due process rights. In the present case, the absence of a recommendation on the alleged moratorium does not deprive the Complaining Parties of the possibility to react to possible problems in the processing of pending applications as they have findings and recommendations on individual product applications. A recommendation on a "general moratorium" that may or may not have ceased to exist, on the other hand, would inadmissibly require the European Communities to defend itself against the moving target of a measure that the Complaining Parties refuse to define.

6.78 On the basis of these considerations, the European Communities is of the view that the Panel should refuse the Complaining Parties' requests to change its finding that the "general moratorium" measure has ceased to exist and should not issue a recommendation.

6.79 The **Panel** found it acceptable to make a number of changes to its findings set out at paragraphs 7.1302 *et seq*. in response to the requests of the Complaining Parties. In particular, the Panel's final reports refrain from expressing a view on whether the general EC moratorium on approvals has ceased to exist subsequent to the date of establishment of the Panel. Furthermore, Section VIII of the final reports now offers a qualified recommendation in relation to the general EC

[196] The European Communities argues that this has been recognised by Canada in its third written submission at para. 197.

moratorium on approvals, except for DS293 (Argentina). The exception for DS293 is necessary because in DS293 the Panel concluded that Argentina had failed to establish that the European Communities breached its WTO obligations by applying a general moratorium between June 1999 and August 2003. Given this conclusion, it would not be appropriate for the Panel to accept Argentina's request that it recommend that the European Communities bring the general moratorium into conformity with its obligations of the *SPS Agreement*. Even a qualified recommendation would be inappropriate in these circumstances.

6.80 Regarding the European Communities' argument based on Article 3.7 of the DSU, the Panel agrees that a positive solution to a dispute is one that takes into account all disputing parties' rights and interests. In the present case, the Panel considers that a qualified recommendation in DS291 and DS292 safeguards and preserves the rights and interests of all Parties concerned and hence is consistent with the aim of securing a positive solution to the dispute referred to the Panel. The Panel is not convinced by the European Communities' argument that a qualified recommendation would "require the European Communities to defend itself against the moving target of a measure that the Complaining Parties refuse to define". In fact, the European Communities itself acknowledges that the Panel has defined the measure at issue[197]. Nor does making a qualified recommendation "leave open the fundamental question underlying these disputes".[198] Indeed, the Panel's findings and conclusions resolve the matter referred to it by the Complaining Parties in their requests for the establishment of a panel, namely, whether the European Communities was applying a general *de facto* moratorium on approvals as of the date of establishment of the Panel, and if so, whether this resulted in the European Communities acting inconsistently with its WTO obligations.

6.81 The Panel also sees no force in the EC argument that the provisions of Article 3.7 "oblige[] it not to refuse to rule on issues it has the ability to rule on".[199] The European Communities provides no support for this interpretation of Article 3.7. If, as the European Communities contends, panels were under an obligation to rule on all issues they have the ability to rule on, they would not be entitled to exercise judicial economy. Yet it is a well established point of WTO jurisprudence that, subject to certain limitations, panels are entitled to exercise judicial economy.[200]

6.82 Additionally, we observe that even if we were to accept that, in the present case, the issue of whether the general EC moratorium has ceased to exist subsequent to the date of establishment of the Panel is an issue we have the ability to rule on, we consider that in view of the findings and conclusions already offered by us a ruling on this issue would not be necessary to enable the DSB to make sufficiently precise recommendations to the European Communities.

6.83 The above-mentioned changes made by the Panel obviate the need for other changes requested by the Complaining Parties in their comments (*e.g.*, the United States' request that the Panel further clarify a finding that is no longer contained in the final reports).

(b) Comments by Canada

6.84 **Canada** submits that, at paragraph 7.460, the Panel appears to have omitted one manner in which the Commission could prevent or delay approvals. According to Canada, a third possible manner arises from the fact that the Commission could fail to adopt, or delay the adoption of a proposed decision to approve, an application following the failure of the Council, within 90 days of its

[197] EC comments on the Complaining Parties' comments, paras. 7 and 16.
[198] *Ibid*., para. 24.
[199] *Ibid*., para. 37.
[200] Appellate Body Report, *Canada – Wheat Exports and Grain Imports*, para. 133.

referral to the Council, either to adopt, or to indicate by a qualified majority that it opposes, the proposed decision. Canada argues that while this scenario might be less likely given that the Commission would have signalled its determination to push a product application to a final approval by putting it before the Council, a severely divided Council might influence the Commission's resolve to take the further step of approving the product itself in the face of the attendant political controversy.

6.85 The **European Communities** does not agree with Canada's comment on the alleged third manner in which the Commission could prevent or delay approvals. Apart from the fact that the approach described would be illegal under the relevant EC legislation, it is of no relevance in the present case. The Complaining Parties have not described, or put forward evidence of, any instance where it would have been employed to give effect to the alleged moratorium.

6.86 The **Panel** does not find it appropriate to make a change to its findings in response to Canada's comment. The Panel's findings clearly state, at paragraph 7.465, that the issue the Panel considers in the relevant sub-section is whether it was possible for EC member States and the Commission to prevent or delay approvals of biotech products "in the manner alleged by the Complaining Parties". Canada points to no portion of its submissions where it alleged that the Commission prevented or delayed approvals by not adopting a draft measure following a failure of the Council to act.[201] At any rate, the information on the record does not indicate that the situation described by Canada ever arose in any of the approval procedures at issue in this dispute.

6.87 **Canada** submits that at the old paragraph 7.1303, the date of August 2003 is incorrect. At that time, the Commission had not yet approved NK603 maize for animal feed and industrial processing. The Commission finally adopted a decision approving this application on 19 July 2004, following the refusal by the member States, both at the Regulatory Committee and Council levels, to support its approval. As far as Canada is aware, there is no record of the lead CA (Spain) issuing the letter of consent.

6.88 The **Panel** removed the relevant statement, but retained a modified version of paragraph 7.1303.

(c) Comments by Argentina

6.89 **Argentina** considers that the phrase "as described by Complaining Parties" at paragraph 7.448 does not reflect integrally the whole characterization set forth by the Complaining Parties when they described the measure at issue and that it would therefore be more accurate for the Panel to consider removing the aforementioned phrase. At the same time, Argentina notes that it is not objecting to the elements pointed out by the Panel.

6.90 The **Panel** has made appropriate changes to paragraph 7.456 in response to this comment.

(d) Comments by the European Communities

6.91 The **European Communities** argues that, the word "main" should be deleted in paragraph 7.448 as it could create confusion as it leaves open what other elements there might be. Alternatively, the Panel could state what the other elements are. Moreover, in the European Communities' view, different wording should be used in the last bullet point to reflect the fact that a final decision can also be negative in nature and does not necessarily have to lead to approval.

[201] Indeed, Canada makes no such allegation at para. 27 of its first oral statement, for instance.

6.92 **Argentina** disagrees with the first amendment proposed by the European Communities, namely, the deletion of the word "main", and recalls its comment on this paragraph. The deletion of the word "main" would imply a further move away from the description of the measure given by the Complaining Parties. Under the European Communities' proposal wording would be: "The elements which characterize the moratorium as described by the Complaining Parties are the following [...]". In other words, through this suggested wording there would be stated not only a closed set of elements which characterizes the moratorium, but also that this is a description supported by the Complaining Parties. In this sense, Argentina proposes that the Panel consider the following options: (a) the deletion of the terms "described by the Complaining Parties" as it was previously suggested; or (b) the deletion of "main" and "described by the Complaining Parties" plus the addition of a footnote to paragraph 7.448 clarifying the particular description supported by the Complaining Parties, in this case by Argentina.

6.93 The **Panel** has made appropriate changes to paragraph 7.456 in response to this EC comment. The Panel did not see a need to use different wording in the last bullet point.

6.94 The **European Communities** submits that, in paragraph 7.457, the first sentence, including the accompanying footnote, needs to be deleted as it does not accurately reflect the position of the European Communities. The sentence implies that the European Communities has taken a position on the issue of "ability to prevent approvals", which is not the case. The issue was never discussed as such. To the extent the European Communities took a position on the individual steps identified by the Panel, this was done not from a perspective of a so-called "ability to prevent" but to explain the different procedural steps set out in the legislation (which has not been challenged). The European Communities points out that the footnote is repeated almost verbatim in paragraph 7.462. The European Communities submits that a new footnote be added at the end of this paragraph in order to refer to the EC second submission where the argument on internal decision-making process is made.

6.95 The **United States** does not agree with the EC suggestion that the Panel should delete the first sentence of paragraph 7.457, which provides that "[t]he European Communities does not contest that it had the ability to prevent approvals of biotech products in the various ways identified by the Complaining Parties." To the contrary, this statement is important in the context of the dispute, and completely accurate. Even though the issue of whether the European Communities adopted a general moratorium on biotech approvals was central to the case, the European Communities in fact did not contest that EC member States and the Commission had the ability to block final decisions on biotech applications. Indeed, the European Communities provided no citation to any prior EC arguments where it did contest this proposition, nor is the United States aware of any such arguments in the European Communities' oral or written submissions. Instead, all the European Communities can do is to imply that it never conceded the issue. But, whether or not the European Communities affirmatively conceded the issue is beside the point: the first sentence of paragraph 7.457 is completely accurate in noting that the European Communities did not contest that the Commission and member States had the ability to block final decisions on biotech products.

6.96 **Canada** also disagrees with the EC suggestion. As Canada understands it, the Panel's point is not that the European Communities expressly admitted that it had the ability to prevent biotech approvals in the manner identified, but that the European Communities did not deny that it was possible under the EC regulatory system for biotech approvals to be prevented in the manner identified by the Complaining Parties.

6.97 **Argentina** likewise does not agree with the deletion of something that constitutes a finding by the Panel. In Argentina's view, it does not refer to any alleged position by the European Communities, but to the fact that the European Communities did not contest this issue.

6.98 The **Panel** has deleted the first sentence of paragraph 7.465 and the accompanying footnote, but sees no reason to add a new footnote at the end of the paragraph.

6.99 The **European Communities** considers that the last bullet point in paragraph 7.459 requires some clarification as the step identified therein does not exist under Regulation 258/97. Moreover, the second sentence in footnote 351 should be deleted, as it seems entirely unnecessary. At the same time, it would seem necessary to point out that these very same steps may be taken for wholly legitimate (scientifically justified) reasons.

6.100 **Canada** has no objection to the European Communities' proposed revision of the text of paragraph 7.459. However, in relation to the footnote, given the Panel's finding that "despite a clear legal obligation to give written consent […] France withheld its consent and thus did what was within its power to prevent these products from being approved",[202] it hardly seems inappropriate for the Panel to point out that the acts and omissions of the European Communities might be inconsistent with the European Communities' own internal law. Canada submits, in addition, that the suggested addition to footnote 351 is unnecessary and should be disregarded. The question is not whether any of the identified methods employed by the EC member States to give effect to the moratorium "necessarily" reflects an intention to prevent or delay final decision, but whether in this case EC member States employed these methods to prevent final approvals.

6.101 **Argentina** believes that the addition in footnote 351 proposed by the European Communities would be misleading and should not be accepted. The Panel is referring to situations in which the member States have the ability to prevent or delay, with no further reference to the intention of the member States. Furthermore, to say in footnote 351 that there "might be no intention" of delaying or preventing, as the European Communities suggests, is certainly contradictory with the Panel's statement in paragraph 7.459, especially since point (b) refers to "objections", point (c) refers to an acting "blocking minority", and point (d) refers to a "refusal" to give consent. All these points refer to situations in which member States do act on purpose, hardly "by accident" or "with no intention". The EC observation to footnote 351 would undermine the sense of paragraph 7.459 as correctly expressed by the Panel. Consequently, Argentina requests this suggested addition not to be accepted.

6.102 The **Panel** has made appropriate changes to paragraph 7.467 in response to this EC comment. The Panel has also deleted the second sentence of footnote 574, but does not find it appropriate to add the sentence suggested by the European Communities.

6.103 The **European Communities** considers that paragraph 7.462 requires some clarification as the scenario identified therein does not exist under Regulation 258/97.

6.104 The **Panel** has made appropriate changes to paragraph 7.470 in response to this comment.

6.105 The **European Communities** contends that the date referred to in paragraph 7.500 should be 31 August 2005 and not 1 September 2005 as the application concerning RR oilseed rape (EC-70) was approved on 31 August 2005.

6.106 The **Panel** has made appropriate changes to paragraph 7.508 in response to this comment, noting that it was the EC letter of 1 September 2005 which suggested the 1 September 2005 approval date.

[202] Interim Reports, paras. 7.1015 and 7.2197.

6.107 The **European Communities** submits that the last two sentences of paragraph 7.501 should be deleted as the Panel's assertion that the European Communities never submitted information on MON863 is not correct. Exhibit EC-106 is a status report on the application for MON863, which is actually a hybrid (MON863 x MON810). In the EC first written submission, at paragraph 335, the application was identified as Monsanto Maize with the right application number (C/DE/02/9), but unfortunately contained an erroneous reference to the hybrid event in question (MON810 x NK603 instead of MON863 x MON810). The Panel itself, in paragraph 7.542 seems to have correctly identified the application. Furthermore, from paragraph 7.543 it can be inferred that the Panel was fully aware of the fact that the application concerned MON863 x MON810.

6.108 **Canada** agrees with the European Communities that the confusion arising from the European Communities' mislabelling of the application for the maize hybrid MON863 x MON810 (C/DE/02/9) is indeed unfortunate. Canada also agrees that some information concerning MON863 maize was submitted to the Panel. Specifically, Canada submitted as evidence the scientific opinions conducted by the European Food Safety Authority (EFSA) for MON863 maize (resistance to certain coleopteran insects) and the hybrid product MON863 x MON810 (resistance to certain lepidopteran insects), dated 2 April 2004. Two opinions were issued, one under Directive 2001/18 and the other under Regulation 258/97, and were submitted as Exhibits CDA-35-O (2 April 2004) and CDA-35-P (2 April 2004), respectively. Canada also agrees with the European Communities that the Panel's discussion in paragraph 7.542 of the application for maize (Exhibit EC-106) and of the novel food application in paragraph 7.543 appears to relate to the applications submitted under Directive 2001/18 and Regulation 258/97 to the competent German authorities for MON863 maize and its hybrid MON863 x MON810. Furthermore, rather than deleting the text in paragraph 7.501 as proposed by the European Communities, Canada suggests modifying the text to reflect the Panel's conclusions in paragraphs 7.542 and 7.543 that the Panel does not consider that the information supplied by the European Communities in respect of these applications is sufficient to support the inference that no general moratorium on final approvals was in effect before or in August 2003.

6.109 The **Panel** is not convinced by the European Communities' assertion that the application concerning MON863 maize was actually an application concerning a hybrid product, namely, MON 863 x MON810 maize. The European Communities points to no evidence on the record in support of its assertion.[203] As we have noted, the European Communities itself distinguishes between the application concerning the parental line MON863 (*see* EC reply to Panel question No. 91) and the hybrid MON863 x MON810 (*see* EC first written submission, paragraph 335 and Exhibit EC-106). We note that in its submissions the European Communities mentioned the same reference C/DE/02/9 when referring to MON863 maize and MON863xMON810 maize. However, the European Communities does not argue that this constitutes conclusive proof that the products are one and the same. At any rate, it has never been suggested to us by any Party that under Directive 2001/18 it would not be possible to submit a single application covering two distinct, but related, biotech products. In the light of the foregoing considerations, the Panel declines the EC request to delete the last two sentences of paragraph 7.501. In response to Canada's comment, the Panel has added a reference to Exhibits CDA-35-O and -P in footnote 398 and made appropriate consequential changes to paragraph 7.509. The Panel does not agree with Canada, however, that paragraphs 7.550 and 7.551 relate, *inter alia*, to applications submitted under Directive 2001/18 and Regulation 258/97 concerning MON863 maize. These paragraphs relate to applications concerning the hybrid maize

[203] We note in passing that in relation to its comment on para. 7.500 regarding the correct approval date in the case of RR oilseed rape (EC-70), the European Communities indicated where in the Official Journal of the European Union the relevant Commission decision may be found. The European Communities did not give the corresponding reference to the Official Journal for the Commission decision concerning MON863 maize.

MON863 x MON810, which is consistent with the fact that both Exhibit EC-106 and paragraph 337 of the EC first written submission refer exclusively to the hybrid maize MON863 x MON810.

6.110 The **European Communities** identified incorrect sub-paragraph numbering in paragraphs 7.516 through 7.523.

6.111 The **European Communities** considers that the term "consistent with" in paragraph 7.544 should be qualified given that in the analysis then following the Panel identifies very diverse kinds of situations. Indeed, in some cases, such as for example in the case of the transgenic potato, the Panel discusses alternative explanations which it considers possible for a given act or omission, but then concludes anyway that the facts are consistent with the assertion that a moratorium existed. Such conclusions only make sense if "consistent with" can be read to mean "neither supports nor contradicts". The European Communities therefore suggests that the Panel add a new sentence to paragraph 7.544 to explain the meaning of the term "consistent with".

6.112 The **United States** does not agree with the EC suggestion that the Panel should add the following underlined sentence in the middle of paragraph 7.544:

> "In the remainder of this Subsection, the Panel will examine all other relevant applications with a view to determining whether they are consistent with the Complaining Parties' contention that during the relevant time period (October 1998 to August 2003) the European Communities applied a general moratorium on final approvals. By 'consistent with' we do not necessarily mean to say that the facts support the Complaining Parties' contention, but that they do not contradict it. The structure of this examination reflects the arguments of the Complaining Parties. More specifically, the Panel's examination is structured according to the acts and omissions through which, in the Complaining Parties' view, the European Communities gave effect to the alleged general moratorium on approvals. The Panel will first address applications submitted under Directives 90/220 and/or 2001/18. Thereafter, the Panel will address applications submitted under Regulation 258/97."

6.113 In the United States' view, the European Communities' suggested gloss on the term "consistent" reflects a misunderstanding of the Panel's mode of analysis. In the remainder of the subsection, the Panel shows how delays in processing individual applications were consistent with a moratorium, even though for certain applications other explanations for delays might have been possible. All such evidence indeed supports the Complaining Parties' contentions: in particular, it is cumulative with all of the other evidence submitted by the Complaining Parties showing the existence of a general moratorium, and it further shows that the European Communities was incorrect in asserting that the application histories proved that no such moratorium ever existed. Thus, the suggested addition is incorrect, and should not be included in the final report.

6.114 **Canada** also disagrees with the suggested qualification for "consistent with" in paragraph 7.544. The qualification changes the Panel's findings in relation to the facts and history of relevant applications. Canada recalls that, in this section of the interim report, the Panel examines whether the approval procedures for relevant applications "confirm" that certain member States and/or the Commission did in fact prevent the final approval of applications in the manner identified by the Complaining Parties.[204] The Panel examines whether the history of relevant applications supports (or "confirms") the Complaining Parties' claim that the European Communities imposed a general moratorium on final approvals or supports (or "confirms") the European Communities' opposing

[204] Interim Reports, para. 7.533.

assertion that "[t]he processing of individual applications continued without interruption, and applications were not systematically stalled."[205] Given that the very purpose of the examination is to determine which of the competing theories is supported by the facts, it would be nonsensical to specify "consistent with" as meaning "neither supports nor contradicts".

6.115 Canada submits, in addition, that the European Communities points to one example (transgenic potatoes, paragraphs 7.664 to 7.668) where the Panel does not categorically reject the European Communities' alternative explanation for the Commission's failure to forward a draft measure to the Regulatory Committee and yet still finds that facts are "consistent with" the Complaining Parties' claim that a moratorium had been put in place. This appears to be the only application history that could be "consistent with" both competing theories. In order to avoid any potential confusion, Canada invites the Panel to clarify that "consistent with" as used in paragraph 7.544 means "supports" or "confirms" and to clarify whether the transgenic potatoes application supports the Complaining Parties' claim, the European Communities' competing theory, or is inconclusive.

6.116 Although **Argentina** could agree that the words "whether they are consistent with" might be clarified, Argentina does not believe that the addition proposed by the European Communities will reflect what the Panel did analyse and conclude, as stated in paragraphs 7.548, 7.758 and 7.997, namely, the conduct of the Commission and the member States. When analysing these conducts, the Panel found, among others issues, that there was an interaction between the Commission and some member States[206], from which the Panel derived the "consistency" of the conducts with the Complaining Parties' assertion about a "*de facto*" moratorium.

6.117 Additionally, Argentina does not believe that the addition proposed by the European Communities would be clarifying. On the contrary, the expression "but that they do not contradict it" seems to be both soft and too incomplete. The consistency of the findings regarding the conduct of the Commission and of some member States does not simply "not contradict" the Complaining Parties' assertions, since they deal with calculated and intended acts, but, on the contrary, do support Argentina's assertion and it is in this sense that the Panel has made these findings. Consequently, Argentina considers that the European Communities' proposed addition will diminish the sense of the word "consistency", as used by the Panel in its findings.

6.118 The **Panel** considers that the phrase "consistent with" at paragraph 7.552 is sufficiently clear and therefore does not find it necessary or appropriate to add the sentence suggested by the European Communities. Nonetheless, for greater clarity, the Panel has included additional language at paragraph 7.552. In relation to the approval procedure concerning the Transgenic potato, the Panel has deleted the old paragraph 7.1921.

6.119 The **European Communities** requests that a footnote be added at the end of paragraph 7.547 to clarify that the Complaining Parties have not challenged the fact that in accordance with Article 35 of Directive 2001/18 an updated dossier had to be submitted which would re-start the approval procedure.

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[205] *Ibid*., para. 7.535.

[206] Argentina refers to, especially, paras. 7.567, 7.584, 7.598, 7.612, 7.629, 7.648, 7.661, 7.670, 7.681, 7.695, 7.711, 7.726, 7.737, and 7.754 of the Interim Reports, referring to the Commission's knowledge of the *explicit intention* of the "Group of Five" and these countries' capability to act as a "blocking minority"; and also paras. 7.768, 7.777, 7.784, 7.798, 7.812, 7.825, 7.856, 7.876, 7.891, 7.901, 7.921, 7.955, 7.969, 7.985, and 7.1015 of the Interim Reports, referring to the member States as either being part of the "Group of Five", or knowing of the *explicit intention* of the "Group of Five" and its capability to act as a "blocking minority").

6.120 **Argentina** opposes the additional footnote proposed by the European Communities. It has already been clearly established several times during the proceedings, and stated in the interim report, that the Complaining Parties are not challenging the EC legislation as such (including Article 35 of Directive 2001/18/EC). Argentina considers this clarification not to be necessary. Besides this, the proposed expression "any aspect of the EC approval legislation" is too broad and misleading, since it could be understood to include, for instance, the "non-application" of the EC approval legislation, which Argentina is indeed challenging.

6.121 The **Panel** has added an appropriate footnote at the end of the first sentence of paragraph 7.555 in response to this EC comment.

6.122 The **European Communities** points out that while it is correct that it only stated the fact, referred to at paragraph 7.841, that the application was withdrawn (*see* EC second written submission, paragraph 149, footnote 60), without providing any document, it is also true that that fact was never contested by the Complaining Parties. That alone should be a reason for the Panel to accept the EC statement as a given fact. Furthermore the Panel never asked for further clarifications or documents. The European Communities considers that this issue can still be clarified at interim stage and that there is no point in waiting for an eventual implementation phase to start producing the document that shows that and when the withdrawal took place. The withdrawal letter is therefore attached as Exhibit EC-167. Based on the letter, the European Communities requests that the Panel include in paragraph 7.841 the date of withdrawal.

6.123 The **United States** argues that the interim review stage of the proceeding is confined to a "review of precise aspects" of an interim report. It is not the place for a party to submit new factual evidence or exhibits concerning the measures at issue, nor does it permit making new findings based on such exhibits. The question of the status of new evidence introduced during the interim review stage of a dispute was discussed by the Appellate Body in its report in *European Communities – Trade Description of Sardines*. In that dispute, the European Communities had attempted to introduce new evidence (in the form of letters from European consumer associations) at the interim review stage. The panel declined to consider the new evidence, and the Appellate Body affirmed, explaining:

> "The interim review stage is not an appropriate time to introduce new evidence. We recall that Article 15 of the DSU governs the interim review. Article 15 permits parties, during that stage of the proceedings, to submit comments on the draft report issued by the panel, and to make requests 'for the panel to review precise aspects of the interim report.' At that time, the panel process is all but completed; it is only – in the words of Article 15 – 'precise aspects' of the report that must be verified during the interim review. And this, in our view, cannot properly include an assessment of new and unanswered evidence. Therefore, we are of the view that the Panel acted properly in refusing to take into account the new evidence during the interim review, and did not thereby act inconsistently with Article 11 of the DSU."[207]

6.124 In addition, the United States notes that the European Communities' submission of new evidence on BXN cotton is inconsistent with the Panel's Working Procedures. Paragraph 12 of those procedures provides:

> "Parties shall submit all factual evidence to the Panel no later than during the first substantive meeting, except with respect to evidence necessary for purposes of rebuttals, answers to questions or comments made for the purpose of rebutting

[207] Appellate Body Report, *EC – Sardines*, para. 301.

> answers provided by others. Exceptions to this procedure will be granted upon a showing of good cause. In such cases, other parties shall be accorded a period of time for comment, as appropriate."

6.125 The United States points out that the European Communities' new exhibit on BXN cotton was not submitted in rebuttal or in response to a Panel question. In addition, the European Communities has not claimed or made a showing of good cause which might warrant an exception to the rule in Paragraph 12. In particular, no showing of "good cause" is possible because the purported withdrawal of the BXN cotton application in the period after the establishment of the Panel is not dispositive with regard to any issue in this dispute. As the United States has explained, under Article 7 of the DSU (establishing the Panel's terms of reference), the measures at issue in this dispute are the measures in existence when the panel was established. Accordingly, information on the withdrawal of BXN cotton after panel establishment is not pertinent to the existence and/or WTO-consistency of the measures at issue.

6.126 The United States further submits that, remarkably, the EC comments make the assertion that "there is no point in waiting for an eventual implementation phase to start producing the document that shows that and when the withdrawal took place." The United States is pleased that apparently the European Communities is predicting that the Panel's recommendations and rulings regarding the BXN cotton application, after a possible review by the Appellate Body, will be adopted by the Dispute Settlement Body and that the European Communities intends to comply with those recommendations and rulings when adopted. Nonetheless, the United States strongly disagrees with the notion that there is "no point" in not allowing the submission of new evidence during the interim review stage on implementation of a possible DSB recommendation and ruling. To the contrary, the consideration of the implementation of possible DSB recommendations and rulings during the interim review stage would be inconsistent with the DSU. As the Appellate Body explained in *EC – Sardines*, the purpose of the interim review stage is to consider "precise aspects" of the report, not to consider new evidence. Instead, the DSU provides other, separate mechanisms to address this situation. For instance, those issues could arise as part of the DSB's surveillance of implementation of the recommendations and rulings. (*See, e.g.*, Article 21.6 of the DSU: "The DSB shall keep under surveillance the implementation of adopted recommendations or rulings.") Should the DSB ultimately adopt the Panel's recommendations and rulings on BXN cotton, the European Communities would be free to claim that it has already complied with the recommendations and rulings, and the DSB in turn would be free to exercise its surveillance authority. Moreover, if there were disagreement about the European Communities' claim, the DSB could establish a panel pursuant to Article 21.5 of the DSU.

6.127 Furthermore, the United States maintains that if the Panel were to accept new evidence at this time, and in a matter not in accordance with the Panel's working procedures, the Complaining Parties would be confronted with precisely the type of unfair "moving target" that the Appellate Body decried in *Chile – Price Band System*.[208] If the European Communities were allowed to present new evidence on its measures at each and every stage of the proceeding – and in particular at this stage – this already lengthy dispute could last indefinitely, as the European Communities could continue to extend the proceedings by continually submitting new evidence, by inviting the Complaining Parties to respond to it, and by asking the Panel continually to revise its findings.

[208] As the Appellate Body explained in that dispute, "the demands of due process are such that a complaining party should not have to adjust its pleadings throughout dispute settlement proceedings in order to deal with a disputed measure as a 'moving target'." Appellate Body Report, *Chile – Price Band System*, para. 144.

6.128 For all of these reasons, the United States submits that the Panel should give no consideration to the new evidence the European Communities has attempted to introduce at the interim review stage in this dispute.

6.129 **Canada** opposes the European Communities' suggested modification for paragraph 7.841 of the Interim Report for two reasons. First, the European Communities appears to suggest that the mere assertion of a fact, apparently uncontested by a Complaining Party, should be "reason for the Panel to accept the EC statement as a given fact." Canada disagrees. It is a well settled principle that the party making an assertion has the burden to prove that assertion. The mere assertion of a fact that has not been specifically contested by an opposing party is not necessarily sufficient to discharge this burden.[209] The failure by the European Communities, in this case, to adduce evidence supporting its assertions exposes it to the risk that the Panel, in making an objective assessment of the facts, may not accept those assertions as fact. Indeed, in this dispute, the European Communities made many vague assertions unsupported by specific evidence. In the present case, the Panel is perfectly entitled, based on the evidence before it, to conclude as it did in paragraph 7.841.

6.130 Second, for the reasons stated below, Canada opposes the European Communities' attempt to supplement the factual record. Having failed to support its assertion with evidence during the course of these proceedings, the European Communities should not be permitted to adduce new evidence at the interim review stage, no matter how innocuous the evidence appears to be.

6.131 Canada objects to the European Communities' attempt at this very late stage of the process to supplement the factual record before the Panel by introducing three new exhibits, EC-167, -168 and -169.[210] The submission of additional evidence after the issuance of the interim report significantly alters the nature of the interim review stage and strains the demands of due process. The interim review stage is an opportunity for parties to "submit a written request for the panel to review precise aspects of the interim report prior to circulation of the final report" (Article 15.2 of the DSU); it is emphatically not an opportunity for a party to correct evidentiary oversights or reopen the factual record.

6.132 Canada notes that the European Communities suggests that the introduction of new evidence presents "no due process issue or prejudice" to the Complaining Parties because they have an opportunity to comment on the new evidence. However, this does not answer the broader due process problem of permitting only one party an opportunity to supplement the record. Permitting the introduction of selective evidence, without providing an opportunity for a fair hearing on all pertinent additional facts, violates due process. On this basis alone, the Panel should disregard these exhibits. The European Communities will have ample opportunity to submit this information during the implementation stage of the proceedings.

6.133 Canada argues that if the Panel is inclined to accept the additional evidence submitted by the European Communities, fairness dictates that the Complaining Parties should be accorded an equal opportunity to submit additional evidence to supplement the factual record. In this regard, the Complaining Parties should not be limited to responding to the evidence recently submitted by the European Communities, but should be free to submit additional evidence on any issue addressed in the Panel's interim report.

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[209] Canada notes that it stated in its submissions that the fact that it had not addressed explicitly any particular legal or factual assertions by the European Communities does not mean that it agrees with those assertions. Canada's second written submission, para. 11.

[210] Canada refers to paras. 53 and 68 of the EC comments.

6.134 The **Panel** notes that Exhibit EC-167 contains a letter dated 18 May 2004. The EC second written submission, in which the European Communities referred to the withdrawal of the application in question, dates from 19 July 2004. Thus, the European Communities could have provided the relevant letter already at the time it filed its second written submission, or at least shortly thereafter. We note that paragraph 12 of the Panel's Working Procedures states in pertinent part that "[p]arties shall submit all factual evidence to the Panel no later than during the first substantive meeting, except with respect to evidence necessary for purposes of rebuttals, answers to questions or comments made for purposes of rebutting answers provided by others. Exceptions to this procedure will be granted upon a showing of good cause." In this instance, the European Communities has not made a showing of good cause for submitting in March 2006 what it could have submitted already in May 2004. The fact that, in the European Communities' view, "there is no point in waiting for an eventual implementation phase to start producing the document" certainly does not amount to the requisite "good cause", since this argument provides no justification for submitting evidence that has been available for more than two years as late as the interim review stage. We also note that in *EC - Sardines* the Appellate Body stated in unqualified terms that "[t]he interim review stage is not an appropriate time to introduce new evidence".[211] For these reasons, the Panel declines to make the change requested by the European Communities.

6.135 The **European Communities** identified mistaken cross-references to Annex H in the Panel's findings, including in the old footnotes 683-684 and 688-689.

6.136 The **European Communities** requests that at paragraph 7.886 the Panel modify its description of what Dr. Andow said so that it is closer to what he stated literally and therefore more accurately reflects his views.

6.137 The **Panel** has made appropriate changes to paragraph 7.894 in response to this comment.

6.138 The **European Communities** requests that a sentence should be added in footnote 774 to paragraph 7.1028 stating that the only application that does not seem to have been submitted both under Regulation 258/97 and Directive 90/220 is the application for Transgenic green-hearted chicory (food use only).

6.139 The **Panel** notes that the European Communities points to no evidence in the record which would support its assertion that there is no application concerning Transgenic green-hearted chicory that was submitted and evaluated under Directive 90/220. The Panel is not convinced by the EC assertion. Indeed, the documents on the record do not support the EC assertion. Exhibit EC-98/At.11 relates to the application concerning the Transgenic green-hearted chicory (food). The Exhibit contains a letter which states "[e]nclosed you find the summary of the evaluation of potential risks to human health and the environment, carried out by the Netherlands competent authority for Directive 90/220/EEC". That summary in turn states that the application submitted under Directive 90/220 concerns "green hearted chicory (*Cichorium intybus* L.) [of] line GM-2-28." Exhibit EC-110/At.7 provides further confirmation, in its general introduction, of the fact that an application concerning the Transgenic green-hearted chicory was submitted under Directive 90/220 and Regulation 258/97 and that the Netherlands was the lead CA in both cases. The Panel therefore declines the EC request that it add a sentence to footnote 999.

6.140 The **European Communities** submits that an addition is required in the last sentence of paragraph 7.1031 to clarify that there were also labelling requirements for GMO-derived products under Regulation 258/97, albeit only for those products which still contained DNA traces (*see* Article

[211] Appellate Body Report, *EC – Sardines*, para. 301.

8 of Regulation 258/97 and Article 1 of Regulation 49/2000 amending Article 2(2) of Regulation 1139/98). Alternatively, the entire last sentence starting with "In particular…" could be taken out, as it does not seem to be of relevance to the issues in this dispute.

6.141 **Argentina** considers that the addition suggested by the European Communities is not clear and, consequently, objects to it, but Argentina supports the suggested deletion of the last sentence.

6.142 The **Panel** has made appropriate changes to para 7.1039 in response to this EC comment.

6.143 The **European Communities** requests that the last sentence of paragraph 7.1300 be deleted as it does not correctly reflect the European Communities' position. In fact, the European Communities has explicitly contested the Panel's authority to make such findings in its reply to Panel question No. 7 as well as in paragraph 151 of its second written submission.

6.144 **Argentina** submits, with regard to the EC reply to Panel question No. 7, that the European Communities stated in its answer that there has been no moratorium at all, when it stated that "[t]he approval procedures have never been suspended or stalled as alleged by the Complainants. In any event, even if certain delays that occurred in the application of Directive 90/220 were to be seen to constitute a 'moratorium', these must have ended with the application of Directive 2001/18." (paragraph 24 of the EC response) and that "[t]herefore, the European Communities respectfully requests the Panel to find that, with regard to applications withdrawn before the panel establishment and the alleged 'moratorium', the Complainants' case is without object and, hence, inadmissible *ab initio*" (paragraph 25 of the EC response). In Argentina's view, the European Communities did not contest the Panel's authority to rule on a measure that had ceased to exist, since the European Communities stated that the measure did not exist at all. Argentina further submits that paragraph 151 of the EC second written submission refers to the European Communities' answer to question No. 7, so the same observation applies here. Therefore, Argentina believes that the original wording in paragraph 7.1296 accurately reflects the EC position on a "measure that ceased to exist", and that the clarification requested by the European Communities should not be taken into account.

6.145 The **Panel** does not agree with how the European Communities describes its position as reflected in its second written submission and Panel question No. 7. Nevertheless, the Panel has added a footnote to paragraph 7.1308, to indicate what the European Communities stated before the Panel.

6.146 The **European Communities** suggests the deletion of a point made at paragraph 7.1303 regarding whether NK603 maize (food) could be marketed regardless of whether NK603 maize (for animal feed use) had obtained the lead CA's written consent. The European Communities submits that a market authorization under Regulation 258/97 is directly applicable and does not require any further consent from the lead CA. As there is no provision to this effect in the legislation nor any such condition in the market authorization itself, the use of this market authorization does not (and cannot legally) depend on the adoption of a market authorization for feed use under Directive 2001/18. This is different from the question of whether under Article 9 of Regulation 258/97 the assessment of environmental risks can be made dependent on a parallel assessment under Directive 90/220 (or Directive 2001/18). Furthermore, as regards NK603 maize (for use such as animal feed), the European Communities says that it would like to inform the Panel that final consent was given by the lead CA on 18 October 2004 (new Exhibit EC-168). Moreover, as regards MON863 maize, final consent was given by the lead CA on 13 February 2006 (new Exhibit EC-169). The European Communities would invite the Panel to take these facts into account and re-draft paragraph 7.1303 accordingly. In inviting the Panel to take these matters into consideration, the European Communities points out that the Complaining Parties have the opportunity to comment on

these comments, and thus the possibility to state if they contest the plain facts, duly evidenced, and if so, on what basis. There is thus no due process issue or prejudice *vis-à-vis* the Complaining Parties.

6.147 The **United States** recalls that it explained in the above discussion of the EC comment on BXN cotton that the DSU and the Panel's own working procedures do not permit a Panel to examine new evidence on the measures at issue submitted during the interim review stage. Accordingly, the United States submits that the Panel should not make the changes to paragraph 7.1303 of the interim report that the European Communities suggests.

6.148 **Canada** similarly states that for the reasons stated above, Canada opposes the EC attempt to reopen the factual record at the interim review stage. The European Communities will have an opportunity to introduce this new evidence during the implementation stage of the proceeding. In addition, Canada submits that Exhibit EC-169 is problematic for another reason; it is a document that has been submitted by the European Communities in the German language only. Canada reiterates its objection, first raised in its letter to the Panel, dated 29 June 2004, to the European Communities' practice of submitting evidence in a language other than one of the official WTO languages. In accordance with long-standing GATT and WTO practice, any document submitted as evidence in dispute settlement proceedings that is in a language other than an official WTO language must be accompanied by a version translated into one of the official languages.[212] The failure to submit a translation of Exhibit EC-169 means that the Panel should disregard this document.

6.149 **Argentina** acknowledges that the European Communities can make several more approvals from now on, and thus expect the Panel to continuously adjust the text of the interim report.. Despite this, we recall our argument in the sense that the matter of whether the "*de facto*" moratorium ceased to exist is not to be assessed, and that the approvals at this later stage should not have any influence on the matter.

6.150 The **Panel** has made appropriate changes at paragraph 7.1303 in response to this EC comment. The Panel notes in this regard that it has accepted the European Communities' request that the Panel delete the latter part of the third sentence of the old paragraph 7.1303. After reviewing the remainder of the third sentence, the Panel has determined that there is no need to retain it. The Panel has therefore deleted the entire third sentence. In the light of this, it is not necessary to consider whether it would be appropriate to take into account Exhibits EC-168 and EC-169, which were submitted only at the interim review stage. In relation to Exhibit EC-169, we note that, in any event, the document is in German and that no translation into any of three official languages of the WTO was provided to the Panel and the other Parties.

6.151 The **European Communities** submits that, the wording of the old paragraph 7.1311 should be changed to "continuing existence of opposition to approvals amongst member States" because the phrase "continuing member State opposition" is too sweeping a statement as there is no such thing as a generalised opposition of member States to approvals. It also overlooks the reasons which explain the opposition of each individual member State in each specific procedure.

6.152 The **United States** considers that the two phrases have slightly different emphases – the phrase drafted by the Panel is clearer, and more accurately reflects the level of member State opposition. The European Communities wishes to soften the Panel finding, but the European Communities presents no valid basis for doing so. The Panel's findings on member State actions in support of the moratorium (*see, e.g.*, paragraph 7.1273) are more than sufficient to support the language currently used in paragraph 7.1311 of the interim report.

[212] Canada refers to Panel Report, *Korea –Dairy*, para. 7.16.

6.153 The **Panel** has made appropriate changes to paragraph 7.1311 in response to this EC comment.

6.154 The **European Communities** identified a missing reference to the year 1999 in paragraph 7.1543.

4. Product-specific measures

(a) Comments by Argentina

6.155 **Argentina** identified words included by oversight in paragraph 7.1873.

(b) Comments by the European Communities

6.156 The **European Communities** contends that the date referred to in paragraph 7.1634 and the accompanying footnote should be August 2005 and not September 2005 as the application concerning RR oilseed rape (EC-70) was approved on 31 August (*see* Official Journal of the European Union N°L 228 of 3 September 2005, at page 11). The European Communities also requests a reference to the application concerning MON863 maize in the relevant footnote.

6.157 The **Panel** has made appropriate changes to paragraph 7.1641 in response to this comment, noting again that it was the EC letter of 1 September 2005 which suggested the 1 September 2005 approval date. The Panel sees no need for referring, in a footnote relating exclusively to RR oilseed rape (EC-70), to the application concerning MON863 maize.

6.158 The **European Communities** requests changes to paragraph 7.1662 and footnote 1143. Specifically, the European Communities suggests the deletion of a point made in footnote 1143 regarding whether NK603 maize (food) could be marketed regardless of whether NK603 maize (for animal feed use) had obtained the lead CA's written consent. The European Communities has addressed this point in its comment on paragraph 7.1303. Furthermore, and as also already explained in the above comment on paragraph 7.1303, regarding NK603 maize (for use such as animal feed), the European Communities contends that final consent was given by the lead CA on 18 October 2004 (new Exhibit EC-168). Moreover, as regards MON863 maize, the European Communities contends that final consent was given by the lead CA on 13 February 2006 (new Exhibit EC-169). The European Communities would invite the Panel to take these facts into account and re-draft the footnote accordingly. In inviting the Panel to take these matters into consideration, the European Communities points out that the Complaining Parties have the opportunity to comment on these comments, and thus the possibility to state if they contest the plain facts, duly evidenced, and if so, on what basis. There is thus no due process issue or prejudice *vis-à-vis* the Complaining Parties.

6.159 The **United States** argues that as for paragraph 7.1303 above, the European Communities invites the Panel to make new findings, based on newly submitted exhibits, with regard to two approvals purportedly made after the establishment of the terms of reference. As the United States explained above, under the DSU and the Panel's working procedures, it would not be proper for the Panel to accept new exhibits on the measures at issue during the interim review stage, nor to make new findings to reflect the information in such exhibits.

6.160 **Canada** similarly states that for the reasons stated above, Canada opposes the EC attempt to reopen the factual record at the interim review stage. The European Communities will have an opportunity to introduce this new evidence during the implementation stage of the proceeding. In addition, Canada recalls that Exhibit EC-169 is problematic for another reason; it is a document that

has been submitted by the European Communities in the German language only. The failure to submit a translation of Exhibit EC-169 means that the Panel should disregard this document.

6.161 **Argentina** also disagrees with the suggested modifications. As Argentina stated before, the approvals in its view do not make any difference, since Argentina believes that the Panel should make no findings about the implication of these late approvals referring to any possible end of the "*de facto*" moratorium.

6.162 The **Panel** has made appropriate changes to paragraph 7.1669 and has deleted the relevant sentence in the footnote. However, the Panel declines the European Communities' invitation to take into account the information provided by the European Communities in the new Exhibits EC-168 and EC-169.

6.163 We first address Exhibit EC-168. Exhibit EC-168 contains a decision of the Spanish Ministry of the Environment dated 18 October 2004. In addressing this Exhibit, we recall the above-referenced provisions of paragraph 12 of the Panel's Working Procedures and observe that, in this instance, the European Communities has not made a showing of good cause for submitting in March 2006 what it could have submitted already in October 2004. Indeed, the European Communities provides no reason for the late filing. The European Communities merely argues that the Complaining Parties still have an opportunity to comment on the new exhibit. This argument is misconceived. Paragraph 12 of the Panel's Working Procedures states that "[p]arties shall submit all factual evidence to the Panel no later than during the first substantive meeting, except with respect to evidence necessary for purposes of rebuttals, answers to questions or comments made for purposes of rebutting answers provided by others", unless an exception is granted on a showing of good cause. The fact that paragraph 18 of the Panel's Working Procedures gives the Parties the opportunity within a time-period specified by the Panel to submit written comments on the other Parties' written requests for review does not excuse the European Communities from complying with the provisions of paragraph 12 of the Working Procedures. We also recall that in *EC - Sardines* the Appellate Body stated in unqualified terms that "[t]he interim review stage is not an appropriate time to introduce new evidence".[213]

6.164 Turning to Exhibit EC-169, we note that this exhibit apparently contains a decision of the German lead CA dated 13 February 2006. As an initial matter, we recall that the document is in German and that no translation into any of three official languages of the WTO was provided. Even disregarding this, the Panel considers that it would be inappropriate to refer to the application concerning MON863 maize in footnote 1365 given that that footnote concerns the product-specific measures challenged by the Complaining Parties. None of the product-specific measures challenged by the Complaining Parties concerns the application concerning MON863 maize.

6.165 The **European Communities** identified a missing reference to the year 1999 in paragraph 7.1809.

6.166 Like Argentina, the **European Communities** identified words included by oversight in paragraph 7.1873.

6.167 The **European Communities** submits that the wording of the third sentence of paragraph 7.2222 should be changed to provide further clarification as to what the issue exactly was.

6.168 The **Panel** has made appropriate changes to paragraph 7.2229 in response to this comment.

[213] Appellate Body Report, *EC – Sardines*, para. 301.

6.169 The **European Communities** requests that a footnote reference be put in paragraph 7.2324 indicating where the arguments summarized in this paragraph have been made in the US submissions. The European Communities has been unable to identify the source of the arguments set out in that paragraph. If the arguments have not been made in the US submission they should of course be deleted from the summary.

6.170 The **United States** notes that the point that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years is made in paragraph 138 of the US first written submission. The United States further notes that additional support for this assertion is provided in Annex II to the US reply to Panel question No. 75(c).

6.171 The **Panel** sees no need for adding a footnote and notes that its argument summary is based on arguments set out at paragraph 138 of the US first written submission which refers to, and should be read together with, Exhibit US-31. As noted by the United States, the United States' reply to Panel question No. 75(c) contains further relevant information. Nonetheless, in response to the EC comment the Panel has deleted the last sentence of paragraph 7.2331, and has modified paragraph 7.2332. Furthermore, in order to ensure consistency across Section VII.E, the Panel has made corresponding changes to all US argument summaries which relate to the other product-specific measures challenged by the United States. In reviewing its findings concerning the US argument about the period of time during which the relevant applications were pending, the Panel also noticed that a small portion of the findings had been inadvertently omitted from the interim reports, and so the Panel has added the missing portion at paragraph 7.1929. In view of this addition, a similar statement included at paragraph 7.2295 became redundant and was therefore deleted.

5. EC member State safeguard measures

(a) Comments common to Canada and Argentina

6.172 **Canada** and **Argentina** identified mistaken references to Argentina in paragraphs 7.3170-7.3171.

(b) Comments by Canada

6.173 **Canada** identified a typographical error at paragraph 7.2963.

6.174 **Canada** also recalls that at paragraph 7.3390, the Panel indicates that, in respect of Canada's claims under Article 2.2 of the *SPS Agreement*, the EC member State safeguard measures are inconsistent with both Articles 5.1 and 5.7, and therefore, by implication, are inconsistent with Article 2.2. Canada submits that the finding of a dual inconsistency with both Articles 5.1 and 5.7 seems to contradict the Panel's earlier reasoning on the issue of whether Articles 5.1 and 5.7 can apply at the same time. Canada understands the Panel's findings and conclusions with respect to Articles 5.1 and 5.7 to be that Article 5.7 does not apply because sufficient scientific evidence existed to complete a risk assessment at the time the safeguard measures were adopted. On that basis, Article 5.1, rather than Article 5.7, applies and the measures are inconsistent with Article 5.1 because they are not based on a risk assessment. Similarly, therefore, Article 2.2, rather than Article 5.7, would apply, and the measures would be inconsistent with it because they are not based on scientific principles, and are being maintained without sufficient scientific evidence. Canada requests the Panel to clarify this issue and make the appropriate changes in the final report.

6.175 The **European Communities** argues that Canada vaguely requests the Panel to "clarify this issue and make the appropriate changes in the final report." In the European Communities' view, this is hardly compatible with the requirement set out in Article 15.2 of the DSU to submit requests to review precise aspects of the interim report. Indeed, neither is it clear what the Panel is to do in order to accede to Canada's request, nor is it possible for the European Communities to make any meaningful comment in the absence of a precise suggestion. Canada's request should therefore be refused.

6.176 The **Panel** has made appropriate changes in Sections VII and VIII of the final reports to clarify the issue identified by Canada. The Panel also notes that it has used the concept of "consistency" in connection with Article 5.7 in view of the Appellate Body's use of that concept in the *Japan – Apples* and *Japan – Agricultural Products II* reports.[214]

6. Conclusions and recommendations

6.177 **Argentina** identified a mistaken reference to Canada at paragraph 8.57(c).

D. OTHER CHANGES TO THE INTERIM REPORTS

6.178 The **Panel** has also made a number of other changes, throughout the reports, which were not specifically requested by the Parties. The Panel has done so in an effort to eliminate typographical errors and edit its reports.

E. REQUEST FOR REDACTION OF PORTIONS DISCLOSING STRICTLY CONFIDENTIAL INFORMATION

6.179 As noted *infra*, at footnote 233, the Panel, at the request of the European Communities, put in place a special set of procedures for the protection of strictly confidential information ("SCI"), notably to protect sensitive company information submitted by the European Communities. The interim reports submitted to the Parties contained references to information designated by the European Communities as SCI, and the Panel identified them as such.

6.180 At the invitation of the Panel, the **European Communities** on 7 April 2006 submitted specific requests for bracketing/redaction of words, sentences and/or paragraphs in the interim reports which, in its view, disclose SCI. The European Communities stated that there was no information contained in the findings of the interim reports that directly constitutes SCI. In contrast, the European Communities identified certain references at paragraphs 271, 621, 622 and 623 of Annex H which it considered to disclose SCI and which it requested to be redacted from the public versions of the final reports.

6.181 The **Complaining Parties** on 18 April 2006 made use of the opportunity granted by the Panel to comment on the EC requests. They indicated that they had no objection to the removal of the SCI designation on information contained in the body of the interim reports or to the requests for redaction as set out in the EC letter of 7 April 2006.

6.182 Taking account of the views expressed by the Parties, the **Panel** made appropriate redactions at paragraphs 271, 621, 622 and 623 of Annex H. They are identified in Annex H as "[xxx]".

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[214] Appellate Body Reports, *Japan – Apples*, paras. 176 and 177; *Japan – Agricultural Products II*, para. 89.

F. PUBLIC DISCLOSURE OF THE PANEL'S CONFIDENTIAL INTERIM REPORTS

6.183 On 7 February 2006, the Panel provided paper and electronic copies of its confidential interim reports to the Parties. On 9 February 2006, the Panel sent a letter to the Parties to draw their attention to the fact that a commercial trade publication had posted on its website the conclusions and recommendations (Section VIII) of the Panel's confidential interim reports. The Panel noted that this was a matter of grave concern to it, recalling that it was critical to the functioning of the interim review process that all Parties maintained the confidentiality of the interim reports. The Panel further recalled that confidentiality at all stages of the process is an inherent part of the WTO dispute settlement system whose purpose is to secure a positive solution to a dispute. The Panel also observed that the maintenance of the confidentiality of the interim reports was particularly important in order to avoid that information contained in the reports and designated as SCI would be disclosed to unauthorized persons. The Panel requested the Parties to provide any information they had as to how the breach of confidentiality had occurred and urged all Parties to take all necessary steps to protect the confidentiality of the interim reports.

6.184 Subsequently, on 2 March 2006, the Panel sent another letter to the Parties to point out that Friends of the Earth (FOE) Europe had posted on its website the Panel's confidential interim reports in their entirety, *i.e.*, the descriptive part as well as the findings and conclusions. The Panel noted that in a statement made available on its web site, FOE claimed to have refrained from disclosing SCI in the version it had published, on the advice of its lawyers. The Panel stated that the leak in question was particularly serious, not just because it was far more comprehensive, but also because unlike the conclusions section of the interim reports which had been previously leaked, the findings section of these reports contained SCI.

6.185 The Panel recalled in this regard that FOE claimed that it did not disclose SCI in its published versions of the findings. In the Panel's view, however, even assuming that no SCI was in fact disclosed as a result of the action of FOE, FOE's action represented another serious incident which could damage the integrity of the WTO dispute settlement system as a whole. The Panel noted in this respect that it is very difficult to see why any private party would wish to provide panels, complaining parties and responding parties with strictly confidential information that is in its sole possession if it cannot have confidence that this information will not be disclosed without its permission during the interim review process.

6.186 The Panel again requested the Parties to provide any information they might have as to how the second breach of confidentiality occurred. The Parties responded to the Panel's letters as indicated below.

6.187 The **United States** observed that it shared the Panel's grave concerns. With regard to the first breach of confidentiality, the United States noted that pertinent information had been posted by the relevant publication that placed Section VIII on the internet. In particular, the website noted that the source for Section VIII was the "Institute for Agriculture and Trade Policy" (IATP). The United States pointed out that IATP is an NGO that, among other things, opposes the adoption of agricultural biotechnology. The United States stated that it was certain that no person provided by the United States with access to the interim reports had any contacts with IATP regarding those reports. Moreover, the United States noted that each person provided by the United States with access to the interim reports was aware of and respected the confidential nature of the interim reports. Thus, the United States contended that it had not been, nor would it be, the source of breaches of confidentiality regarding the interim reports.

6.188 Regarding the publication by "Friends of the Earth Europe" of a complete copy of the findings (Section VII) on the internet, the United States noted that the source of the leak appeared to be the same as the source of the 8 February leak of Section VIII of the interim reports. The United States submitted that the Friends of the Earth Europe website included a press release, datelined Geneva/Brussels 8 February 2006, stating that three NGOs – Institute for Agriculture and Trade Policy, Friends of the Earth Europe, and Greenpeace – jointly published Section VIII of the interim reports on the internet. Moreover, the United States asserted that in a separate briefing paper, Friends of the Earth Europe states: "Friends of the Earth has, on legal advice, deleted limited company-specific information from the interim report we are publishing in order to avoid legal action against us." According to the United States, this statement indicates that Friends of the Earth Europe has received a complete copy of Section VII, including SCI. Furthermore, the United States emphasized, the version of the report that Friends of the Earth Europe published on the internet in fact contained several pages, without any redactions, that the cover sheet of the reports indicated as containing SCI. The United States noted in this regard that it agreed with the Panel that a leak of material containing SCI was of extraordinary concern.

6.189 In respect of this second breach of confidentiality, the United States contended that it was not the source of the leak of the confidential interim reports. According to the United States, no person provided by it with access to the interim reports had any contacts with Friends of the Earth Europe regarding the interim reports. Moreover, in accordance with the Panel's strict rules governing SCI supplied by other Parties, the United States stated that it had tightly controlled distribution and use of any portion of the interim reports containing SCI. Furthermore, the United States asserted that it was apparent from the content of the "Briefing Paper" (entitled "Looking behind the US spin: WTO ruling does not prevent countries from restricting or banning GMOs") by Friends of the Earth Europe that no Complaining Party would have had reason to provide a copy of the findings to Friends of the Earth Europe.

6.190 In addition, the United States noted that the Panel's additional SCI procedures permitted at least one possible scenario under which provision of SCI to Friends of the Earth Europe would not have been a breach of those procedures. According to the United States, the Panel's SCI rules "do not apply to a party's treatment of its own SCI", and the European Communities was the only Party that had submitted SCI in this dispute.

6.191 **Canada** stated that as regards the "leak" of the findings and conclusions set out in the interim report it shared the Panel's concerns. Furthermore, Canada stated that it was in no way involved in these incidents, and deplored such breaches of confidentiality. Canada noted that, despite media demands for comments based on the leak, the Government of Canada had refused to make any public statement beyond acknowledging that it has received the interim report and was studying it. Finally, Canada remarked that should any information come to its knowledge as to how the breach of confidentiality occurred it would forward this information to the Panel and the Secretariat without delay.

6.192 **Argentina** stated that it was not involved in any way in the reported leaks referenced in the Panel's letters. Moreover, Argentina stated that it had no information to provide about how the breach of confidentiality had occurred. Argentina noted, finally, that should any information come to its knowledge regarding these regrettable incidents, it would forward this information to the Panel and the Secretariat without delay.

6.193 The **European Communities** stated that it was concerned by the serious breach of the confidentiality of Panel proceedings. With regard to the first breach of confidentiality, involving the disclosure of the conclusions of the interim reports, the European Communities pointed out that as far

as it could establish the leak first occurred via a United States based NGO, the Institute for Agriculture and Trade Policy, as the relevant document was posted on their website.

6.194 In respect of the second breach of confidentiality, which occurred via Friends of the Earth Europe, the European Communities said it would refrain from making groundless accusations or insinuations, or from speculating about which Party might or might not have profited from the public dissemination of the document. Instead, the European Communities said, it could confirm that it had no information about the source of the leak and no indication that there had been any breach of confidentiality attributable to the European Communities. On the contrary, the European Communities maintained, it had systematically ensured that all persons having access to the interim reports were informed of its confidentiality and the need to preserve it.

6.195 The **Panel** notes with satisfaction that all Parties deplored and condemned the serious breaches of the confidentiality of the interim reports which occurred in this case. The Panel further notes that each Party formally stated that it had no involvement in the leaks of the confidential interim findings and conclusions. It is plain to see that these statements cannot easily be reconciled with the fact that these leaks did occur. However, as is apparent from the above summary of the Parties' responses to the Panel's letters, the Panel was not provided sufficient reliable information to determine the origin(s) of the leaks. The Panel subsequently sent a letter to the Parties to inform them that it intended to take appropriate action to try to avoid further leaks of the reports upon issuance of the final reports (*see* the Panel's letter to the Parties contained in Annex K).

6.196 It should be noted, in addition, that the Institute for Agriculture and Trade Policy and Friends of the Earth submitted *amicus curiae* (friend-of-the-court) briefs, requesting the Panel to accept and consider their briefs.[215] The Panel acknowledged receipt of these briefs, shared them with the Parties and Third Parties, and accepted them as such.[216] In the light of this, it is surprising and disturbing that the same NGOs which claimed to act as *amici*, or friends, of the Panel when seeking to convince the Panel to accept their unsolicited briefs subsequently found it appropriate to disclose, on their own websites, interim findings and conclusions of the Panel which were clearly designated as confidential.

VII. FINDINGS

7.1 The Panel observes that the United States, Canada, Argentina and the European Communities (hereafter "the Parties") have used different terms to refer to the products at issue in this dispute. The separate requests for the establishment of a panel by the United States, Canada and Argentina (hereafter collectively referred to as "the Complaining Parties") all refer to measures affecting "biotech products".[217] The European Communities' legislation identified by all of the Parties as relevant to the case in hand refers to genetically modified organisms (hereafter "GMOs").[218] All of the Parties to the dispute agree that, technically, the specific products at issue in this case are plants (and the products thereof) developed through the use of recombinant DNA techniques.

[215] *See infra*, Section VII.A.2.
[216] *Ibid*.
[217] WT/DS291/23, WT/DS292/17 and WT/DS293/17.
[218] Council Directive 90/220/EEC "on the deliberate release into the environment of genetically modified organisms"; Regulation (EC) No 258/97 "concerning novel foods and novel food ingredients"; and Directive 2001/18/EC of the European Parliament and of the Council "on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC".

7.2 In its consideration of the matter before it, the Panel uses interchangeably the terms biotech products, GMOs, GM plants, GM crops or GM products, without prejudice to the views of the Parties to the dispute.

A. PROCEDURAL AND OTHER GENERAL MATTERS

7.3 In this opening section, we address a number of procedural and other general matters. First of all, we explain how in preparing this document we have taken account of the fact that the Complaining Parties in this dispute have brought legally separate complaints. Then we set out how we have dealt with the unsolicited *amicus curiae* briefs sent to the Panel. Next we address how we have reached and implemented our decision to consult individual scientific experts and international organizations. We then go on to explain that certain annexes to this document are available only on-line, and we offer some general remarks on the challenges faced by the Panel in conducting these proceedings. After that, we reproduce in full our preliminary ruling on whether the Complaining Parties' separate requests for the establishment of a panel are inconsistent with Article 6.2 of the DSU, as claimed by the European Communities. Finally, we address the issue of the relevance of non-WTO rules of international law to the interpretation of the WTO agreements at issue in this dispute.

1. Multiple complaints

7.4 The Complaining Parties in this dispute did not bring a joint complaint against the European Communities. Instead, they filed legally separate complaints, and separately requested the establishment of a panel. Since these requests for the establishment of a panel related to the same matter, the DSB, consistent with the procedures for multiple complaining parties provided for in Article 9.1 of the DSU, established a single panel to examine the three complaints.

7.5 Article 9.2 of the DSU provides that when a single panel is established to examine multiple complaints, the panel is to submit separate reports on the dispute concerned if one of the parties to the dispute so requests. We have sought the views of the Parties to this dispute on the question of separate panel reports. None of the Parties requested that we submit separate panel reports. Instead, as we understand it, all Parties effectively agreed that the Panel could issue a single document constituting three reports; that the introductory and descriptive parts could be common to all reports; that the findings could be common to the three reports, except where the claims presented and the evidence submitted by the Complaining Parties were different; and that the conclusions and recommendations should be different for each report.

7.6 The Panel saw no reason to disagree with the approach suggested by the Parties. Accordingly, we decided to prepare and issue one single document constituting three separate panel reports. This is why the present document bears the symbols and DS numbers of all three complaints, *i.e.*, DS291 for the complaint by the United States, DS292 for the complaint by Canada and DS293 for the complaint by Argentina. The present document comprises a common introductory part and some common annexes. The descriptive part and certain annexes contain separate sections for each Party. Thus, the description of, *e.g.*, the United States' arguments is part of the report concerning the United States' complaint. The description of the European Communities' arguments is basically relevant to all three reports, as the European Communities has provided an integrated defence in this case. However, some portions of the European Communities' arguments are relevant to only one report.

7.7 Regarding the findings section of the three reports, we have particularized the findings for each of the Complaining Parties only where we found it necessary to do so. Thus, many (although not all) of the legal interpretations developed by the Panel are common to all three reports. On the other hand, we have particularized the conclusions for each claim made by a Complaining Party. To

distinguish the complaint-specific conclusions, we use the appropriate DS numbers. Hence, a conclusion which is part of the report concerning the United States' complaint is preceded by the reference "DS291 (United States)". Where we have made findings, or relied on materials submitted as evidence[219], which are specific to one of the three complaints, we have indicated this by using the relevant DS number, if it was not otherwise clear from the relevant context. Also, in summarizing the Complaining Parties' arguments, we have provided separate summaries for each Complaining Party where the arguments were different; where the Complaining Parties' arguments were identical or very similar, we have generally prepared an integrated argument summary for all Complaining Parties.

7.8 With regard to the final section of this document, entitled "Conclusions and Recommendations", we note that the conclusions we reached and the recommendations we made have been particularized for each Complaining Party. Accordingly, this document contains three independent sets of conclusions and recommendations.

7.9 In our view, the approach outlined above satisfies the requirement contained in Article 9.2 that a single panel present its findings to the DSB in such a manner that the rights which the parties to the dispute would have enjoyed had separate panels examined the complaints are in no way impaired. We also consider that this approach is consistent with the approach followed in a similar situation by the panel in *US – Steel Safeguards*.[220]

2. *Amicus curiae* briefs

7.10 In the course of these proceedings, we received three unsolicited *amicus curiae* briefs: on 6 May 2004 we received an *amicus curiae* brief from a group of university professors[221]; on 27 May 2004 we received an *amicus curiae* brief from a group of non-governmental organizations[222] represented by the Foundation for International Environmental Law and Development (FIELD); and on 1 June 2004 we received an *amicus curiae* brief from a group of non-governmental organizations[223] represented by the Center for International Environmental Law (CIEL). These briefs were submitted to us prior to the first substantive meeting of the Panel with the Parties, and the Parties and Third Parties were given an opportunity to comment on these *amicus curiae* briefs.[224]

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[219] We note that the Complaining Parties have only partly submitted the same factual evidence in support of their claims. In some cases, the Complaining Parties have explicitly relied on evidence submitted by another Complaining Party, but no Complaining Party has stated that, for the purposes of its complaint, it wished to rely also on all evidence submitted by the other Complaining Parties.

[220] Panel Reports, *US – Steel Safeguards*, para. 10.725.

[221] Lawrence Busch (Michigan State University), Robin Grove-White (Lancaster University), Sheila Jasanoff (Harvard University), David Winickoff (Harvard University) and Brian Wynne (Lancaster University).

[222] Gene Watch, Foundation for International Environmental Law and Development (FIELD), Five Year Freeze, Royal Society for the Protection of Birds (RSPB)(UK), the Center for Food Safety (USA), Council of Canadians, Polaris Institute (Canada), Grupo de Reflexión Rural Argentina, Center for Human Rights and the Environment (CEDHA) (Argentina), Gene Campaign, Forum for Biotechnology and Food Security (India), Fundación Sociedades Sustentables (Chile), Greenpeace International (The Netherlands), Californians for GE-Free Agriculture, International Forum on Globalisation.

[223] Center for International Environmental Law (CIEL), Friends of the Earth – United States (FOE-US), Defenders of Wildlife, the Institute for Agriculture and Trade Policy (IATP), and the Organic Consumers Association (OCA).

[224] Only the United States and the European Communities referred to these briefs. The United States comments extensively on the arguments in the *amicus curiae* briefs in its second written submission, but concludes that the information provided in those briefs are of no assistance to the Panel in resolving this dispute. US second written submission, attachment III. The European Communities refers to the argument in the *amicus curiae* briefs in its first oral statement. The European Communities' first oral statement, para. 15.

7.11 We note that a panel has the discretionary authority either to accept and consider or to reject any information submitted to it, whether requested by a panel or not, or to make some other appropriate disposition thereof.[225] In this case, we accepted the information submitted by the *amici curiae* into the record. However, in rendering our decision, we did not find it necessary to take the *amicus curiae* briefs into account.

3. Consultation of individual scientific experts and international organizations

7.12 We now address the Panel's decision to consult individual scientific experts and certain international organizations. In this regard, Article 11.2 of the *SPS Agreement* provides that:

> "In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative."

7.13 Articles 14.2 and 14.3 of the *TBT Agreement* provides that:

> "14.2 At the request of a party to a dispute, or at its own initiative, a panel may establish a technical expert group to assist in questions of a technical nature, requiring detailed consideration by experts.
>
> 14.3 Technical expert groups shall be governed by the procedures of Annex 2."

7.14 Finally, Article 13.1 of the DSU provides in relevant part:

> "Each panel shall have the right to seek information and technical advice from any individual or body which it deems appropriate."

7.15 In light of the claims of the Complaining Parties that the measures at issue violated, *inter alia*, the *SPS Agreement* and/or the *TBT Agreement*, at the time of the organizational meeting the Panel established a deadline for the Parties to request the Panel to seek appropriate scientific and technical advice pursuant to the provisions of these agreements.

7.16 On 27 May 2004, the European Communities formally requested the Panel to seek advice from scientific and technical experts at an appropriate stage. In particular, the European Communities suggested that the Panel seek advice from the most relevant sources reflecting a representative spectrum of views, including individual experts and perhaps competent international organizations. Shortly thereafter, the European Communities submitted a proposal for the terms of reference for scientific and technical advice. The Complaining Parties expressed the view that they did not consider it necessary for the Panel to seek any scientific and technical advice, *inter alia* because they were not challenging the opinions or assessments of the EC scientific committees.

7.17 The Panel decided to take a decision regarding the need for expert advisers only in the light of the second written submissions by the Parties, and provided the Parties with a further opportunity to comment on the need for expert advice. The European Communities repeated its request for input from experts; the Complaining Parties continued to argue that no expert advice was necessary in the circumstances of this case.

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[225] Appellate Body Report, *US – Shrimp*, paras. 104 and 108.

7.18 On 4 August 2004, the Panel informed the Parties that it considered that certain aspects of the Parties' submissions raised scientific and/or technical issues in respect of which the Panel might benefit from expert advice. Accordingly, the Panel decided to consult individual experts to obtain their opinion on certain scientific and/or technical issues raised in the Parties' submissions.[226] In particular, the Panel indicated that it would seek expert advice on three categories of issues:

(a) for each product application, the scientific or technical grounds for: the comments and/or objections raised by EC member States, the requests for additional information, and the time taken to evaluate the additional information provided;

(b) for each product for which a safeguard measure was taken by one of the relevant EC member States, how the scientific or other documentation relied upon by these member States compares with various standards for risk assessment, and whether the documentation relied upon by these member States was sufficient to support the safeguard measures taken; and

(c) for each biotech product subject to the complaint, whether there are significant differences in the risks arising to human, plant or animal health, or to the environment, from the consumption and use of: products of biotechnology approved by the European Communities prior to October 1998; comparable novel non-biotech products; and foods produced with biotech processing aids.

7.19 Also on 4 August 2004, the Panel decided that it would seek information from certain international organizations which might assist the Panel in determining the meaning of selected terms and concepts. Most of these terms and concepts appear in the WTO agreements at issue in this dispute (*e.g.*, "pest"). We note in this regard that the European Communities argued that the Panel also needed to consult scientific experts on the meaning of the relevant terms. The Complaining Parties opposed the European Communities' request, arguing that the terms in question were terms appearing in WTO agreements and that, as such, the Panel needed to determine their meaning by applying the customary rules of interpretation of public international law, as required by Article 3.2 of the DSU.

(a) Consultation of individual experts

7.20 The Panel invited the Parties to suggest specific questions on the three issues it had identified. All of the Parties suggested specific questions on these issues. In addition, the European Communities suggested that the Panel seek the advice of at least two experts competent in at the least the following fields of expertise: agrobiodiversity, agronomy, allergology, animal husbandry, animal pathology, biochemistry, biological diversity, control and inspection methods, crop husbandry, DNA amplification, ecology, epidemiology, entomology, environmental impact monitoring methods, environmental sciences, food and feed safety, gene expression, gene sequencing, genetics, genetic modification detection methods, genomic stability, handling transport and packaging methods, herbicide chemistry, histopathology, immunology, malherberology and weed sciences, medicine, medical microbiology and antibiosis, molecular biology, nutrition, ornithology, phytopathology, plant breeding, plant development, plant-microbe interactions, plant protection and residues of plant protection products, plant reproduction and plant biology, population genetics, risk assessment and

[226] The Panel decided to seek advice from individual scientific and technical experts as no party formally requested that such information be sought from an expert group. The approach of the Panel is consistent with the approach followed by previous panels considering alleged violations of the *SPS Agreement* and the *TBT Agreement*.

risk analysis processes, sampling methods, soil chemistry and soil sciences, soil microbiology therapeutics, toxicology, and veterinary medicine.

7.21 On 19 August 2004, the Panel requested the assistance of the CBD, Codex, FAO, IPPC, OIE and WHO to identify appropriate experts to address the issues identified above. Thirty individuals were identified by these organizations, and each of these experts was contacted by the Secretariat. Those experts who were available and interested in providing advice to the Panel were requested to provide a curriculum vitae (hereafter "CV"). Nineteen experts responded positively and their CVs were provided to the Parties. The Parties were given the opportunity to comment on each expert and in particular to make known to the Panel any compelling objections they might have to the Panel's consulting that individual with respect to the case at hand. The Parties submitted their compelling objections with regard to many of the experts by pointing, for example, that: they were actually involved in the procedures at issue in this dispute; they were employees of either party to this dispute; and they had been involved in activities which might cast doubts on their impartiality.

7.22 The Parties were also invited to submit suggestions for experts with respect to the issues before the Panel. These experts were also contacted by the Secretariat, and those interested and available to assist the Panel were invited to submit a CV. These CVs were also provided to the Parties, who were again given the opportunity to comment on the experts suggested and to identify any compelling objections. Seventy additional experts were identified by the Parties, and CVs were received from 29 of these.

7.23 On 13 October 2004, the Panel informed the Parties of the names of the experts it had selected. Argentina had expressed objections to one of the experts subsequently selected by the Panel. The Panel reconsidered the qualifications of the individual concerned, as well as the information provided by the expert with respect to any potential conflicts of interest, and determined that the objections raised by Argentina did not provide compelling grounds for not selecting this expert.

7.24 According to the additional working procedures for the consultation of experts adopted by the Panel in consultation with the Parties, the experts were requested to act in their individual capacities and not as representatives of any organisation. They were not informed of the identities of the other experts advising the Panel, until such time as they were provided with the written responses to the Panel's questions from all of the experts.

7.25 The experts selected by the Panel were:

> Dr. David Andow, Department of Entomology, University of Minnesota, St. Paul, Minnesota, USA;
>
> Dr. Marilia Regini Nutti, Director, National Research Center for Food Technology, Brazilian Agricultural Research Corporation (EMBRAPA), Rio de Janeiro, Brazil;
>
> Dr. Allison Snow, Department of Evolution, Ecology & Organismal Biology, Ohio State University, Columbus, Ohio, USA; and
>
> Dr. Geoff Squire, Scottish Crop Research Institute, Dundee, United Kingdom.

One expert selected by the Panel, Dr. David J. Hill of the Department of Allergy, Royal Children's Hospital, Melbourne, Australia, subsequently informed the Panel that he was unable to assist the Panel.

7.26 The Parties were consulted with regard to the questions to be submitted to the experts in writing. The experts were provided with all relevant parts of the Parties' submissions (including exhibits and Strictly Confidential Information) on a confidential basis. Each selected expert was requested immediately to inform the Panel of those questions which he/she did not intend to answer because they did not consider that they had the appropriate expertise. Following clarification of some of its written questions, the Panel identified two issues on which the selected experts were not likely to provide advice: the molecular characterization of certain oilseed rape and starch potato products, and quantitative detection methods.

7.27 On 15 November 2004, the Panel invited the Parties to submit names of individuals with expertise on these two particular issues, preferably from among individuals who had previously indicated their willingness to advise the Panel, and to provide the CV for any new expert they wished to be considered by the Panel and the other Parties. A total of 22 individuals with expertise in one or both of these issues were identified by the Parties, including 13 new experts. The Parties were given an opportunity to comment on each of these experts and to make known any compelling objections to their selection as advisers to the Panel. The European Communities expressed objections to one of the additional experts selected by the Panel. The Panel reconsidered the qualifications of the individual concerned, as well as the information provided by the expert with respect to any potential conflicts of interest, and determined that the objections raised by European Communities did not provide compelling grounds for not selecting this expert to address the two issues identified. The Panel subsequently selected the following two additional experts to respond exclusively to questions concerning the aforementioned two issues:

> Dr. Marion Healy, Chief Scientist, Food Standards Australia New Zealand (FSANZ), ACT, Australia;
>
> Dr. John W Snape, Crop Genetics, John Innes Center, Norwich, United Kingdom.

7.28 The procedures described in paragraph 7.24 above were also followed with respect to Drs. Healy and Snape.

7.29 The Panel's 114 questions, and the written responses from the experts, are compiled in Annex H. The questions were sent to the experts on 22 October 2004, and additional questions were sent on 19 November 2004. The written responses from all of the experts to the questions by the Panel were received on 5 January 2005. The Parties were given an opportunity to comment on the replies by the experts, and subsequently to comment on the comments of the other Parties. The Parties' comments were also provided to the experts. On 17-18 February 2005, the Panel met with all of the experts; the Parties were invited to participate in this meeting. The experts were given the opportunity to provide further information regarding the questions of the Panel, to respond to the comments made by the Parties, and to respond to further questions from the Panel and the Parties. A transcript of the Panel's meeting with the experts is contained in Annex J.

7.30 The Panel wishes to record its appreciation of the experts and of their contributions to the resolution of this dispute. They provided detailed and comprehensive responses to a large number of questions from the Panel and the Parties, respecting the strict time constraints which had to be established by the Panel. They provided the necessary scientific input to assist the Panel in understanding the issues raised by the Parties and to resolve the trade dispute before it. The clarity of their explanations and their professionalism was particularly appreciated by the Panel.

(b) Consultation of international organizations

7.31 Regarding the Panel's decision to seek information from international organizations, it should be noted that the Parties were consulted both on the international organizations from which information would be sought and on the list of terms on which information would be sought. Taking into account the Parties' view, the Panel decided that it would seek information from the secretariats of the CBD, Codex, FAO, IPPC, OIE, UNEP and WHO. In December 2004, the Panel contacted these organizations and invited them to identify appropriate standard references (scientific or technical dictionaries, documents adopted or circulated by the relevant international organization, etc.) that would assist the Panel in ascertaining the meaning of certain terms and concepts. The Parties were given an opportunity to comment in writing on the materials provided to the Panel by the international organizations.

7.32 The Panel appreciates the assistance provided by the secretariats of the CBD, Codex, FAO, IPPC, OIE, UNEP and WHO with respect to its requests.

4. Annexes available on-line only

7.33 The Panel has consulted the Parties on the need of including in the panel reports: (i) the experts' replies to the Panel's questions; (ii) the Parties' comments on these replies and on each other's comments; (iii) the transcript of the expert meeting of 17-18 February 2005; and (iv) the Parties' replies to the Panel's and each others' questions. In the event the Parties saw a need for including these documents in the panel reports, the Panel also sought the views of the Parties on whether the aforementioned documents could be made available on-line only.

7.34 After consideration of the views expressed by the Parties, the Panel decided to annex the documents in question to the three reports. However, in order to limit the page number of the paper copies of the reports circulated to Members, the Panel also decided that, except for the Parties and Third Parties to this dispute, the relevant annexes would be available electronically only, that is to say, through the WTO's public web site. The annexes in question are available in the three official WTO languages and they form an integral part of the three panel reports.

7.35 For clarity, we list below the annexes which are available on-line only:

- Annex C: Replies by the Parties to Questions Posed by the Panel on 3 June 2004 (11 pages);
- Annex D: Replies by the Parties to Questions Posed by the Panel in the Context of the First Substantive Meeting (165 pages);
- Annex E: Replies by the Parties to Questions Posed by Other Parties in the Context of the First Substantive Meeting (15 pages);
- Annex F: Replies by the Parties to Questions Posed by the Panel and Comments by the Parties on the Other Parties' Replies in the Context of the Second Substantive Meeting (191 pages);
- Annex G: Replies by Third Parties to Questions Posed by the Panel and the Parties (16 pages);

– Annex H: Replies by the Scientific Experts Advising the Panel to Questions Posed by the Panel (238 pages);

– Annex I: Comments by the Parties on the Replies by the Scientific Experts to the Questions Posed by the Panel (391 pages); and

– Annex J: Transcript of the Panel's Joint Meeting with Scientific Experts of 17 and 18 February 2005 (171 pages).

– Annex K: Letter of the Panel to the Parties of 8 May 2006 (3 pages).

7.36 The above-mentioned annexes can be found on *Documents online* (http://docsonline.wto.org/) with the document symbols, WT/DS291/R, WT/DS292/R, WT/DS293/R, plus addenda.

5. Challenges faced by the Panel in the conduct of the proceedings

7.37 The Panel notes that completing the present proceedings and preparing the panel reports has, unfortunately, taken considerably longer than is the case for typical WTO panel proceedings. It is fair to say, however, that the present proceedings were quite different from typical panel proceedings, and not just because typical panel proceedings involve one complaint rather than three.

7.38 Four factors in particular have made the conduct of these proceedings a challenging task for the Panel and the small group of Secretariat officials assisting it, and have contributed to the delays that have occurred in the disposition of this case.[227] They are: (i) the volume of materials to be considered by the Panel, (ii) the need for additional fact-finding in the course of the panel proceedings, (iii) the procedural and substantive complexity of the case, and (iv) the limited co-ordination of the Complaining Parties' submissions to the Panel. It is useful to offer a few explanatory observations on each of these factors.

7.39 The volume of the materials to be considered by the Panel in this dispute was, quite simply, enormous.[228] A few facts and figures serve to illustrate this point. The Panel asked a total of 201 written questions of the Parties, and a total of 114 written questions of the six scientific experts advising it. The Parties posed a total of 22 written questions to each other. The Panel received an estimated 2580 pages of written submissions (including oral statements, comments relating to the expert consultation and replies to questions) from the four Parties. An estimated 292 pages were received from the scientific experts advising the Panel. The Third Parties submitted an additional 102 pages of written submissions (including oral statements and replies to questions).[229] The *amici curiae* filed briefs totalling 96 pages. Furthermore, the Parties submitted an estimated total of 3136 documents to the Panel in support of their claims and arguments.[230] While some of these documents are short, others extend over more than one hundred pages.

[227] It is well to recall in this connection that this Panel was established on 29 August 2003, but not composed until 4 March 2004. Thus, there was an initial delay of more than six months even before the beginning of the Panel's work.

[228] The scientific experts advising the Panel also expressed this sentiment.

[229] We note that Norway alone submitted a total of 53 pages of submissions to the Panel.

[230] Of the estimated 3136 documents submitted to the Panel, the Complaining Parties submitted 417 documents and the European Communities 2719 documents. We note that there is some double-counting involved in our estimate in that the Complaining Parties in part submitted the same exhibits. The 2719 documents submitted by the European Communities include the documents provided in response to the Panel's request for information.

7.40 Another characteristic of these proceedings was the fact that very substantial amounts of information were exchanged among the Parties, not before, but during the panel proceedings. What is more, most of that information was not provided to the Panel until after the first substantive meeting of the Panel with the Parties. More specifically, the European Communities indicated at the first substantive meeting that the Panel was still lacking certain important information which the European Communities alleged supported its position in this case. The European Communities stated that it was willing to provide that information, but noted that it was to a large extent in the possession of its member States. The European Communities told the Panel that a formal request for information from the Panel would assist it in obtaining the information from its member States. With the support of the Complaining Parties, the Panel then sought additional information of the European Communities pursuant to Article 13 of the DSU.

7.41 While much information was subsequently provided by the European Communities, the information submitted was in important respects incomplete, numerous documents had not been translated into an official WTO language, and the way the European Communities initially numbered its own exhibits was confusing. This led the Panel to request the missing information, translation of relevant documents and a more user-friendly system for numbering exhibits. The European Communities complied with the Panel's follow-up request. However, in view of the delayed provision of the information requested by the Panel, the Complaining Parties requested that the second substantive meeting be postponed for several months and that they be given an opportunity, prior to the second substantive meeting, to make further written submissions (hereafter "third written submissions") with regard to the new information provided by the European Communities. The Panel acceded to these two requests.[231]

7.42 The above-mentioned situation meant that the Panel and Complaining Parties did not have all the information requested of the European Communities until seven months after the Panel was composed, and that the second substantive meeting, which at the Parties' request was held back-to-back with the Panel's meeting with the experts, was not held until almost one year after the Panel was composed. It is clear that if the information provided by the European Communities in the course of the proceedings had been available to the Complaining Parties from the outset, the proceedings could have been conducted more efficiently and with a clearer focus.[232]

7.43 The third factor we have identified is the procedural and substantive complexity of the case. On the procedural side, we have already mentioned the extensive fact-finding which had to be undertaken in the course of the proceedings.[233] We have also mentioned the expert selection process

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[231] We note that the scheduling of the second substantive meeting was also linked to the Parties' request that that meeting be held immediately following the Panel's meeting with the experts. In order for the experts to be able to reply to the Panel's questions, the experts needed to be given sufficient time to familiarize themselves with the entirety of the information submitted to the Panel.

[232] As we do not have the facts to determine why more information was apparently not gathered or provided at an earlier stage in these dispute settlement proceedings, we can only re-emphasize what the Appellate Body stated in *India – Patents (US)*:

> All parties engaged in dispute settlement under the DSU must be fully forthcoming from the very beginning both as to the claims involved in a dispute and as to the facts relating to those claims. Claims must be stated clearly. Facts must be disclosed freely. This must be so in consultations as well as in the more formal setting of panel proceedings. In fact, the demands of due process that are implicit in the DSU make this especially necessary during consultations. (Appellate Body Report, *India – Patents (US)*, para. 94.)

[233] As an aside, we note that in connection with this fact-finding process we put in place, in consultation with the Parties, a special set of procedures for the protection of strictly confidential information (hereafter "SCI"), notably because of sensitive company information submitted by the European Communities.

and the process through which we have identified the questions to be asked of the experts. In addition to this, a very large number of letters were exchanged between the Panel and the Parties on various other procedural and organizational matters. Thus, until the second substantive meeting with the Parties most of the Panel's time was spent either attending to the aforementioned procedural matters or studying the Parties' submissions. Regarding the substantive aspects of this case, we note that the Panel's work was made difficult not just because of the often technical and/or scientific nature of the material submitted to us, but also because the Parties' submissions raised a series of fundamental legal issues (*e.g.*, concerning the scope of the *SPS Agreement*) which required careful consideration.

7.44 The last factor to be explained is the limited co-ordination of the Complaining Parties' submissions to the Panel. By this we mean that, with few exceptions, the Complaining Parties did not put forward the same arguments or adopt each others' arguments. We recognize that since the Complaining Parties' brought three legally distinct complaints, they were under no obligation to co-ordinate their submissions to the Panel. We also recognize that the measures challenged and the claims presented by the Complaining Parties were not identical. However, there is a significant overlap among the three complaints. Given the complexity of this case and the vast amount of information to be taken into account, it would have alleviated our burden – and that of the Responding Party – if the Complaining Parties had been able more consistently to provide the same, or at least substantially the same, argumentation on common elements of their complaints.[234] Indeed, in view of the differences among the Complaining Parties' submissions, even simple tasks, like summarizing the Complaining Parties' arguments on a particular issue, required much time. Needless to say, the submission of different arguments by the Complaining Parties also meant that there were more arguments which the Panel needed to consider and address in its reports.

7.45 While the four foregoing factors have contributed to the successive delays in the disposition of this case, we furthermore note another factor which contributed to, at least, the last postponement of the deadline for our interim report: the reduced availability of some of the Secretariat staff assisting the Panel, notably because of the preparations for the Ministerial Conference in Hong Kong. Due to the need for familiarity with the case file it was not possible adequately to address this problem by assigning other staff to the case.

7.46 Having outlined some of the challenges faced by the Panel, we want to acknowledge that each of the Parties to this dispute, and perhaps Argentina in particular given its status as a developing country Member, has faced considerable difficulties of its own in coping with all the information put before the Panel, in responding to the claims and arguments presented by the other Parties and in meeting the generally tight deadlines imposed by the Panel. At the end of the second substantive meeting, the Panel expressed its appreciation for the Parties' co-operation and for their contributions, which had to be made under difficult circumstances.

6. Consistency of the Complaining Parties' panel requests with Article 6.2 of the DSU

7.47 On 8 April 2004, the Panel issued a preliminary ruling in response to a request by the European Communities that the separate requests for the establishment of a panel made by the United States, Canada and Argentina are inconsistent with the requirements of Article 6.2 of the DSU. The Panel's preliminary ruling is reproduced below as it was sent to the Parties, with original footnotes appearing as endnotes at the end of the reproduced ruling.

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[234] We note in this regard that in the panel proceedings in *US – Steel Safeguards* the eight complaining parties at least in part divided among themselves the argumentation on common elements of their complaints. Panel Report, *US – Steel Safeguards*, para. 10.726.

"**1. Procedural background**

1. On 8 March 2004, the European Communities submitted to the Panel a request for a preliminary ruling. The European Communities requested that the Panel rule, as early as possible in the proceedings, that the separate requests for the establishment of a panel (hereafter "panel requests") made by the United States[1], Canada[2] and Argentina[3] are inconsistent with the requirements of Article 6.2 of the DSU.

2. After consultations with the parties regarding the procedural implications of the European Communities' preliminary ruling request, the Panel decided to issue a preliminary ruling before the due date of the Complaining Parties' first written submissions. The Panel gave an opportunity to the Complaining Parties to submit written comments on the European Communities' request and also invited the third parties to submit any written comments they might have in response to the views expressed by the parties.[4] The Complaining Parties filed their comments on 24 March 2004. The third parties' comments were due on 29 March 2004, but none were filed. The Panel also put a number of written questions to the parties. The parties provided written replies to these questions on 29 March 2004. The Panel issued its ruling to the parties and third parties on 8 April 2004.

2. The European Communities' request for a preliminary ruling

3. Article 6.2 of the DSU provides in relevant part:

> The request for the establishment of a panel shall […] identify the specific measures at issue and provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly.

4. In respect of Article 6.2 the Appellate Body observed that:

> […] compliance with the requirements of Article 6.2 must be demonstrated on the face of the request for the establishment of a panel. Defects in the request for the establishment of a panel cannot be "cured" in the subsequent submissions of the parties during the panel proceedings.[5] […] Moreover, compliance with the requirements of Article 6.2 must be determined on the merits of each case, having considered the panel request as a whole, and in the light of attendant circumstances.[6]

5. In its preliminary ruling request of 8 March 2004, the **European Communities** asserts that the Complaining Parties' panel requests fail to satisfy the requirements set out in Article 6.2 of the DSU, specifically, the requirement to identify the specific measures at issue, and the requirement to provide a brief summary of the legal basis of the complaints sufficient to present the problem clearly. According to the European Communities, the requirement to identify the specific measures at issue is not met because the Complaining Parties' panel requests speak of two distinct measures – one being the "suspension of consideration of applications/approvals" and the other being the "failure to grant approvals" – but fail to describe what these measures consist of. Regarding the requirement to provide a

summary of the legal basis of the complaints, the European Communities further asserts that the Complaining Parties' panel requests do not meet this requirement because they merely list a large number of provisions and fail to indicate which provisions are alleged to be violated by which measures. In the European Communities' view, the Panel's jurisdiction cannot, therefore, be clearly defined and the European Communities has been prevented from properly preparing its defence.

6. The **Complaining Parties** all consider that the European Communities' preliminary ruling request lacks merit and that it should, therefore, be rejected. In particular, the Complaining Parties consider that their panel requests clearly specify the specific measures in dispute. According to the Complaining Parties, what the European Communities is asking in this case is that the Panel require the Complaining Parties to identify the evidence supporting the existence of the measures identified. The Complaining Parties further consider that, contrary to what the European Communities suggests, their panel requests do provide a brief summary of the legal basis of the complaints sufficient to present the problem clearly. In the Complaining Parties' views, the European Communities' arguments in respect of the summary of the legal basis are based on a suggestion which has already been rejected by the Appellate Body, namely, that a complaining party must summarize its legal arguments in its panel request. Finally, the Complaining Parties argue that, in any event the European Communities has failed to establish its claim that its ability to defend itself has been prejudiced by the alleged lack of specificity in the Complaining Parties' panel requests.[7]

7. The **Panel** will first address the European Communities' assertion that the Complaining Parties' panel requests do not meet the requirement to identify the specific measures at issue. Thereafter, the Panel will examine the European Communities' assertion that the panel requests fail to satisfy the requirement to provide a brief summary of the legal basis of the complaints sufficient to present the problem clearly. Should the Panel find that any of the panel requests falls short of either of the two aforementioned requirements, the Panel will proceed to address the issue of the prejudice, if any, suffered by the European Communities as a result of the allegedly defective panel request(s).

3. Identification of the specific measures at issue

(a) Relevant text of the panel requests at issue

(i) The United States' panel request

8. The United States' panel request describes the relevant EC measures as follows:[8]

> Since October 1998, the European Communities ("EC") has applied a moratorium on the approval of products of agricultural biotechnology ("biotech products"). Pursuant to the moratorium, the EC has suspended consideration of applications for, or granting of, approval of biotech products under the EC approval system. In particular, the EC has blocked in the approval process under EC legislation[9] all applications for placing biotech products on the market, and has not considered any application for final approval.

The approvals moratorium has restricted imports of agricultural and food products from the United States.

In addition, EC member States maintain a number of national marketing and import bans on biotech products even though those products have already been approved by the EC for import and marketing in the EC. The national marketing and import bans have restricted imports of agricultural and food products from the United States.

The measures affecting biotech products covered in this panel request are:

(1) as described above, the suspension by the EC of consideration of applications for, or granting of, approval of biotech products;

(2) as described above, the failure by the EC to consider for approval applications for the biotech products mentioned in Annexes I and II to this request; and

(3) national marketing and import bans maintained by member States, as described in Annex III to this request.

(ii) Canada's panel request

9. Canada's panel request describes the relevant EC measures as follows:[10]

Since October 1998, the European Communities ("EC") has maintained a moratorium on the approval of products of agricultural biotechnology, which are food or food ingredients that contain or consist of, or are produced from, genetically modified organisms, and genetically modified organisms intended for release into the environment ("biotech products"). The EC effectively has suspended the consideration of applications for approval of biotech products, and the granting of approvals for those products, under the relevant EC approvals processes.[11] Specific examples of such applications, and a brief description of the actions taken to block their consideration or approval, are set out in Annex I.

In addition to the moratorium, France, Greece, Austria and Italy maintain national measures prohibiting the importation, marketing or sale of biotech products that had already been approved, prior to October 1998, under the relevant EC approvals processes, for importation, marketing or sale in the EC. These national measures, and the products to which they apply, are identified in Annex II.

[…]

> The measures covered in this panel request are:
>
> 1. the general suspension by the EC of its own processes for the consideration of applications for, and the granting of, approval for biotech products;
>
> 2. the failure by the EC to consider or approve, without undue delay, applications for approval of the products identified in Annex I; and
>
> 3. the national measures identified in Annex II prohibiting the importation, marketing or sale of the specified EC-approved biotech products.

(iii) Argentina's panel request

10. Argentina's panel request describes the relevant EC measures as follows:[12]

> The European Communities has applied a *de facto* moratorium on the approval of agricultural biotechnology products since October 1998. This *de facto* moratorium[13] has led to the suspension of and failure to consider various applications for approval of agricultural biotechnology products as well as to undue delays in finalizing the processing of applications for the approval of such products under Community legislation.[14]
>
> Furthermore, several EC member States have introduced bans on a number of agricultural biotechnology products which have already been approved at Community level, thereby infringing both WTO rules and Community legislation.
>
> This action taken by the European Communities […] adversely affects agricultural biotechnology products from Argentina.
>
> The measures at issue and in relation to which the establishment of a panel is requested are as follows:
>
> (1) Suspension of consideration of and failure to consider various applications for endorsement or approval of agricultural biotechnology products;
>
> (2) undue delays in finalizing consideration of various applications for approval of agricultural biotechnology products; and
>
> (3) bans on agricultural biotechnology products introduced by EC member States[15] which infringe both WTO rules and Community legislation.

(b) Analysis

11. The **European Communities** notes that all three panel requests make an explicit distinction between, on the one hand, an alleged "suspension" of the approval process and, on the other hand, an alleged "failure" to act. The European Communities asserts that it is "in the dark" on the meaning of the reference to an alleged "suspension" because none of three panel requests contains any explanation or description of what the alleged "suspension" is as opposed to the "failure" to proceed in the approval process.

12. The European Communities argues that if the Complaining Parties intended to use the term "suspension" to refer to the action of blocking the approval process, then that action is not described anywhere. The European Communities notes in this regard that there is no indication in the panel requests whether there is some kind of executive or normative act (e.g., moratorium legislation) pursuant to which the European Communities would have proceeded to suspend the approval process. If, on the other hand, the Complaining Parties intended to use the term "suspension" to refer to a situation where "nothing is happening", then it would seem impossible to distinguish "suspension" from the alleged inaction – the failure to consider or grant approvals. In the European Communities' view, if a Member is supposed to defend itself against two distinct measures, what these are and how they differ from each other should be specified in the panel request.

13. Based on the foregoing, the European Communities requests the Panel to find that by speaking of two distinct measures, one being the suspension of consideration of applications, or of approvals, and the other being the failure to grant approvals, without describing what these two measures consist of, the panel requests do not "identify the specific measures at issue".

14. The **Panel** notes that the three panel requests use different wording to describe the measures at issue. Therefore, the Panel will consider the three panel requests separately.

15. Before proceeding to consider the three panel requests, it is useful to recall that the requirement to "identify the specific measures at issue" has recently been addressed by the panel in *Canada – Measures Relating to Exports of Wheat and Treatment of Imported Grain*. That panel found that "the ordinary meaning of the phrase 'identify the specific measures at issue' is 'to establish the identity of the precise measures at issue'".[16] The panel then went on to state the following:[17]

> In considering whether a panel request can be said to have identified the specific, or precise, measures at issue, we find relevant the statement by the Appellate Body that whether the actual terms used in a panel request to identify the measures at issue are sufficiently precise to meet the requirements of Article 6.2 "depends […] upon whether they satisfy the purposes of [those] requirements".[18] We also find relevant the statement by the Appellate Body that "compliance with the requirements of Article 6.2 must be determined on the merits of each case, having considered the panel request as a whole, and in the light of attendant circumstances".

> […]
>
> We consider that in the absence of an explicit identification of a measure of general application by name, […] sufficient information must be provided in the request for establishment of a panel itself that effectively identifies the precise measures at issue. Whether sufficient information is provided on the face of the panel request will depend, as noted above, on whether the information provided serves the purposes of Article 6.2, and in particular its due process objective, as well as the specific circumstances of each case, including the type of measure that is at issue.

16. The Panel agrees with this analysis and, accordingly, will follow it in this case.

(i) The United States' panel request

17. The **United States** argues that the European Communities does not and cannot explain how the United States' description of the measures at issue amounts to a failure to meet the requirement of Article 6.2 "to identify the specific measures issue". According to the United States, it is difficult to see how the concept of a "suspension" of the consideration and granting of approvals is at all ambiguous. The United States considers that in the light of statements by EC officials acknowledging the existence of a *de facto* moratorium, the European Communities' claim that the meaning of "suspension" is unclear is not credible. The United States further argues that the European Communities cannot profit from its own lack of transparency by arguing that the United States has not identified the moratorium with sufficient specificity.

18. The United States also asserts that, in the context of its panel request, the reason for using the phrases "the suspension of consideration" and "the failure to consider" is quite clear. The first phrase is used to describe the European Communities' "across-the-board moratorium affecting all biotech products". The second phrase is used to describe the European Communities' conduct as it affects the specific products identified in the annexes to the panel request. According to the United States, the two phrases are "simply two different wordings for the same concept", although the word "suspension" fits better with the European Communities' conduct as it affects all biotech applications, while the phrase "failure to consider" fits better with specific applications.

19. The **Panel** begins its analysis by recalling that the first measure referred to in the United States' panel request is described as follows:

> "(1) as described above, the suspension by the EC of consideration of applications for, or granting of, approval of biotech products".

20. The noun "suspension" is defined as "the action of suspending or the condition of being suspended".[19] In turn, the verb "to suspend" is defined as "to halt temporarily".[20] It is clear from these dictionary definitions that the measure the United States is complaining about is the "temporary halting" by the European

Communities of the consideration of applications for approval of biotech products and of the granting of approval for such products.

21. The introductory paragraph of the United States' panel request provides additional information on the first measure referred to in the panel request.[21] In particular, the introductory paragraph explains that the European Communities has suspended the consideration of applications and the granting of approvals of biotech products "pursuant to" an "approvals moratorium" which the European Communities has allegedly "applied" "[s]ince October 1998". In a footnote to the introductory paragraph, the United States also identifies relevant EC approval legislation by name and place and date of publication.

22. The European Communities has pointed out that the United States' panel request refers to an "approvals moratorium" without identifying, either by name or date of adoption, any executive decree or legislative act through which the moratorium has been implemented. In response, the United States notes that the moratorium in question is a "*de facto* measure"[22]. We recall in this connection that the panel in *Canada – Wheat Exports and Grain Imports* observed that a determination of whether a panel request contains sufficient information that effectively identifies the precise measures at issue must take into account, *inter alia*, "the specific circumstances of each case, including the type of measure that is at issue".[23] The panel in *Canada – Wheat Exports and Grain Imports* distinguished between measures of general application and particular actions taken pursuant to such measures.[24] We consider that another appropriate distinction is that between formal (*de iure*) governmental measures and informal (*de facto*) governmental measures.[25] In our view, the informal nature of a governmental measure may affect the degree of precision with which such a measure can be set out in a panel request. Notably, it will often not be possible to identify informal measures by their name, date of adoption and/or legal status.

23. In the present case, it is unclear whether the United States could have identified the alleged *de facto* moratorium with more specificity than it has. The United States alleges that the European Communities has not been sufficiently transparent with respect to the alleged moratorium. The United States notably asserts that, during the consultations prior to the establishment of the Panel, the European Communities denied that the moratorium even exists although EC officials had previously acknowledged its existence in public statements.[26] As indicated above, the European Communities mentions that the panel request does not describe whether there is "supposed to be a decision or some other kind of normative or executive act, perhaps a moratorium legislation of the kind New Zealand had".[27] However, the European Communities has adduced no evidence which would support the view that the United States could have described the alleged *de facto* moratorium with greater precision. We recall in this regard that, for the purposes of this preliminary ruling, it is the European Communities as the party claiming an inconsistency with Article 6.2 which bears the burden of proof.

24. Even assuming that the United States could have provided further details on the alleged *de facto* moratorium, we consider that the description of the first measure covered in the panel request, when read together with the introductory paragraph, adequately identifies the specific measure that is being challenged. In our view, the information provided is sufficient to meet the due process objective inherent in

Article 6.2 of the DSU. In particular, the European Communities has not persuaded us that the information contained in the description of the first measure and the introductory paragraph does not allow the European Communities to "begin preparing its defence"[28] in a meaningful way.[29]

25. Before reaching a final conclusion, however, we need to consider the European Communities' argument that the reference to "suspension of consideration" in the description of the first measure covered in the United States' panel request is so similar to the reference to "failure to consider" in the description of the second measure that it is effectively impossible, in the absence of some explanation in the panel request, to know the difference between the first and second measure set out in the United States' panel request.

26. The United States submits that the phrases "suspension of consideration" in the description of the first measure and "failure to consider" in the description of the second measure are intended to express the same general idea.[30] But this does not mean that the first and second measure set out in the United States' panel request are essentially indistinguishable. As the United States has pointed out, the first measure concerns applications for approval of "biotech products", that is to say, applications for approval of any and all biotech products. In contrast, the second measure concerns applications for approval of "the biotech products mentioned in Annexes I and II to this request". Thus, it is clear to us from the descriptions of the two measures in the United States' panel request that the first measure has a broader product scope than the second measure.

27. In the light of this important difference in the description of the two measures in question, we do not agree with the European Communities that "by speaking of two distinct measures, one being the suspension of consideration of applications/of approvals, and the other being the failure to grant approvals"[31], the United States' panel request fails to identify the specific measures at issue.

28. In conclusion, we find that the European Communities has failed to establish that the United States' panel request, and in particular the reference to an alleged "suspension" of the approval processes, does not satisfy the requirement in Article 6.2 to identify the specific measures at issue.

(ii) Canada's panel request

29. **Canada** argues that the phrase "the general suspension by the EC of its own processes for consideration of applications for, and the granting of, approval of biotech products" sufficiently identifies the specific measure at issue. Canada submits that the aforementioned phrase is a more detailed description of the moratorium referred to in the introductory paragraph of Canada's panel request.[32] Canada further points out that, in Annex I, its panel request sets out specific examples of applications for approval of biotech products, including a brief description of the actions taken to block their consideration or approval. According to Canada, the repeated failures by the European Communities to consider or approve these applications are examples of the moratorium. Canada also notes that the moratorium has not been formally adopted. Canada submits that if the European Communities had adopted the moratorium as a formal measure and complied with various transparency requirements of the *WTO Agreement*, Canada would have been in a

position to identify the moratorium by name, date of adoption, etc. Canada argues that the European Communities cannot use its own lack of regulatory transparency as a shield against a WTO challenge. Canada observes, finally, that it is in any event difficult to understand that the European Communities is unable to identify the measure at issue. According to Canada, the existence of the moratorium has been widely recognized and discussed by EC officials.

30. Canada further submits that the phrases "the general suspension" and "the failure to consider or approve" are used to describe different aspects of the European Communities' conduct. Canada notes in this regard that the phrase "general suspension" is used to describe the European Communities' conduct in relation to the whole class of biotech products, while the phrase "failure to consider or approve" is used to describe the European Communities' conduct as it affects the four specific products identified in Annex I to the panel request.

31. The **Panel** recalls that the first measure referred to in Canada's panel request is described as follows:

> "1. the general suspension by the EC of its own processes for consideration of applications for, and the granting of, approval of biotech products".

32. As noted above[33], it is clear from the dictionary meanings of the word "suspension" that the measure Canada is complaining about is the general "temporary halting" by the European Communities of its own processes for the consideration of applications for approval of biotech products and for the granting of approval for such products.

33. The introductory paragraph of Canada's panel request provides additional information on the first measure referred to in the panel request. In particular, the introductory paragraph explains that "[s]ince October 1998", the European Communities has "maintained" a "moratorium" on the approval of biotech products and that the European Communities has "effectively" suspended the consideration of applications and the granting of approvals of biotech products under the relevant EC approval processes. In a footnote to the introductory paragraph, Canada identifies by name and place and date of publication EC legislation which sets out the relevant approval processes.

34. The European Communities has pointed out that Canada's panel request refers to a "moratorium" without identifying, either by name or date of adoption, any executive decree or legislative act through which the moratorium has been implemented. Canada notes in this regard that the moratorium has not been adopted as a formal legal measure. As we have noted above[34], in our view, the informal nature of a governmental measure may affect the degree of precision with which such a measure can be set out in a panel request. In the present case, it is unclear whether Canada could have identified the alleged *de facto* moratorium with more specificity than it has. Canada argues in this respect that the European Communities should not be allowed to profit from its own lack of regulatory transparency. In addition, Canada asserts that the existence of the moratorium has been recognized by EC officials in public statements.[35] As indicated above[36], the European Communities has

adduced no evidence which would support the view that Canada could have described the alleged *de facto* moratorium with greater precision.

35. Even assuming that Canada could have provided further details on the alleged *de facto* moratorium, we consider that the description of the first measure covered in the panel request, when read together with the introductory paragraph, adequately identifies the specific measure that is being challenged. In our view, the information provided is sufficient to meet the due process objective inherent in Article 6.2 of the DSU. In particular, the European Communities has not persuaded us that the information contained in the description of the first measure and the introductory paragraph does not allow the European Communities to "begin preparing its defence"[37] in a meaningful way.[38]

36. Before reaching a final conclusion, however, we need to consider the European Communities' argument that the reference to "the general suspension" in the description of the first measure covered in Canada's panel request is so similar to the reference to "the failure to consider or approve" in the description of the second measure that it is effectively impossible, in the absence of some explanation in the panel request, to know the difference between the first and second measure set out in Canada's panel request.

37. We note Canada's explanation that the references to "the general suspension" in the description of the first measure and to "the failure to consider or approve" in the description of the second measure reflect the fact that the two measures concern different aspects of the European Communities' conduct. According to Canada, the reference to "the general suspension" is used because the first measure concerns applications for approval for "biotech products". In other words, as Canada puts it, the first measure concerns the European Communities' conduct in relation to the whole class of biotech products. Regarding the reference to "the failure to consider or approve", Canada notes that it was used because the second measure concerns the European Communities' conduct in relation to specific applications for approval of the four biotech products "identified in Annex I". In our view, Canada's explanation is consistent with a natural reading of the descriptions in question. That the first measure has a broader product scope than the second measure is further confirmed by the fact that Canada refers to the general suspension by the European Communities of "its own processes" for the consideration of applications for, and the granting of, approval of biotech products. The approval processes in question would appear to apply to all qualifying biotech products, not just the four identified in the annex to Canada's panel request.

38. In the light of this important difference in the description of the two measures in question, we do not agree with the European Communities that "by speaking of two distinct measures, one being the suspension of consideration of applications/of approvals, and the other being the failure to grant approvals"[39], Canada's panel request fails to identify the specific measures at issue.

39. In conclusion, we find that the European Communities has failed to establish that Canada's panel request, and in particular the reference to an alleged "general suspension" of the approval processes, does not satisfy the requirement in Article 6.2 to identify the specific measures at issue.

(iii) Argentina's panel request

40. **Argentina** argues that the word "suspension" can be easily understood by reading the relevant paragraph, which links the word suspension to the phrase "various applications for approval of agricultural biotechnology products". Argentina submits that it is clear that the measure at issue is the *de facto* suspension of consideration of various applications within the pipeline defined by the EC regulatory scheme. Argentina further notes that the second paragraph of its panel request makes clear that the action which led to the suspension of consideration of various applications is the *de facto* moratorium applied by the European Communities. According to Argentina, the type of measure at issue necessarily affects the extent and nature of information required to present a claim. Argentina recalls in this respect the informal nature of the EC moratorium which, Argentina says, is not contained in a particular legal act or executive order.

41. Regarding the distinction between the phrases "suspension of consideration" and "failure to consider", Argentina notes that "suspension of consideration" describes a situation where applications have been considered but where the consideration is suffering a delay, whereas "failure to consider" describes a situation where applications were submitted but there is a failure to consider them. Argentina points out that the status of various applications within the EC regulatory scheme is an issue that was discussed at length during consultations with the European Communities.

42. The **Panel** recalls that the first measure referred to in Argentina's panel request is described as follows:

> (1) Suspension of consideration of and failure to consider various applications for endorsement or approval of agricultural biotechnology products.

43. As noted above[40], it is clear from the dictionary meanings of the word "suspension" that what Argentina is complaining about is the "temporary halting" by the European Communities of the consideration of various applications for endorsement or approval of biotech products.

44. The second paragraph of Argentina's panel request provides additional information on the first measure referred to in the panel request.[41] In particular, the second paragraph explains that "[s]ince October 1998", the European Communities has "applied" a "*de facto* moratorium"[42] on the approval of biotech products, which has "led to the suspension of and failure to consider various applications for approval [...] under Community legislation". In a footnote to the second paragraph, Argentina also identifies relevant EC legislation by name and place and date of publication.

45. The European Communities has pointed out that Argentina's panel request refers to a "moratorium" without identifying, either by name or date of adoption, any executive decree or legislative act through which the moratorium has been implemented. Argentina responds that the nature of the measure in question, which in this case is a *de facto* measure, necessarily affects the extent and nature of the information that needs to be provided. As we have noted above[43], in our view, the informal nature of a governmental measure may affect the degree of precision with

which such a measure can be set out in a panel request. In the present case, it is unclear whether Argentina could have identified the alleged *de facto* moratorium with more specificity than it has. Argentina suggests that the Panel should resist what it considers is an effort by the European Communities to obtain a detailed factual description of the alleged moratorium. In Argentina's view, it is not necessary to provide a detailed factual description in a panel request, since this is a matter to be dealt with in the course of the panel proceedings. As indicated above[44], the European Communities has adduced no evidence which would support the view that Argentina could have described the alleged *de facto* moratorium with greater precision.

46. Even assuming that Argentina could have provided further details on the alleged *de facto* moratorium, we consider that the description of the first measure covered in the panel request, when read together with the second paragraph, adequately identifies the specific measure that is being challenged. In our view, the information provided is sufficient to meet the due process objective inherent in Article 6.2 of the DSU. In particular, the European Communities has not persuaded us that the information contained in the description of the first measure and the second paragraph does not allow the European Communities to "begin preparing its defence"[45] in a meaningful way.[46]

47. Before reaching a final conclusion, however, we need to consider the European Communities' argument that the reference to "suspension of consideration" in Argentina's description of the first measure is so similar to the reference to "failure to consider" in the description of the same measure that it is effectively impossible, in the absence of some explanation in the panel request, to know the difference between these two aspects.

48. We note Argentina's explanation that the references to "suspension of consideration" and to "failure to consider" reflect the fact that various applications for approval have been affected by the *de facto* moratorium at different stages of the approval process. According to Argentina, some applications were considered and then the consideration was suspended, while others were submitted for consideration, but were not in fact considered. We have no difficulty accepting Argentina's explanation. We think Argentina's explanation is consistent with the ordinary meaning of the phrases "suspension of consideration" and "failure to consider"[47], and we do not, therefore, consider that it was necessary for Argentina's panel request to provide further explanation in this regard.

49. In the light of this, we do not agree with the European Communities that "by speaking of two distinct measures, one being the suspension of consideration of applications/of approvals, and the other being the failure to grant approvals"[48], Argentina's panel request does not properly identify the specific measures at issue.

50. In conclusion, we find that the European Communities has failed to establish that Argentina's panel request, and in particular the reference to an alleged "suspension" of the approval processes, does not satisfy the requirement in Article 6.2 to identify the specific measures at issue.

4. Provision of a brief summary of the legal basis of the complaint sufficient to present the problem clearly

51. The Panel next turns to examine the European Communities' assertion that the Complaining Parties' panel requests do not provide a brief summary of the legal basis of the complaints sufficient to present the problem clearly.

(a) Relevant text of the panel requests at issue

(i) The United States' panel request

52. The United States' panel request summarizes the legal basis of the United States' complaint as follows:[49]

> These measures appear to be inconsistent with the following provisions of the *Agreement on the Application of Sanitary and Phytosanitary Measures* ("SPS Agreement"), the *General Agreement on Tariffs and Trade 1994* ("GATT 1994"), the *Agreement on Agriculture* ("Agriculture Agreement"), and the *Agreement on Technical Barriers to Trade* ("TBT Agreement"):
>
> (1) SPS Agreement, Articles 2.2, 2.3, 5.1, 5.2, 5.5, 5.6, 7 and 8, and Annexes B(1), B(2), B(5), C(1)(a), C(1)(b), and C(1)(e);
>
> (2) GATT 1994, Articles I:1, III:4, X:1, and XI:1;
>
> (3) Agriculture Agreement, Article 4.2; and
>
> (4) TBT Agreement, Articles 2.1, 2.2, 2.8, 2.9, 2.11, 2.12, 5.1.1, 5.1.2, 5.2.1, 5.2.2, 5.6 and 5.8.
>
> The EC's measures also appear to nullify or impair the benefits accruing to the United States directly or indirectly under the cited agreements.

(ii) Canada's panel request

53. Canada's panel request summarizes the legal basis of Canada's complaint as follows:[50]

> These measures are inconsistent with the obligations of the EC under the SPS Agreement, the TBT Agreement, the Agreement on Agriculture and the GATT 1994. In particular, the measures violate the following provisions of these agreements:
>
> - Articles 2.2, 2.3, 5.1, 5.2, 5.5, 5.6, 7, 8, and paragraphs 1, 2 and 5 of Annex B, and paragraphs 1(a), 1(b), 1(c), and 1(e) of Annex C of the SPS Agreement;

- Articles 2.1, 2.2, 2.8, 2.9, 2.11, 2.12, 5.1, 5.2.1, 5.2.2, 5.2.3, 5.6 and 5.8 of the TBT Agreement;

- Articles I:1, III:4, X:1 and XI:1 of the GATT 1994;

- Article 4.2 of the Agreement on Agriculture.

These violations nullify or impair the benefits accruing to Canada under these agreements. In addition, the measures nullify and impair the benefits accruing to Canada in the sense of Article XXIII:1(b) of the GATT 1994.

(iii) Argentina's panel request

54. Argentina's panel request summarizes the legal basis of Argentina's complaint as follows:[51]

> The measures in question taken by the European Communities and several of its member States infringe the following provisions of the WTO Agreements:
>
> (a) Articles 2.2, 2.3, 5.1, 5.2, 5.5, 5.6, 7, 8 and 10.1 and Annexes B(1) and (5) and C(1)(a), (b), (c), (d) and (e) of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement);
>
> (b) Article 4.2 of the Agreement on Agriculture (AoA);
>
> (c) Articles I.1, III.4, X.1, X.3(a) and XI.1 of the GATT 1994;
>
> (d) Articles 2.1, 2.2, 2.8, 2.9, 2.11, 5.1, 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.6, 5.8 and 12 of the Agreement on Technical Barriers to Trade (TBT Agreement).
>
> The measures at issue nullify or impair the benefits accruing to Argentina under these Agreements.

(b) Analysis

55. The **European Communities** asserts that none of the Complaining Parties' panel requests provides a brief summary of the legal basis of the complaints sufficient to present the problem clearly. Specifically, the three panel requests do not make it clear (1) which obligations are alleged to be violated and (2) which measures are in violation of which obligations.

56. The **Panel** will address the two issues identified by the European Communities separately.

57. Before going further, it is useful briefly to set out relevant Appellate Body jurisprudence. Thus, in *Thailand – H-Beams*, the Appellate Body observed that:[52]

> Article 6.2 of the DSU calls for sufficient clarity with respect to the legal basis of the complaint, that is, with respect to the "claims" that are being asserted by the complaining party.[53] A defending party is entitled to know what case it has to answer, and what violations have been alleged so that it can begin preparing its defence.[54] Likewise, those Members of the WTO who intend to participate as third parties in panel proceedings must be informed of the legal basis of the complaint. This requirement of due process is fundamental to ensuring a fair and orderly conduct of dispute settlement proceedings.

58. In Korea – Definitive Safeguard Measure on Imports of Certain Dairy Products, the Appellate Body stated that:[55]

> Identification of the treaty provisions claimed to have been violated by the respondent is always necessary both for purposes of defining the terms of reference of a panel and for informing the respondent and the third parties of the claims made by the complainant; such identification is a minimum prerequisite if the legal basis of the complaint is to be presented at all.[56] But it may not always be enough. There may be situations where the simple listing of the articles of the agreement or agreements involved may, in the light of attendant circumstances, suffice to meet the standard of *clarity* in the statement of the legal basis of the complaint. However, there may also be situations in which the circumstances are such that the mere listing of treaty articles would not satisfy the standard of Article 6.2. This may be the case, for instance, where the articles listed establish not one single, distinct obligation, but rather multiple obligations. In such a situation, the listing of articles of an agreement, in and of itself, may fall short of the standard of Article 6.2.

59. Finally, in *US – Carbon Steel*, the Appellate Body clarified that:[57]

> […] whether […] a listing [of the treaty provisions allegedly violated] is *sufficient* to constitute a "brief summary of the legal basis of the complaint sufficient to present the problem clearly" within the meaning of Article 6.2 will depend on the circumstances of each case, and in particular on the extent to which mere reference to a treaty provision sheds light on the nature of the obligation at issue.[58]

(i) Listing of provisions

60. The **European Communities** asserts that the mere listing of treaty provisions is not sufficient in this case. The European Communities notes in this regard that several of the treaty provisions identified in the panel requests contain multiple obligations. Specifically, the European Communities refers to Articles 2.2, 2.3, 5.5, 7, 8, Annex B(5) and Annex C(1)(b) of the *SPS Agreement* as well as Articles 2.9, 5.2.2, 5.6 and 12 of the *TBT Agreement*. The European Communities submits that the mere listing of the aforementioned provisions makes it impossible to know the obligations that are alleged to have been violated.

61. The European Communities further notes that several of the provisions listed are either mutually exclusive (such as those contained in the *SPS Agreement* and in the *TBT Agreement*) or subordinated (such as those of the GATT 1994 in relation to the ones contained in the other WTO agreements at issue). The European Communities notes that the panel requests do not explain how the claims would be articulated. For instance, they do not explain whether all provisions apply simultaneously to different aspects of the measures, or whether some are listed only subsidiarily.

62. The **United States** notes that it has applied the following method in citing provisions. Where an article consisted of more than one paragraph, the paragraph has been identified. Where an article has sub-paragraphs, in most cases, sub-paragraphs have been identified. The United States notes that there are three exceptions, namely, Annex B(5) of the *SPS Agreement* and Articles 2.9 and 5.6 of the *TBT Agreement*. According to the United States, these three exceptions contain several sub-paragraphs establishing related transparency obligations. The United States did not identify specific sub-paragraphs because it considers that the EC measures at issue are inconsistent with each of the sub-paragraphs.

63. The United States also notes that it was required to cite provisions of the *SPS Agreement* and the *TBT Agreement* because the European Communities has refused to acknowledge that the alleged moratorium falls within the scope of the *SPS Agreement*. According to the United States, it is difficult to understand, therefore, how the European Communities could claim any confusion or prejudice from citing provisions of both agreements.

64. **Canada** argues that the it has adequately identified the obligations at issue. Canada notes that it has applied the following method in citing provisions in its panel request. Where a provision contains more than one discrete obligation, Canada listed the specific obligation that it believes has been violated by referring to the paragraph or sub-paragraph in the article pertaining to the violated obligation. Canada notes that there are two exceptions to this rule. *First*, where a provision contains more than one obligation and Canada considers that the measures at issue are inconsistent with all of them, Canada did not specify sub-paragraphs, but cited the provision as a whole. *Second*, in the case of Article 5.5 of the *SPS Agreement*, Canada argues that it is clear that Canada did not mean to challenge the European Communities with respect to its obligation to cooperate in the development of guidelines to further the implementation of Article 5.5.

65. Canada further notes that neither the DSU nor WTO jurisprudence suggest that in cases where a large number of provisions are listed more details need to be provided regarding the obligations at issue than in cases where few provisions are listed.

66. **Argentina** notes that its panel request is much more precise than its consultation request and argues that the panel request sufficiently details, at the paragraph or sub-paragraph level, the obligations at issue. Argentina also recalls that there are panels which have accepted the citation of general provisions only, without requiring specifications of paragraphs. Argentina further argues that not all of the provisions referred to by the European Communities set forth different obligations. According to Argentina, some of these provisions, such as Article 2.2 of the

SPS Agreement, rather set forth different conditions that must be met to fulfil one obligation.

Listing of provisions containing multiple obligations

67. The **Panel** notes that with one exception – Article 12 of the *TBT Agreement*, which is referred to only by Argentina – the panel requests cite the relevant provisions not just at the article level, but at the paragraph level. In some cases, the provisions are cited at the sub-paragraph level. The European Communities nevertheless considers that, in some specified instances, this falls short of the requirement in Article 6.2 to provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly. More specifically, the European Communities considers that the following references in the Complaining Parties' panel requests are insufficient:[59]

- Articles 2.2, 2.3, 5.5, 7, 8, Annex B(5) and Annex C(1)(b) of the *SPS Agreement*; and

- Articles 2.9, 5.2.2, 5.6 and 12 of the *TBT Agreement.*

68. We find it convenient, for analytical purposes, to place the aforementioned provisions into two categories. The *first* category encompasses Annex B(5) of the *SPS Agreement* and Articles 2.9, 5.6 and 12 of the *TBT Agreement*. The structure of these provisions would, in principle, have allowed for a more precise citation than the Complaining Parties chose to adopt. For instance, Article 2.9 of the *TBT Agreement* contains four sub-paragraphs, yet the Complaining Parties did not specify any of the sub-paragraphs in their panel requests. The *second* category encompasses Articles 2.2, 2.3, 5.5, 7, 8 and Annex C(1)(b) of the *SPS Agreement* and Article 5.2.2 of the *TBT Agreement*. These provisions contain two or more distinct obligations under a single article, paragraph or sub-paragraph number. But these particular provisions do not contain any paragraphs (Articles 7 and 8 of the *SPS Agreement*), sub-paragraphs (Articles 2.2, 2.3 and 5.5 of the *SPS Agreement*) or further sub-division (Annex C(1)(b) of the *SPS Agreement* and Article 5.2.2 of the *TBT Agreement*).

69. We will now analyse the two above-mentioned categories separately.

(a) Annex B(5) of the SPS Agreement and Articles 2.9, 5.6 and 12 of the TBT Agreement

70. In examining the first category of provisions, we note as an initial matter that we do not understand the Appellate Body report in *Korea – Dairy* to have established that the identification of particular paragraph numbers would, *ipso facto*, be sufficient to constitute a "brief summary of the legal basis of the complaint sufficient to present the problem clearly" within the meaning of Article 6.2. In our view, whether specification of particular paragraph numbers is sufficient, will depend on the circumstances of each case, and in particular on the extent to which specification of particular paragraph numbers sheds light on the nature of the obligation at issue.[60]

71. It is useful to examine Annex B(5) of the *SPS Agreement* and Articles 2.9 and 5.6 of the *TBT Agreement* together. They all contain four sub-paragraphs which establish separate obligations. The United States and Canada have confirmed that in

their respective panel requests they did not identify particular sub-paragraphs because they consider that the specific measures at issue are inconsistent with each of the four sub-paragraphs.[61] The United States and Canada argue that this is consistent with their overall approach to the listing of provisions in their panel requests. Essentially, the United States and Canada argue that they have generally cited provisions as precisely as their structure allowed, i.e., at the paragraph or sub-paragraph level, except in cases such as Annex B(5) of the *SPS Agreement* where they wished to allege a violation of all sub-paragraphs. A review of the provisions listed in the United States' and Canada's panel requests supports this interpretation.[62] We therefore accept that, in the specific context of the United States' and Canada's panel requests, the references to Annex B(5) of the *SPS Agreement* and Articles 2.9 and 5.6 of the *TBT Agreement* are sufficient, as such, to give notice to the European Communities that violations are being alleged of each of the sub-paragraphs of these provisions. In reaching this conclusion, we also attach importance to two additional circumstances. *Firstly*, we note that the provisions in question set forth "notice and comment" obligations which, by definition, are interrelated. *Secondly*, we note that none of the sub-paragraphs of the provisions in question appears to be obviously irrelevant to the complaints at hand.

72. Unlike the United States and Canada, Argentina has not explicitly indicated whether it considers the specific measures at issue to be inconsistent with each of the four sub-paragraphs of Annex B(5) of the *SPS Agreement* and Articles 2.9 and 5.6 of the *TBT Agreement*. Argentina has merely said that it has identified the relevant paragraph numbers in its panel request and that there is no requirement to go further and identify sub-paragraph numbers as well.[63] As we have noted above, we do not think that identification of paragraph numbers is automatically sufficient to meet the minimum requirements of Article 6.2. We also note, however, that in *Thailand – H-Beams*, the Appellate Body made the following statement:[64]

> With respect to Article 5 [of the *Anti-Dumping Agreement*], Poland stated that "Thai authorities initiated and conducted this investigation in violation of the procedural ... requirements of Article VI of GATT 1994 and Article 5 ... of the Antidumping Agreement". Article 5 sets out various but closely related procedural steps that investigating authorities must comply with in initiating and conducting an anti-dumping investigation. In view of the interlinked nature of the obligations in Article 5, we are of the view that, in the facts and circumstances of this case, Poland's reference to "the procedural ... requirements" of Article 5 was sufficient to meet the minimum requirements of Article 6.2 of the DSU.[65]

73. In our view, like the procedural obligations in Article 5 of the *Anti-Dumping Agreement*, the "notice and comment" obligations contained in Annex B(5) of the *SPS Agreement* and Articles 2.9 and 5.6 of the *TBT Agreement* are "closely related" and "interlinked". For example, sub-paragraph (d) of Annex B(5) of *SPS Agreement* requires Members to allow a reasonable time for other Members to make comments in writing on a proposed regulation. If this proposed regulation has not been published at an early stage, as required in sub-paragraph (a) of Annex B(5) and brought to the attention of other Members through the notification required in sub-paragraph (b) of Annex B(5), and copies provided upon request as established in sub-paragraph (c) of Annex B(5), it is difficult to imagine how an interested Member

would gain sufficient knowledge of the content fo the proposed regulation to be able to avail itself of the opportunity to submit comments as foreseen in sub-paragraph (d) of Annex B(5). Therefore, we consider that the fact that Argentina's panel request identifies the relevant article and paragraph numbers sheds sufficient light on "the nature of the obligation at issue"[66] to meet the minimum requirements of Article 6.2.

74. We now turn to Article 12 of the *TBT Agreement*, which is listed only in Argentina's panel request. Article 12 is entitled "Special and Differential Treatment of Developing Country Members". It contains ten separate paragraphs. Nevertheless, in response to a question by the Panel, Argentina asserted that Article 12 does not contain multiple obligations, but rather a single obligation to provide differential and more favourable treatment to developing country Members "through several requirements that should be fulfilled"[67]. In support of this view, Argentina points to Article 12.1, which states that "Members shall provide differential and more favourable treatment to developing country Members [...] through the following provisions as well as through the relevant provisions of other Articles of this Agreement".

75. We do not consider that the text of Article 12.1 supports Argentina's view that Article 12 contains a single obligation as opposed to a number of separate obligations. For instance, Article 12.3 requires that in preparing and applying technical regulations, standards and conformity assessment procedures, Members take account of the special needs of developing country Members. This obligation is clearly very different from the obligation set forth in Article 12.10, which requires the Committee on Technical Barriers to Trade to examine periodically the special and differential treatment granted to developing country Members on national and international levels, for instance.

76. Argentina's panel request refers to Article 12, but does not specify particular paragraph numbers. We recall that the Appellate Body has made it quite clear that it is important for panel requests to be precise in identifying the legal basis of the relevant complaint.[68] We have asked Argentina to indicate why it referred to Article 12 without specifying any paragraph numbers. Argentina replied that this is because during the consultations the European Communities failed to answer a question by Argentina "related to the general obligation embodied in Article 12 [...] regarding the behaviour due by the EC to Argentina in the treatment and approval of agricultural biotech products"[69]. We acknowledge that failure by a responding party to co-operate promptly may affect the clarity with which a complaining party can set out its claims in a panel request.[70] However, Argentina has adduced no evidence which would enable us to determine whether the European Communities failed to answer Argentina's question. Nor is it clear to us from Argentina's reply precisely how the alleged lack of co-operation by the European Communities affected the precision with which Argentina identified the obligations at issue.

77. We note that the European Communities recognizes that of the various obligations set out in Article 12, four are potentially relevant to Argentina's complaint.[71] In our view, the potentially relevant obligations are those contained in Articles 12.1, 12.2, 12.3 and 12.7.[72] Article 12.1 is relevant whenever there is a violation of one of the other provisions of Article 12, such as Articles 12.2, 12.3 or 12.7. Article 12.3 is a specific application of the obligation in Article 12.2 to take account of developing country needs in the implementation of the *TBT Agreement* at

the national level. As regards Article 12.7, however, it becomes clear, upon closer inspection, that that provision cannot reasonably be considered to be applicable in this dispute. Article 12.7 requires the European Communities to provide technical assistance to developing country Members. But Argentina's panel request does not challenge the European Communities with respect to a failure to provide technical assistance. The request only refers to an alleged failure by the European Communities to consider applications for approval of biotech products. In the light of the above elements, and in particular the fact that Articles 12.4 to 12.10 are not applicable in this dispute, the above-noted substantive similarity between Articles 12.2 and 12.3 and the fact that Article 12.1 incorporates the obligations set out in Articles 12.2 and 12.3 by reference, we consider that Argentina's reference to Article 12 sheds sufficient light on "the nature of the obligation at issue"[73] to allow the European Communities to begin preparing its defence. We, therefore, find that, in the specific circumstances of this case, the reference to Article 12 is sufficient to meet the minimum requirements of Article 6.2.

(b) Articles 2.2, 2.3, 5.5, 7, 8 and Annex C(1)(b) of the SPS Agreement and Article 5.2.2 of the TBT Agreement

78. We now address the second category of provisions. It will be recalled that this category consists of provisions which contain two or more distinct obligations under a single article, paragraph or sub-paragraph number, but which do not contain any paragraphs, sub-paragraphs or further sub-division. Argentina argues, without much elaboration, that, in such cases, there is no requirement to identify specific clauses or sub-clauses within an article, paragraph or sub-paragraph. The United States notes in this regard that it is unaware of any panel or Appellate Body report faulting a panel request for not citing to specific clauses or sub-clauses within an article, paragraph or sub-paragraph.

79. We do not consider that, for the purposes of an Article 6.2 inquiry, the structure of the provisions contained in the WTO agreements constitutes some kind of "safe haven", such that it would always be sufficient to specify sub-paragraph numbers in cases where a provision has several sub-paragraphs, etc. In our view, whether a particular manner of citing provisions is sufficient will depend on the circumstances of each case, and in particular on the extent to which the particular citation sheds light on the nature of the obligation at issue. Having said this, we think that the fact that two or more distinct obligations are set out, e.g., in one and the same sub-paragraph may provide a strong indication that those obligations are very similar in nature. In such cases, specification of the relevant sub-paragraph number may shed sufficient light on the nature of the obligation at issue to meet the minimum standard of precision required under Article 6.2.

80. In the present case, the European Communities has identified a number of provisions where it considers that citation in keeping with the maximum level of precision envisaged in the structure of the relevant agreement is not sufficient. In view of this assertion, we find it appropriate to do a provision-by-provision analysis.

81. We begin our analysis with Annex C(1)(b) of the *SPS Agreement* and Article 5.2.2 of the *TBT Agreement*. We analyse these provisions together, since they have almost identical wording. Both provisions contain a number of sub-clauses which set out certain procedural obligations that Members must observe in the

operation of approval or conformity assessment procedures. The United States and Canada argue that in their respective panel requests they did not identify particular sub-clauses because they consider that the specific measures at issue are inconsistent with each of the sub-clauses of the provisions in question.[74] Argentina has not explicitly indicated whether it considers the specific measures at issue to be inconsistent with each of the sub-clauses of Annex C(1)(b) and Article 5.2.2. Argentina has merely said that it has identified the relevant paragraph numbers in its panel request and that there is no requirement to go further and identify particular sub-clauses as well.[75] In our view, in much the same way as the "notice and comment" obligations contained in Annex B(5) of the *SPS Agreement* and Articles 2.9 and 5.6 of the *TBT Agreement*, the various procedural obligations set out in Annex C(1)(b) and Article 5.2.2 are closely related and interlinked. Therefore, we consider that the fact that the Complaining Parties' panel requests identify the relevant article and paragraph numbers sheds sufficient light on "the nature of the obligation at issue"[76] to meet the minimum requirements of Article 6.2.

82. Article 2.2 of the *SPS Agreement* appears to set out three different "basic" obligations: (1) that SPS measures must be applied only "to the extent necessary" to protect life or health, (2) that they must be "based on scientific principles" and (3) that they must not be "maintained without sufficient scientific evidence". The three obligations contained in Article 2.2 are further spelt out and applied in different provisions of the *SPS Agreement*, namely, Articles 5.1, 5.2 and 5.6.[77] We note that all Complaining Parties have listed Articles 5.1, 5.2 and 5.6 in their panel requests as separate legal bases. In the light of this, we consider that it is sufficiently clear from the Complaining Parties' panel requests that each of the obligations contained in Article 2.2 is at issue in the three complaints. Accordingly, we find that, in the circumstances of this case, referring to Article 2.2 is sufficient to meet the minimum requirements of Article 6.2.

83. Article 2.3 of the *SPS Agreement* stipulates that SPS measures must not arbitrarily or unjustifiably discriminate between Members and that they must not be used in a manner which would constitute a disguised restriction on trade. In addressing the sufficiency of a listing of Article 2.3, we find relevant the fact that all Complaining Parties have also listed Articles I:1, III:4 and XI:1 of the GATT 1994 as legal bases of their complaints. Articles I:1 and III:4 of the GATT 1994 prohibit certain forms of discrimination against foreign products, whereas Article XI:1 of the GATT 1994 prohibits quantitative import restrictions. We think it can be inferred from the references to these GATT 1994 provisions that both obligations set out in Article 2.3 – i.e., the obligation to avoid arbitrary or unjustifiable discrimination and the obligation not to apply SPS measures in a manner which would constitute a disguised restriction on trade – are at issue in the three complaints. We therefore find that, in the circumstances of this case, referring to Article 2.3 is sufficient to meet the minimum requirements of Article 6.2.

84. Article 5.5 of the *SPS Agreement* obligates Members (1) to avoid arbitrary or unjustifiable distinctions in the levels of sanitary or phytosanitary protection which they consider to be appropriate in different situations and (2) to co-operate in the Committee on Sanitary and Phytosanitary Measures to develop guidelines to further the practical implementation of that article. None of the three panel requests suggests that the European Communities is being challenged in respect of a failure to co-operate with a view to developing certain guidelines. Indeed, as noted by Canada,

Members have already discharged their collective obligation to develop appropriate guidelines.[78] Thus, it is clear that the obligation at issue in the three panel requests is the obligation to avoid arbitrary or unjustifiable distinctions in the levels of sanitary or phytosanitary protection. Therefore, we consider that the reference in the Complaining Parties' panel requests to Article 5.5 is sufficient to meet the minimum requirements of Article 6.2.

85. Article 7 of the *SPS Agreement* imposes an obligation on Members to notify changes in SPS measures and to provide information on SPS measures in accordance with the provisions of Annex B of the *SPS Agreement*. Regarding the obligation to "provide information" on SPS measures, we note that the Complaining Parties have specified in their panel requests which particular provisions of Annex B they consider to have been violated. We therefore think it is clear that the reference to Article 7 cannot be taken as an indication that the Complaining Parties are alleging violations of *all* provisions of Annex B. Regarding the obligation to "notify changes" in SPS measures, we note that it is not necessary, for the purposes of our preliminary ruling, to determine whether that obligation is, or is not, further elaborated in Annex B. We consider that that obligation is very similar in nature to the other obligation set out in Article 7, that is to say, the obligation to "provide information" on SPS measures in accordance with Annex B. As a result, it is our view that the reference in the Complaining Parties' panel requests to Article 7 sheds sufficient light on "the nature of the obligation at issue"[79] to meet the minimum requirements of Article 6.2.

86. Article 8 of the *SPS Agreement* requires Members to observe the provisions of Annex C in the operation of control, inspection and approval procedures and to otherwise ensure that their procedures are not inconsistent with the *SPS Agreement*. Here, too, it seems clear that the Complaining Parties cannot be understood to allege violations of *all* provisions of Annex C, given that they have specified particular provisions of Annex C which they consider to have been violated. Regarding the obligation to "otherwise ensure" compliance with the *SPS Agreement*, we consider that in view of the very similar nature of this obligation and the obligation to observe the provisions of Annex C, the reference in the Complaining Parties' panel requests to Article 7 is sufficient to meet the minimum requirements of Article 6.2.

Listing of provisions which are mutually exclusive or subject to other provisions

87. We note that another concern expressed by the European Communities relates to the fact that the Complaining Parties' panel requests list certain provisions which are mutually exclusive (such as those contained in the *SPS Agreement* and in the *TBT Agreement*) or otherwise in a clearly defined relationship with one another (such as the provisions of the GATT 1994 in relation to the provisions contained in the other WTO agreements at issue). According to the European Communities, it is unclear, due to the mere listing of these provisions, whether these provisions are alleged to apply to different aspects of the same measure, or whether some of these provisions are alleged to apply only if the Panel determines that other listed provisions are not applicable.

88. We recall that in accordance with Article 6.2 a panel request is to provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly. Thus, the requirement is to state clearly what is the alleged legal basis of a complaint.[80] Neither the text of Article 6.2 nor relevant jurisprudence suggests that a

complaining party needs to explain, in the panel request, the reasons for identifying particular treaty provisions. Such explanation is to be provided through arguments to be developed in the complaining party's written submissions and oral statements.[81] Accordingly, we do not consider that the Complaining Parties' panel requests are defective because they do not explain why certain provisions are listed even though they may be mutually exclusive or may apply subject to other provisions. Nor do we consider that the panel requests are defective because they do not make it clear whether all of the provisions listed are alleged to apply to the same aspect of a particular measure, or whether some provisions are alleged to apply to different aspects of the same measure. It is sufficient to recall in this regard that a panel request need not set out arguments "as to which specific aspects of the measures at issue relate to which specific provisions of [the] agreements [alleged to have been violated]"[82].

(ii) Indication of which measures violate which provisions

89. The **European Communities** argues that where a panel request covers several measures, it should indicate which provisions may be relevant for the examination of each measure, possibly describing the substantive aspects or the effects of the measures which are allegedly in breach of those provisions. The European Communities argues that the panel requests do not provide the slightest explanation in this regard. According to the European Communities, it is completely in the dark about which provisions are alleged to have been violated by which measures.

90. The European Communities further asserts that the fact that over sixty obligations have been listed means that, in total, there could be more than three thousand possible claims in respect of which the European Communities might have to prepare a defence. The European Communities considers that it has a right to know what case it will have to defend. In the European Communities' view, the panel request must contain the necessary information.

91. The **United States** argues that its panel request clearly alleges that each of the listed EC measures violates each of the provisions cited in the panel request. According to the United States, the language used – "These measures appear to be inconsistent with the following provisions […]" – is clear in tying the covered measures to the claimed violations.

92. The United States further argues that the European Communities overstates the number of obligations covered in the United States' panel request. The United States also contends that Article 6.2 does not impose an entirely different standard on a panel request on the basis that the responding party has engaged in violations of numerous WTO provisions. Finally, the United States expects that during the course of the panel proceeding, not all violations of the provisions in its panel request will receive the same level of attention.

93. **Canada** recalls that its panel request indicates that "[t]hese measures are inconsistent with the obligations of the EC" and then goes on to specify which provisions are being violated. Canada also notes that the listing of the specific provisions alleged to be violated must be read in the overall context of the panel request. According to Canada, some provisions are obviously relevant to some

claims, and just as obviously irrelevant to other claims. Specifically, Canada argues that those provisions establishing procedural obligations for the approval procedures and conformity assessment procedures (Article 8 and Annex C(1)(a), C(1)(b), C(1)(c), and C(1)(e) of the *SPS Agreement* and Articles 5.1, 5.2.1, 5.2.2, 5.2.3, 5.6 and 5.8 of the *TBT Agreement*) are not relevant to the national measures by EC member States which ban products that have already been approved by the European Communities. Canada submits that they are relevant only to those measures which concern the functioning of the European Communities' pre-marketing approval processes.

94. Canada further argues that the European Communities is incorrect in suggesting that Canada's panel request "should indicate which provisions may be relevant for the examination of each measure, possibly describing the substantive aspects or the effects of the measures which are allegedly in breach of those provisions". Canada submits that what the European Communities is complaining about here is that Canada has not provided an indication as to the legal arguments it intends to pursue, which, according to the jurisprudence, Canada is not required to do in its panel request.

95. **Argentina** maintains that its panel request is clear in relation to the link between the provisions alleged to be violated and the measures at issue. Argentina also maintains that the way in which the listed provisions are violated is a matter to be developed in Argentina's first written submission and subsequent statements.

96. The **Panel** notes that the panel in *Canada – Wheat Exports and Grain Imports* also confronted the issue whether a particular panel request made it clear which measures were alleged to violate which provisions. The panel in that case reached the following conclusion:

> We do not agree with Canada's assertion that the panel request does not make it clear which laws, regulations or actions are inconsistent with which obligation. The panel request states that "the laws, regulations *and* actions of the Government of Canada and the CWB related to exports of wheat appear to be […] inconsistent with paragraph 1(b) of Article XVII of the GATT 1994 […]" (emphasis added). This wording suggests to us – and we consider that it should suggest to Canada and the third parties as well – that the United States may have wished to claim before us that each of the three categories of measures identified – laws, regulations and actions – is inconsistent with both obligations of Article XVII:1(b). This way of presenting the Article XVII claim does not, in our view, have as a consequence that Canada does not know what case it has to answer and so cannot begin to prepare its defence, or that the third parties are uninformed as to the legal basis of the complaint and thus lack an opportunity effectively to respond to the United States' complaint.[83]

97. In the present case, the three panel requests each set out the three different EC measures at issue[84] and then go on to state:

> (a) "These measures appear to be inconsistent with the following provisions [...]" (United States' panel request)[85];

(b) "The measures violate the following provisions [...]" (Canada's panel request)[86]; and

(c) "The measures in question taken by the European Communities and several of its member States infringe the following provisions [...]" (Argentina's panel request)[87].

98. Thus, similar to the situation in *Canada – Wheat Exports and Grain Imports*, the wording of the panel requests in the present case suggests that each of the measures at issue in the three requests is inconsistent with each of the provisions identified in the three requests.

99. Referring to its own request, Canada points out, however, that the provisions establishing procedural obligations for approval procedures and conformity assessment procedures are "obviously irrelevant" to the third EC measure identified in its panel request, namely, the marketing and import bans allegedly maintained by certain EC member States, because these member State measures ban biotech product that have already been approved by the European Communities.[88] Neither the United States nor Argentina have expressed the view that the procedural provisions referred to by Canada are "obviously irrelevant" to the alleged member State marketing and import bans which they are also challenging in their respective requests. But the United States has noted that it "*currently* does not intend to pursue its claims that the procedures used in the adoption of national marketing and import bans violate the EC's WTO obligations" (emphasis added).[89] This statement suggests that, originally, the United States may have wished to pursue such claims. It also suggests that the irrelevance of the procedural provisions in question to the third EC measure covered in the three panel requests is perhaps not as obvious as Canada makes it out to be.

100. As noted by us above, the three panel requests as worded indicate that each of the measures at issue in these requests is alleged to violate each of the provisions identified. We consider, therefore, that the claims that may be pursued are "sufficiently identified in the panel request[s]"[90] and that the European Communities knows what case it may have to answer and that it can begin to prepare its defence based on that knowledge. If Canada never intended to claim that the marketing and import bans allegedly maintained by certain EC member States violate the provisions establishing procedural obligations for approval procedures and conformity assessment procedures, its panel request could arguably have stated that intention more clearly. As currently worded, Canada's panel request leaves little doubt that Canada may have wished to pursue such a claim.

101. The European Communities has noted that if the panel requests are read to mean that each of the measures identified is alleged to violate each of the provisions listed, the European Communities might have to begin to prepare a defence against a large number of claims. We agree.[91] However, we do not think that this fact supports a different reading of the panel requests. Nor do we think that this means that the legal standard of clarity against which these panel requests must be measured is higher than it would have been had the panel requests identified fewer claims. Having said this, we certainly share the European Communities' view that where a panel request sets forth a large number of claims it is particularly important that a complaining party identify the claims it may wish to pursue with as much clarity as possible.

102. The European Communities also suggests that the panel requests should have described and explained "the substantive aspects or the effects of the measures which are allegedly in breach of those provisions". Here again, we agree that it is desirable for a complaining party to provide this type of information in its panel request. However, we recall that the Appellate Body in *EC – Bananas III* agreed with the panel in that case that a panel request need not set out arguments "as to which specific aspects of the measures at issue relate to which specific provisions of those agreements".[92]

(iii) Conclusion

103. In the light of the above considerations[93], the Panel concludes that the European Communities has failed to establish that any of the Complaining Parties' panel requests falls short of the requirement in Article 6.2 that a panel request provide a brief summary of the legal basis of the complaint sufficient to present the problem clearly.

5. Overall conclusion

104. In view of our conclusions in Sections 4 and 5 above, there is no need to examine the issue of the prejudice, if any, sustained by the European Communities as a result of the allegedly defective panel request(s).

105. Overall, we thus conclude that the European Communities has failed to establish that any of the Complaining Parties' panel requests, when examined on its face and in the light of the attendant circumstances, is inconsistent with Article 6.2 of the DSU. Accordingly, we decline the European Communities' request that we issue a preliminary ruling to the effect that the Complaining Parties' panel requests do not meet the requirements of Article 6.2 of the DSU.

ANNEX

Provisions of the *SPS* And *TBT Agreements* referred to by the European Communities

(a) SPS Agreement

(i) Article 2.2

> Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.

(ii) Article 2.3

> Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members

where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

(iii) Article 5.5

With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.

(iv) Article 7

Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B.

(v) Article 8

Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement.

(vi) Annex B(5)

Whenever an international standard, guideline or recommendation does not exist or the content of a proposed sanitary or phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation, and if the regulation may have a significant effect on trade of other Members, Members shall:

(a) publish a notice at an early stage in such a manner as to enable interested Members to become acquainted with the proposal to introduce a particular regulation;

(b) notify other Members, through the Secretariat, of the products to be covered by the regulation together with a brief

indication of the objective and rationale of the proposed regulation. Such notifications shall take place at an early stage, when amendments can still be introduced and comments taken into account;

(c) provide upon request to other Members copies of the proposed regulation and, whenever possible, identify the parts which in substance deviate from international standards, guidelines or recommendations;

(d) without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account.

(vii) Annex C(1)(b)

Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that: [...] the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained;

(b) TBT Agreement

(i) Article 2.9

Whenever a relevant international standard does not exist or the technical content of a proposed technical regulation is not in accordance with the technical content of relevant international standards, and if the technical regulation may have a significant effect on trade of other Members, Members shall:

2.9.1 publish a notice in a publication at an early appropriate stage, in such a manner as to enable interested parties in other Members to become acquainted with it, that they propose to introduce a particular technical regulation;

2.9.2 notify other Members through the Secretariat of the products to be covered by the proposed technical regulation, together with a brief indication of its objective and rationale. Such notifications shall take place at an early appropriate stage,

when amendments can still be introduced and comments taken into account;

2.9.3 upon request, provide to other Members particulars or copies of the proposed technical regulation and, whenever possible, identify the parts which in substance deviate from relevant international standards;

2.9.4 without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account.

(ii) Article 5.2.2

When implementing the provisions of paragraph 1, Members shall ensure that: [...] the standard processing period of each conformity assessment procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the assessment in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the conformity assessment if the applicant so requests; and that, upon request, the applicant is informed of the stage of the procedure, with any delay being explained;

(iii) Article 5.6

Whenever a relevant guide or recommendation issued by an international standardizing body does not exist or the technical content of a proposed conformity assessment procedure is not in accordance with relevant guides and recommendations issued by international standardizing bodies, and if the conformity assessment procedure may have a significant effect on trade of other Members, Members shall:

5.6.1 publish a notice in a publication at an early appropriate stage, in such a manner as to enable interested parties in other Members to become acquainted with it, that they propose to introduce a particular conformity assessment procedure;

5.6.2 notify other Members through the Secretariat of the products to be covered by the proposed conformity assessment procedure, together with a brief indication of its objective and rationale. Such notifications shall take place at an early appropriate stage, when amendments can still be introduced and comments taken into account;

5.6.3 upon request, provide to other Members particulars or copies of the proposed procedure and, whenever possible, identify the parts which in substance deviate from relevant guides or recommendations issued by international standardizing bodies;

5.6.4 without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account.

(iv) Article 12

12.1 Members shall provide differential and more favourable treatment to developing country Members to this Agreement, through the following provisions as well as through the relevant provisions of other Articles of this Agreement.

12.2 Members shall give particular attention to the provisions of this Agreement concerning developing country Members' rights and obligations and shall take into account the special development, financial and trade needs of developing country Members in the implementation of this Agreement, both nationally and in the operation of this Agreement's institutional arrangements.

12.3 Members shall, in the preparation and application of technical regulations, standards and conformity assessment procedures, take account of the special development, financial and trade needs of developing country Members, with a view to ensuring that such technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to exports from developing country Members.

12.4 Members recognize that, although international standards, guides or recommendations may exist, in their particular technological and socio-economic conditions, developing country Members adopt certain technical regulations, standards or conformity assessment procedures aimed at preserving indigenous technology and production methods and processes compatible with their development needs. Members therefore recognize that developing country Members should not be expected to use international standards as a basis for their technical regulations or standards, including test methods, which are not appropriate to their development, financial and trade needs.

12.5 Members shall take such reasonable measures as may be available to them to ensure that international standardizing bodies and international systems for conformity assessment

are organized and operated in a way which facilitates active and representative participation of relevant bodies in all Members, taking into account the special problems of developing country Members.

12.6 Members shall take such reasonable measures as may be available to them to ensure that international standardizing bodies, upon request of developing country Members, examine the possibility of, and, if practicable, prepare international standards concerning products of special interest to developing country Members.

12.7 Members shall, in accordance with the provisions of Article 11, provide technical assistance to developing country Members to ensure that the preparation and application of technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to the expansion and diversification of exports from developing country Members. In determining the terms and conditions of the technical assistance, account shall be taken of the stage of development of the requesting Members and in particular of the least-developed country Members.

12.8 It is recognized that developing country Members may face special problems, including institutional and infrastructural problems, in the field of preparation and application of technical regulations, standards and conformity assessment procedures. It is further recognized that the special development and trade needs of developing country Members, as well as their stage of technological development, may hinder their ability to discharge fully their obligations under this Agreement. Members, therefore, shall take this fact fully into account. Accordingly, with a view to ensuring that developing country Members are able to comply with this Agreement, the Committee on Technical Barriers to Trade provided for in Article 13 (referred to in this Agreement as the "Committee") is enabled to grant, upon request, specified, time-limited exceptions in whole or in part from obligations under this Agreement. When considering such requests the Committee shall take into account the special problems, in the field of preparation and application of technical regulations, standards and conformity assessment procedures, and the special development and trade needs of the developing country Member, as well as its stage of technological development, which may hinder its ability to discharge fully its obligations under this Agreement. The Committee shall, in particular, take into account the special problems of the least-developed country Members.

12.9 During consultations, developed country Members shall bear in mind the special difficulties experienced by developing country Members in formulating and implementing standards and technical regulations and conformity assessment procedures, and in their desire to assist developing country Members with their efforts in this direction, developed country Members shall take account of the special needs of the former in regard to financing, trade and development.

12.10 The Committee shall examine periodically the special and differential treatment, as laid down in this Agreement, granted to developing country Members on national and international levels."

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[1] WT/DS291/23.
[2] WT/DS292/17.
[3] WT/DS293/17.
[4] None of the parties requested a preliminary hearing on the issues raised in the European Communities' request of 8 March 2004.
[5] (original footnote) *Ibid*., para. 143.
[6] Appellate Body Report, *United States – Countervailing Duties on Certain Corrosion-Resistant Carbon Steel Flat Products from Germany* ("*US – Carbon Steel* "), WT/DS213/AB/R and Corr.1, adopted 19 December 2002, para. 127 (footnotes omitted).
[7] The United States has further argued that, in addition to being groundless, the European Communities' objections to the United States' panel request are also untimely and that the Panel should reject the European Communities' preliminary ruling request also on that basis. See United States' comments on the European Communities' preliminary ruling request, para. 38. The issue of the timeliness of the European Communities' objections needs to be addressed only if the Panel concludes that the European Communities has failed to establish that the United States' panel request does not meet the requirements of Article 6.2 of the DSU.
[8] WT/DS291/23, paras. 1-3.
[9] (original footnote) Directive 2001/18, O.J. L 106 17.4.2001, p. 1 (and its predecessor, Directive 90/220, O.J. L 117, 8.5.1990, p. 15, as amended by Directive 94/15, O.J. L 103, 22.4.1994, p. 20 and Directive 97/35, O.J. L 169, 27.6.1997, p. 72); and Regulation 258/97, O.J. L 043, 14.2.1997, p. 1.
[10] WT/DS292/17, paras. 1, 2 and 5.
[11] (original footnote) As set out in EC Directive No. 2001/18 of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EC ([2001] O.J. L 106/1) (and its predecessor, EEC Directive No. 90/220 of 23 April 1990 on the deliberate release into the environment of genetically modified organisms ([1990] O.J. L117/15), EC Regulation No. 258/97 of 27 January 1997 concerning novel foods and novel food ingredients ([1997] O.J. L 43/1), and related legislative instruments specifically referred to in them.
[12] WT/DS293/17, paras. 2-5.
[13] (original footnote) See Annex I.
[14] (original footnote) EC legislation on biotech product approval includes Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001, published in Official Journal No. 106 of 17 April 2001, pages 0001-0039 (and its predecessor Council Directive 90/220/EEC of 23 April 1990, published in Official Journal No. 117 of 8 May 1990 and amended by Directive 94/15, published in Official Journal No. 103 of 22 April 1994, and by Directive 97/35, published in Official Journal No. 169 of 27 June 1997), and Regulation (EC) No. 258/1997 of the European Parliament and of the Council of 27 January 1997, published in Official Journal No. 043 of 14 February 1997.
[15] (original footnote) See Annex II.

[16] Panel Report, *Canada – Measures Relating to Exports of Wheat and Treatment of Imported Grain* ("*Canada – Wheat Exports and Grain Imports*"), WT/DS276/R, dated 6 April 2004, not yet adopted, para. 6.10, Article 6.2 ruling para. 14.
[17] *Ibid*, Article 6.2 ruling paras. 17 and 20.
[18] Appellate Body Report, Appellate Body Report, *European Communities – Customs Classification of Certain Computer Equipment* ("*EC – Computer Equipment*"), WT/DS62/AB/R, WT/DS67/AB/R, WT/DS68/AB/R, adopted 22 June 1998, DSR 1998:V, 1851, para. 69.
[19] *The Concise Oxford Dictionary*, 10th ed., J. Pearsall (ed.) (Clarendon Press, 1999), p. 1443.
[20] *Ibid*.
[21] For the text of the introductory paragraph, see, *supra*, para. 8.
[22] United States' comments on the European Communities' preliminary ruling request, para. 4. The United States' panel request does not explicitly refer to a "*de facto*" moratorium. However, at the first DSB meeting at which the United States' panel request was discussed, the United States confirmed the *de facto* nature of the moratorium, saying that "[t]he existence of the moratorium [is] indisputable: the EC [has] not considered a biotech product for approval in nearly five years, and high-level EC officials [have] acknowledged its existence in public statements". See WT/DSB/M/154, p. 6.
[23] Panel Report, *Canada – Wheat Exports and Grain Imports*, Article 6.2 ruling para. 20.
[24] *Ibid*., Article 6.2 ruling paras. 20 and 27.
[25] We note that this distinction has played a role in a number of GATT/WTO dispute settlement proceedings. See, notably, Panel Report, *Japan – Trade in Semi-Conductors* ("*Japan – Semi-Conductors* "), adopted 4 May 1988, BISD 35S/116, paras. 110-117.
[26] United States' comments on the European Communities' preliminary ruling request, paras. 4, 5 and 16; Exhibits US-1 and US-2.
[27] European Communities' preliminary ruling request, para. 22.
[28] Appellate Body Report, *Thailand – Anti-Dumping Duties on Angles, Shapes and Sections of Iron or Non-Alloy Steel and H-Beams from Poland* ("*Thailand – H-Beams* "), WT/DS122/AB/R, adopted 5 April 2001, para. 88.
[29] We consider that the United States' panel request also adequately informs the third parties of the specific measure that is being challenged. We note in this regard that none of the third parties has offered any comments on the European Communities' objections to the United States' panel request.
[30] United States' comments on the European Communities' preliminary ruling request, para. 18.
[31] European Communities' preliminary ruling request, para. 25.
[32] For the text of the introductory paragraph, see, *supra*, para. 9.
[33] See, *supra*, para. 20.
[34] See, *supra*, para. 22.
[35] Canada's comments on the European Communities' preliminary ruling request, paras. 18-19; Exhibits CDA-4 and CDA-5.
[36] See, *supra*, para. 23.
[37] Appellate Body Report, *Thailand – H-Beams*, para. 88.
[38] We consider that Canada's panel request also adequately informs the third parties of the specific measure that is being challenged. We note in this regard that none of the third parties has offered any comments on the European Communities' objections to Canada's panel request.
[39] European Communities' preliminary ruling request, para. 25.
[40] See, *supra*, para. 20.
[41] For the text of the second paragraph, see, *supra*, para. 10.
[42] It appears that Argentina intends to illustrate the "*de facto* moratorium" by referring to Annex I of its panel request, which sets out specific biotech products and the status of the corresponding applications for approval.
[43] See, *supra*, para. 22.
[44] See, *supra*, para. 23.
[45] Appellate Body Report, *Thailand – H-Beams*, para. 88.
[46] We consider that Argentina's panel request also adequately informs the third parties of the specific measure that is being challenged. We note in this regard that none of the third parties has offered any comments on the European Communities' objections to Argentina's panel request.
[47] We note that at the first meeting of the DSB at which Argentina's panel request was discussed, Argentina similarly explained that "[t]he measures at issue include[...], depending on the case, failure to consider *or* the

suspension of consideration of applications for the endorsement or approval of agricultural biotechnology products [...]" (emphasis added). See WT/DSB/M/154, p. 7.
[48] European Communities' preliminary ruling request, para. 25.
[49] WT/DS291/23, para. 4.
[50] WT/DS292/17, paras. 6-7.
[51] WT/DS293/17, paras. 5-6.
[52] Appellate Body Report, *Thailand – H-Beams*, para. 88.
[53] (original footnote) *Ibid*., para. 123.
[54] (original footnote) While arguments will be further clarified in the first written submission, and in subsequent documents, there is, as we [the Appellate Body] said in *European Communities – Bananas*, a significant difference between the *claims* identified in the request for the establishment of a panel, which establish the panel's terms of reference under Article 7 of the DSU, and the *arguments* supporting those claims. See Appellate Body Report, *supra*, footnote 30, para. 142.
[55] Appellate Body Report, *Korea – Definitive Safeguard Measure on Imports of Certain Dairy Products* ("*Korea – Dairy* "), WT/DS98/AB/R, adopted 12 January 2000, DSR 2000:I, 3, para. 124.
[56] (original footnote) See Appellate Body Report, *Brazil – Desiccated Coconut*, *supra*, footnote 21, p. 22; Appellate Body Report, *European Communities – Bananas*, *supra*, footnote 13, paras. 145 and 147; and Appellate Body Report, *India – Patents*, *supra*, footnote 21, paras. 89, 92 and 93.
[57] Appellate Body Report, *US – Carbon Steel*, para. 130.
[58] (original footnote) Appellate Body Report, *Korea – Dairy*, para. 124.
[59] We set out the text of these provisions in the Annex to the present preliminary ruling. While the European Communities appears to suggest that it has identified these particular provisions merely by way of "illustration" (European Communities' request for a preliminary ruling, para. 38), it is for the European Communities to indicate precisely how and why the Complaining Parties' panel requests are deficient. The Panel will therefore limit its analysis to those provisions which have been specified by the European Communities.
[60] See Appellate Body Report, *US – Carbon Steel*, para. 130, quoted, *supra*, at para. 54.
[61] United States' comments on the European Communities' preliminary ruling request, note 15; Canada's reply to Panel question No. 5.
[62] We note that there appears to be one inconsistency in the United States' panel request, in that the United States did not cite Article 5.1 of the *TBT Agreement* as a whole, but instead specified both of its two sub-paragraphs. However, this inconsistency does not detract from our view that, when all of the provisions listed in the United States' panel request are considered together, the United States' failure to specify sub-paragraph numbers in referring to Annex B(5) of the *SPS Agreement* and Articles 2.9 and 5.6 of the *TBT Agreement* suggests that it wished to allege violations of each of the sub-paragraphs.
[63] Argentina's reply to Panel question No. 9.
[64] Appellate Body Report, *Thailand – H-Beams*, para. 93.
[65] (original footnote) See also Appellate Body Report, *United States – Import Measures on Certain Products from the European Communities*, WT/DS165/AB/R, adopted 10 January 2001, para. 111.
[66] Appellate Body Report, *US – Carbon Steel*, para. 130, quoted, *supra*, para. 54.
[67] Argentina's reply to Panel question No. 8.
[68] Specifically, the Appellate Body noted that "[i]n view of the importance of the request for the establishment of a panel, we encourage complaining parties to be precise in identifying the legal basis of the complaint". Appellate Body Report, *Thailand – H-Beams*, para. 97.
[69] Argentina's reply to Panel question No. 8.
[70] See Panel Report, *Canada – Wheat Exports and Grain Imports*, Article 6.2 ruling para. 43.
[71] European Communities' preliminary ruling request, para. 38. The European Communities does not indicate the paragraph numbers which contain these four obligations.
[72] Article 12.4 deals with measures taken by developing country Members. Articles 12.5 and 12.6 relate to Members' obligations in connection with the work of international standardizing bodies. Article 12.8 concerns the problems faced by developing country Members in discharging their obligations under the *TBT Agreement* and the possibility of obtaining time-limited exceptions from obligations under the *TBT Agreement*. Article 12.9 relates to "consultations" in a situation where a developing country Member is "formulating and implementing" standards, technical regulations or conformity assessment procedures. However, Argentina's panel request nowhere suggests that the European Communities failed to comply with its obligations during

consultations between Argentina and the European Communities. Also, Argentina's complaint plainly is not about the formulation and implementation of its own standards, technical regulations or conformity assessment procedures. Article 12.10 sets out a requirement to be satisfied by the Committee on Technical Barriers to Trade.
[73] Appellate Body Report, *US – Carbon Steel*, para. 130, quoted, *supra*, para. 54.
[74] United States' reply to Panel question No. 3; Canada's reply to Panel question No. 5.
[75] Argentina's reply to Panel question No. 9.
[76] Appellate Body Report, *US – Carbon Steel*, para. 130, quoted, *supra*, para. 54.
[77] See Appellate Body Report, *Australia – Measures Affecting Importation of Salmon* ("*Australia – Salmon* "), WT/DS18/AB/R, adopted 6 November 1998, DSR 1998:VIII, 3327, para. 138; Panel Report, *EC Measures Concerning Meat and Meat Products* (*Hormones*) *– Complaint by Canada* ("*EC – Hormones* (*Canada*)"), WT/DS48/R/CAN, adopted 13 February 1998, as modified by the Appellate Body Report, WT/DS26/AB/R, WT/DS48/AB/R, DSR 1998:II, 235, para. 8.99.
[78] See G/SPS/15.
[79] Appellate Body Report, *US – Carbon Steel*, para. 130, quoted, *supra*, para. 54.
[80] See, e.g., Appellate Body Report, *US – Carbon Steel*, para. 172.
[81] See Appellate Body Report, *European Communities – Regime for the Importation, Sale and Distribution of Bananas* ("*EC – Bananas III* "), WT/DS27/AB/R, adopted 25 September 1997, DSR 1997:II, para. 141.
[82] *Ibid*.
[83] Panel Report, *Canada – Wheat Exports and Grain Imports*, Article 6.2 ruling para. 29.
[84] See, *supra*, paras. 8, 9 and 10. It is important to note that in listing the three EC measures, all three panel requests use the separator "and".
[85] WT/DS291/23.
[86] WT/DS292/17.
[87] WT/DS293/17.
[88] Canada's comments on the European Communities preliminary ruling request, para. 33; Canada's reply to Panel question No. 6. For a list of the relevant provisions, see, *supra*, para. 93.
[89] United States' reply to Panel question No. 2, note 1.
[90] Appellate Body Report, *US – Carbon Steel*, para. 173.
[91] We are not convinced, however, that the European Communities might potentially have to defend itself against more than three thousands claims. In particular, we note that the European Communities itself is of the view that some of the provisions cited in the panel requests are mutually exclusive or subject to other provisions. European Communities' preliminary ruling request, para. 40.
[92] Appellate Body Report, *EC – Bananas III*, para. 141.
[93] We note, in addition, that just like we do not consider that the summaries of the legal basis of the complaints provided in the Complaining Parties' panel requests result in the European Communities not knowing what case it has to answer and hence being unable to begin preparing its defence, so also we do not consider that those summaries result in the third parties being uninformed as to the legal basis of the Complaining Parties' complaints and thus unable effectively to respond to these complaints. We recall in this regard that none of the third parties has offered any comments on the European Communities' objections to the Complaining Parties' panel requests.

7.48 In relation to the above preliminary ruling, we note that in *US – Gambling*, the Appellate Body found that "without demonstrating the source of the prohibition, a complaining party may not challenge a 'total prohibition' as a "measure", *per se*, in dispute settlement proceedings under the GATS".[235] This statement relates to a measure which was different in nature from the first measure challenged by the Complaining Parties in this case (the alleged general EC moratorium). Indeed, in *US – Gambling*, the Appellate Body's conclusion was based on the argument that without knowing the precise source of the "total prohibition", the responding party in that case was not in a position to prepare adequately its defence, particularly because it had been alleged that numerous federal and

[235] Appellate Body Report, *US – Gambling*, para. 126.

state laws underlay the "total prohibition".[236] In the present case, there is no allegation that numerous EC laws and regulations underlie the first measure challenged by the Complaining Parties. The Complaining Parties are alleging the very opposite, namely, that there are no formal laws or regulations underlying the first measure and that, as a result, no such laws or regulations could have been identified. In the light of this, we see no inconsistency between our approach and that of the Appellate Body in *US – Gambling*.[237] In any event, we have determined above that the description of the first measure covered in the Complaining Parties' respective panel requests, when read together with other information provided in those requests, adequately identifies the specific measure that is being challenged, and that the European Communities has failed to persuade us that the information contained in the Complaining Parties' respective descriptions of the first measure did not allow the European Communities to prepare adequately its defence.

7. Relevance of other rules of international law to the interpretation of the WTO agreements at issue in this dispute

7.49 The **European Communities** argues that in *US – Gasoline* the Appellate Body stated that "the General Agreement is not to be read in clinical isolation from public international law". More specifically, the European Communities notes that the WTO agreements – including the *SPS Agreement*, the *TBT Agreement* and the GATT 1994 – must be interpreted and applied by reference to relevant rules of international law arising outside the WTO context, as reflected in international agreements and declarations. The European Communities notes that notwithstanding the aforementioned statement by the Appellate Body, the Complaining Parties in these proceedings treat the legal issues concerning the authorization and international trade of GMOs as though they are regulated exclusively by WTO rules, and make no reference whatsoever to the relevant rules of public international law which have been adopted to regulate the concerns and requirements which arise from the particular characteristics of GMOs.

7.50 In view of the European Communities' argument, the **Panel** now turns to address the issue of the relevance of other rules of international law to the interpretation of the WTO agreements at issue in this dispute.

(a) Other applicable rules of international law as an interpretative element to be taken into account together with the "context" (Article 31(3)(c) of the *Vienna Convention on the Law of Treaties*)

7.51 In approaching this issue, we first consider whether there are other applicable rules of international law which we are required to take into account in interpreting the WTO agreements at issue in this dispute.

7.52 The **European Communities** asserts that the Panel is required to interpret the relevant rules of WTO law consistently with other rules of international law that may be relevant to these proceedings. The European Communities notes in this regard that the customary rules of interpretation of public international law are reflected in Articles 31 and 32 of the *Vienna Convention on the Law of Treaties* (hereafter "the *Vienna Convention*") and they include the requirement to take into account other relevant rules of international law, in addition to the context of the treaty itself. The European Communities notes in this regard that the Appellate Body has interpreted WTO rules by reference to treaties which are not binding on all parties to the proceedings. More specifically, the European Communities refers to treaties invoked by the Appellate Body in the *US – Shrimp* case – in

[236] *Ibid*., para. 125.
[237] For our approach, *see* Preliminary Ruling, paras. 22-24, 34-35 and 45-46.

support of arguments made by the United States – treaties which that country had not signed or had signed but not ratified. The European Communities asserts that the Panel is bound to follow the approach set forth in *US – Shrimp.*

7.53 The European Communities considers that the binding international law instruments relevant to this case are the *1992 Convention on Biological Diversity* (hereafter "the *Convention on Biological Diversity*") and the *2000 Cartagena Protocol on Biosafety to the Convention on Biological Diversity* (hereafter "the *Biosafety Protocol*"). According to the European Communities, the *Convention on Biological Diversity* is binding on the European Communities, Argentina and Canada and has been signed by the United States. Regarding the *Biosafety Protocol*, the European Communities points out that the *Protocol* is binding on the European Communities (which has obligations under it *vis-à-vis* third parties) and has been signed by Argentina and Canada. Regarding the United States, the European Communities indicates that the United States is participating in the *Protocol's* Clearing-House Mechanism (under Articles 11 and 20) and must therefore be taken to have no objection to the approach required by the *Protocol*. More generally, the European Communities argues that under Article 18 of the *Vienna Convention* (which, according to the European Communities, reflects customary international law) a State which has signed a treaty is bound to "refrain from acts which would defeat [its] object and purpose".

7.54 The European Communities argues that the *Biosafety Protocol* is the international agreement which is most directly relevant to the matters raised by the present proceedings. The relationship between the *Protocol* and other international agreements, including trade agreements, is addressed by the last three recitals of the Preamble. They recall the concept of mutual supportiveness between trade and environment agreements; they furthermore affirm that the *Protocol* shall not be interpreted as implying a change in the rights and obligations of Parties under any other existing international agreement, but recall that such statement shall not mean that the *Protocol* is subordinated to other international agreements. The European Communities submits that the Complaining Parties ignore the rules of international law reflected in the *Biosafety Protocol* on the precautionary principle and on risk assessment.

7.55 The European Communities argues that although the *Biosafety Protocol* has not been invoked in previous WTO dispute settlement proceedings, there is ample authority to support the proposition that the *Biosafety Protocol* and the *SPS Agreement* (as well as the *TBT Agreement* and GATT 1994) are so closely connected that they should be interpreted and applied consistently with each other, to the extent that is possible (as is the case in this dispute). The European Communities indicates in this regard that there is no *a priori* inconsistency between the WTO agreements (*SPS Agreement*, *TBT Agreement*, GATT 1994) and the *Biosafety Protocol*; that the two instruments are complementary; and that the Protocol's provisions on precaution and risk assessment inform the meaning and effect of the relevant provisions of the WTO agreements. Furthermore, the European Communities submits that the negotiators of the *Biosafety Protocol* were acutely aware of its relationship with WTO agreements and cannot have intended that there should be an inconsistency of approach. Reasonable governments have concluded that the authorization of GMOs (including import requirements) requires a particular approach, and they can hardly have intended that approach to be inconsistent with WTO rules. The European Communities argues, finally, that the application of its internal measures is fully consistent with the WTO agreements, and that this is confirmed by the requirements of the *Biosafety Protocol*.

7.56 The **United States** argues that there are no binding international law instruments of relevance to this dispute, other than the *WTO Agreement*. Furthermore, the United States notes that under the DSU, the Panel's terms of reference are to examine the matter at issue "in light of the relevant provisions [...] in the covered agreements cited by the parties to the dispute". The matter is *not* to be

considered in light of the provisions of the *Biosafety Protocol*, nor of other sources of international law.

7.57 The United States argues that the only way other sources of international law could be pertinent to this dispute is if, under Article 3.2 of the DSU, those other sources of law would assist the Panel in "clarifying the existing provisions of the [covered] agreements in accordance with customary rules of interpretation of public international law". As pertinent here, customary rules of interpretation of public international law are reflected in Article 31 of the *Vienna Convention*. This provision states that the terms of a treaty must be interpreted "in accordance with [their] ordinary meaning [...] in their context and in the light of [the treaty's] object and purpose". The United States notes that international law other than the *WTO Agreement* is only pertinent in so far as it would assist the Panel in interpreting the particular terms of the covered agreements at issue in this dispute.

7.58 The United States disagrees with any notion that the *Biosafety Protocol* is a rule of international law for the purposes of interpreting the *WTO Agreement* in accordance with the principles in Article 31(3) of the *Vienna Convention*. Under Article 31(3), the international rule must be "applicable in the relations between the parties". The United States notes that in this case, the *Biosafety Protocol* is not applicable to relations between the United States and the European Communities, because the United States is not a party to the *Biosafety Protocol*. The United States indicates that the European Communities' argument to the contrary is entirely without merit. The European Communities notes that the United States participates in the *Biosafety Protocol* Clearing-House Mechanism, and from this the European Communities leaps to the conclusion that the United States must thus have no objection to the "approach" required by the *Biosafety Protocol*. The United States argues that its good-faith effort to share information regarding living modified organisms that have completed regulatory review in the United States is in no way an endorsement of the *Protocol* itself.

7.59 Moreover, the United States does not agree that the Panel would need to look to the *Biosafety Protocol* in interpreting the *WTO Agreement* even in a dispute between WTO Members that were both parties to the *Biosafety Protocol*. The United States submits that the European Communities itself acknowledges that the *Protocol* explicitly provides that parties may not disregard their existing international obligations in their implementation of the *Biosafety Protocol*. The United States submits that the *Biosafety Protocol* has a clear and unequivocal statement that the *Protocol* does not change the rights and obligations under any existing international agreement. In addition, the United States notes that in this dispute, the European Communities has not identified how the *Biosafety Protocol* or a "precautionary principle" would be of relevance to interpreting any particular provision of the *WTO Agreement*. Moreover, the United States notes that the European Communities does not argue that any provision of the *Protocol* is in any way inconsistent with the European Communities' full compliance with its WTO obligations. According to the United States, the *Biosafety Protocol* foresees a functioning regulatory system in each Party country – a system that works in a predictable manner to make informed decisions on imports of "living modified organisms" within a specified timeframe. Nowhere does the *Protocol* require or even condone the adoption of moratoria on decision-making, or undue delays in such decision-making.

7.60 **Canada** argues that with the possible exception of the 1979 *International Plant Protection Convention*, there are no binding international law instruments relevant to this case. In relation to the *Biosafety Protocol*, Canada notes that the only possible relevance of the *Protocol* to this dispute could be for interpretive purposes. Initially, Canada submitted in this regard that in view of the fact that the Complaining Parties to this dispute are not parties to the *Biosafety Protocol*, the *Biosafety Protocol* is not a "relevant rule[] of international law applicable in the relations between the parties" (Article 31(3)(c) of the *Vienna Convention*). However, at a later stage Canada argued that the

reference to "parties" in Article 31(3)(c) is a reference to the parties to the treaty that is being interpreted. On that basis, Canada submitted that in the case of the *WTO Agreement*, the rules of international law in question would have to be applicable in the relations among all the WTO members.

7.61 Canada further argues that, in any event, the *Biosafety Protocol* should not be taken into account in the interpretation of the obligations under the *WTO Agreement*, given that the *Protocol*'s own terms emphasize that "this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements." Furthermore, Canada notes that the European Communities has offered no explanation for how the *Biosafety Protocol* might assist it. In particular, the *Biosafety Protocol* does not entitle the European Communities to take measures that disregard the conclusions of its scientific risk assessments or suspend the working of its risk assessment process. According to Canada there is no inconsistency between the obligations of the *Biosafety Protocol* and the WTO obligations relevant to this dispute. The *Biosafety Protocol* is premised on transparent, scientifically-sound risk assessment as the basis for decisions regarding the importation of the products to which it applies. Canada argues that the European Communities' measures – its moratorium, its product-specific marketing bans and its member State bans – are stark refutations of this premise. Also, the scope of the *Biosafety Protocol* is limited to "living modified organisms" or LMOs. The European Communities repeatedly attempts to equate the term LMOs with GMOs. As the *Biosafety Protocol* is concerned with the impact of LMOs on biodiversity, even under the European Communities' theory, the *Protocol* is of no relevance to the risk assessment of biotech products for food use under Regulation 258/97. Canada submits that, for all these reasons, the European Communities will find no justification for its measures under the *WTO Agreement* by appealing to other international agreements.

7.62 **Argentina** argues that according to Article 3.2 of the DSU, as interpreted by the Appellate Body, any treaty interpreter must resort to the *Vienna Convention* in order to interpret the covered agreements. Argentina indicates that in this case, with respect to the "extra-WTO" rules invoked by the European Communities, it is necessary to resort to Article 31 of the *Vienna Convention*.

7.63 Furthermore, Argentina argues that the rules of international law referred to by the European Communities are clearly not an agreement "relating to the treaty which was made between all the parties in connection with the conclusion of the treaty" within the meaning of Article 31(2)(a) of the *Vienna Convention*. Nor are they an "instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty" within the meaning of Article 31(2)(b) of the *Vienna Convention*. Moreover, Argentina submits that the rules cited by the European Communities are not a "subsequent agreement between the parties regarding the interpretation of the treaty or the applications of its provisions" within the meaning of Article 31.3(a). In addition, Argentina asserts that the *Biosafety Protocol* cannot be regarded as "any relevant rule of international law applicable in the relations between the parties" within the meaning of Article 31(3)(c) of the *Vienna Convention*, since the European Communities is the only party in this WTO dispute bound by the provisions of the *Biosafety Protocol*.

7.64 The **Panel** begins its analysis by offering some general observations before considering the relevance of the rules of international law which the European Communities claims should have a bearing on our interpretation of WTO provisions.

(i) General

7.65 Pursuant to Article 3.2 of the DSU, we are to interpret the WTO agreements "in accordance with customary rules of interpretation of public international law". These customary rules are reflected, in part, in Article 31 of the *Vienna Convention*.[238]

7.66 Article 31 provides in relevant part:

> Article 31
> General rule of interpretation
>
> 1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.
>
> 2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes:
>
> (a) any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty;
>
> (b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.
>
> 3. There shall be taken into account, together with the context:
>
> (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;
>
> (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation;
>
> (c) any relevant rules of international law applicable in the relations between the parties.

7.67 Article 31(3)(c) directly speaks to the issue of the relevance of other rules of international law to the interpretation of a treaty. In considering the provisions of Article 31(3)(c), we note, initially, that it refers to "rules of international law". Textually, this reference seems sufficiently broad to encompass all generally accepted sources of public international law, that is to say, (i) international conventions (treaties), (ii) international custom (customary international law), and (iii) the recognized general principles of law. In our view, there can be no doubt that treaties and customary rules of international law are "rules of international law" within the meaning of Article 31(3)(c). We therefore agree with the European Communities that a treaty like the *Biosafety Protocol* would qualify as a "rule of international law". Regarding the recognized general *principles* of law which are applicable in international law, it may not appear self-evident that they can be considered as "*rules* of international law" within the meaning of Article 31(3)(c). However, the Appellate Body in *US – Shrimp* made it clear that pursuant to Article 31(3)(c) general principles of international law are to be

[238] Appellate Body Report, *US – Carbon Steel*, paras. 61-62.

taken into account in the interpretation of WTO provisions.[239] As we mention further below, the European Communities considers that the principle of precaution is a "general principle of international law". Based on the Appellate Body report on *US – Shrimp*, we would agree that if the precautionary principle is a general principle of international law, it could be considered a "rule of international law" within the meaning of Article 31(3)(c).

7.68 Furthermore, and importantly, Article 31(3)(c) indicates that it is only those rules of international law which are "applicable in the relations between the parties" that are to be taken into account in interpreting a treaty. This limitation gives rise to the question of what is meant by the term "the parties". In considering this issue, we note that Article 31(3)(c) does not refer to "one or more parties".[240] Nor does it refer to "the parties to a dispute".[241] We further note that Article 2.1(g) of the *Vienna Convention* defines the meaning of the term "party" for the purposes of the *Vienna Convention*. Thus, "party" means "a State which has consented to be bound by the treaty and for which the treaty is in force". It may be inferred from these elements that the rules of international law applicable in the relations between "the parties" are the rules of international law applicable in the relations between the States which have consented to be bound by the treaty which is being interpreted, and for which that treaty is in force.[242] This understanding of the term "the parties" leads logically to the view that the rules of international law to be taken into account in interpreting the WTO agreements at issue in this dispute are those which are applicable in the relations between the WTO Members.[243]

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[239] Appellate Body Report, *US – Shrimp*, para. 158 and footnote 157. The Appellate Body found in that case that the principle of good faith was at once a general principle of law and a general principle of international law.

[240] We note that, by contrast, Article 31(2)(b) of the *Vienna Convention* refers to "one or more parties".

[241] By contrast, Article 66 of the *Vienna Convention*, which deals with procedures for judicial settlement, arbitration and conciliation, refers to "the parties to a dispute". We note that the absence of a reference to "the parties to a dispute" in Article 31 is not surprising given that Article 31 does not purport to lay down rules of interpretation which are applicable solely in the context of international (quasi-)judicial proceedings.

[242] We are aware that Article 31(2)(a) of the *Vienna Convention* refers to "all the parties". However, we do not consider that Article 31(2)(a) rules out our interpretation of the term "the parties" in Article 31(3)(c). In our view, the reference to "all the parties" is used in Article 31(2)(a) to make clear the difference between the class of documents at issue in that provision (namely, agreements relating to a treaty which were made between "all the parties") and the class of documents at issue in Article 31(2)(b) (namely, instruments made by "one or more parties" and accepted by "the other parties" as related to a treaty). In other words, we think that the use of the term "all the parties" in Article 31(2)(a) is explained, and necessitated, by the existence of Article 31(2)(b). Consistent with this view, we think that the absence of a reference to "all the parties" in Article 31(3)(c) is explained by the fact that Article 31(3) contains no provision like Article 31(2)(b), *i.e.*, that Article 31(3) contains no provision which refers to "one or more parties" and hence could render unclear or ambiguous the reference to "the parties" in Article 31(3)(c).

It is useful to note, in addition, that the view that the term "the parties" in Article 31(3)(c) should be understood as referring to all the parties to a treaty has also been expressed by Mustafa Yasseen, "L'interprétation des Traités d'après la Convention de Vienne sur le Droit des Traités", in *Recueil des Cours de l'Académie de Droit International* (1976), Vol. III, p. 63, para. 7.

[243] We find further support for this view in the provisions of Article 31(3)(b). Article 31(3)(b), which is part of the immediate context of Article 31(3)(c), provides that a treaty interpreter must take into account "any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation". Like Article 31(3)(c), this provision makes reference to "the parties". In *EC – Chicken Cuts*, the Appellate Body appeared to agree with the panel in that case that the term "the parties" in Article 31(3)(b) means the parties to a treaty and in the WTO context must be understood as meaning the WTO Members. Appellate Body Report, *EC – Chicken Cuts*, paras. 272 (referring to "a treaty party" and agreement with a practice by "other WTO Members") and 273 (referring to the "issue of how to establish the agreement by

7.69 It is important to note that Article 31(3)(c) mandates a treaty interpreter to take into account other rules of international law ("[t]here shall be taken into account"); it does not merely give a treaty interpreter the option of doing so.[244] It is true that the obligation is to "take account" of such rules, and thus no particular outcome is prescribed. However, Article 31(1) makes clear that a treaty is to be interpreted "in good faith". Thus, where consideration of all other interpretative elements set out in Article 31 results in more than one permissible interpretation, a treaty interpreter following the instructions of Article 31(3)(c) in good faith would in our view need to settle for that interpretation which is more in accord with other applicable rules of international law.[245]

7.70 Taking account of the fact that Article 31(3)(c) mandates consideration of other applicable rules of international law, and that such consideration may prompt a treaty interpreter to adopt one interpretation rather than another, we think it makes sense to interpret Article 31(3)(c) as requiring consideration of those rules of international law which are applicable in the relations between all parties to the treaty which is being interpreted. Requiring that a treaty be interpreted in the light of other rules of international law which bind the States parties to the treaty ensures or enhances the consistency of the rules of international law applicable to these States and thus contributes to avoiding conflicts between the relevant rules.

7.71 The European Communities appears to suggest that we must interpret the WTO agreements at issue in this dispute in the light of other rules of international law even if these rules are not binding on all Parties to this dispute.[246] In addressing this argument, we first recall our view that Article 31(3)(c) should be interpreted to mandate consideration of rules of international law which are applicable in the relations between all parties to the treaty which is being interpreted.[247] The parties to a dispute over compliance with a particular treaty are, of course, parties to that treaty. In relation to the present dispute it can thus be said that if a rule of international law is not applicable to one of the four WTO Members which are parties to the present dispute, the rule is not applicable in the relations

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Members that have not engaged in a practice"). *See also* Appellate Body Report, *Japan – Alcoholic Beverages II*, p. 13 (referring to "the agreement of the parties [to a treaty] regarding its interpretation"). It is true that the Appellate Body found that "the interpretation of a treaty provision on the basis of subsequent practice is binding on all parties, including those that have not actually engaged in such practice". Appellate Body Report, *EC – Chicken Cuts*, para. 273. But it also found that it is necessary "to establish agreement of those that have not engaged in a practice". Appellate Body Report, *EC – Chicken Cuts* , para. 271. Thus, our interpretation of the term "the parties" in Article 31(3)(c) is consistent with, and indeed supported by, the Appellate Body's interpretation of the same term in Article 31(3)(b). In our view, it would be incongruous to allow the interpretation of a treaty to be affected by rules of international law which are not applicable in the relations between all parties to the treaty, but not by a subsequent practice which does not establish the agreement of all parties to the treaty regarding the meaning of that treaty.

[244] This view is confirmed by the negotiating history of Article 31(3). The International Law Commission, in its commentary to Article 27 of the draft *Vienna Convention*, which contained language identical to the current Article 31 of the *Vienna Convention*, stated that "the three elements [the three sub-paragraphs of what is now Article 31(3)] are all of an obligatory character and by their very nature could not be considered to be norms of interpretation in any way inferior to those which precede them". *Yearbook of the International Law Commission* (1966), Vol. II, p. 220, para. 9.

[245] We are not suggesting that other applicable rules of international law invariably or exclusively serve as a kind of "tie-breaker" in the interpretative process.

[246] The European Communities considers that the Appellate Body report on *US – Shrimp* supports its view. We do not agree. In our view, that report does not stand for the proposition that panels are required to interpret WTO agreements in the light of other rules of international law even if they are not applicable to all parties to a dispute. We further address the Appellate Body report on *US – Shrimp*, and in particular how we understand it, in the next sub-section.

[247] We recall that we have reached this view after determining that the text and context of Article 31(3)(c) do not support interpreting the term "the parties" as meaning "the parties to a dispute".

between all WTO Members. Accordingly, based on our interpretation of Article 31(3)(c), we do not consider that in interpreting the relevant WTO agreements we are required to take into account other rules of international law which are not applicable to one of the Parties to this dispute. But even independently of our own interpretation, we think Article 31(3)(c) cannot reasonably be interpreted as the European Communities suggests. Indeed, it is not apparent why a sovereign State would agree to a mandatory rule of treaty interpretation which could have as a consequence that the interpretation of a treaty to which that State is a party is affected by other rules of international law which that State has decided not to accept.[248]

7.72 Before applying our interpretation of Article 31(3)(c) to the present case, it is important to note that the present case is not one in which relevant rules of international law are applicable in the relations between all parties to the dispute, but not between all WTO Members, and in which all parties to the dispute argue that a multilateral WTO agreement should be interpreted in the light of these other rules of international law. Therefore, we need not, and do not, take a position on whether in such a situation we would be entitled to take the relevant other rules of international law into account.

(ii) Convention on Biological Diversity and Biosafety Protocol

7.73 With the foregoing observations in mind, we now consider whether the multilateral treaties identified by the European Communities are "relevant rules of international law applicable in the relations between the parties". The European Communities has identified two multilateral treaties, the *Convention on Biological Diversity* and the *Biosafety Protocol*. We first address the *Convention on Biological Diversity*.

7.74 We note that like most other WTO Members, Argentina, Canada and the European Communities have ratified the *Convention on Biological Diversity* and are thus parties to it.[249] The United States has signed it in 1993, but has not ratified it since.[250] Thus, the United States is not a party to the *Convention on Biological Diversity*, and so for the United States the *Convention* is not in force. In other words, the *Convention on Biological Diversity* is not "applicable" in the relations between the United States and all other WTO Members. The mere fact that the United States has signed the *Convention on Biological Diversity* does not mean that the *Convention* is applicable to it.[251] Nor does it mean that the United States will ratify it, or that it is under an obligation to do so. We

[248] It is useful to recall that there are several ways in which a sovereign State can decide not to accept other rules of international law. Thus, in the case of other rules of international law embodied in a treaty, a State may have decided not to participate in the negotiation of the treaty; it may have decided not to sign the final text of the treaty in question; or the legislature of a State may have decided not to ratify the treaty after it had been signed by its executive branch. There are also cases of ratifications with objections/exceptions. In the case of customary rules of international law, a State may have persistently objected to such a rule during its formation.

[249] The *Convention on Biological Diversity* entered into force on 29 December 1993.

[250] We have no information on whether the United States has ever made its intentions clear after 1993 as to whether it still wished to become a party to the 1992 Convention.

[251] We note that pursuant to Article 18 of the *Vienna Convention* a State which has signed a treaty must refrain from acts which would defeat the object and purpose of that treaty, at least until it has made its intention clear not to become a party. Initially, we note that there is an issue whether the provisions of Article 18 reflect customary international law. Even disregarding this issue, we note that Article 18 refers to "acts" which rise to the level of "defeat[ing] the object and purpose" of a treaty, not to acts which are inconsistent with specific terms of that treaty. It does not follow from Article 18 that a State which has signed a treaty has obligations pursuant to the specific terms of that treaty and that the treaty is applicable to it as such. In any event, Article 31(3)(c) refers to applicable "rules" of international law. We think the "object and purpose" of a treaty cannot be reasonably considered to constitute a "rule" of international law.

have said that if a rule of international law is not applicable to one of the Parties to this dispute, it is not applicable in the relations between all WTO Members. Therefore, in view of the fact that the United States is not a party to the *Convention on Biological Diversity*, we do not agree with the European Communities that we are required to take into account the *Convention on Biological Diversity* in interpreting the multilateral WTO agreements at issue in this dispute.

7.75 Turning to the *Biosafety Protocol*, we note that it entered into force only on 11 September 2003, *i.e.*, after this Panel was established by the DSB. Among the WTO Members parties to the *Biosafety Protocol* is the European Communities. Argentina and Canada have signed the *Biosafety Protocol*, but have not ratified it since.[252] Hence, they are not parties to it. The United States has not signed the *Biosafety Protocol*. While this does not preclude the United States from ratifying the *Protocol*, the United States has so far not done so.[253] Accordingly, it, too, is not a party to the *Biosafety Protocol*. We do not consider that the rules of the *Biosafety Protocol* can be deemed to be applicable to the United States merely because the United States participates in the Protocol's Clearing-House Mechanism. It follows that the *Biosafety Protocol* is not in force for Argentina, Canada or the United States.[254] We deduce from this that the *Biosafety Protocol* is not "applicable" in the relations between these WTO Members and all other WTO Members. As we have said above, in our view, the mere fact that WTO Members like Argentina and Canada have signed the *Biosafety Protocol* does not mean that the *Protocol* is applicable to them. In view of the fact that several WTO Members, including the Complaining Parties to this dispute, are not parties to the *Biosafety Protocol*, we do not agree with the European Communities that we are required to take into account the *Biosafety Protocol* in interpreting the multilateral WTO agreements at issue in this dispute.

(iii) Precautionary principle

7.76 We have stated earlier that, in our view, the relevant rules of international law to be taken into account include general principles of law. The European Communities contends that the so-called "precautionary principle" is a relevant principle of this kind, and so we address this issue below, after summarizing the Parties' arguments.

7.77 The **European Communities** states that certain GMOs present potential threats to human health and the environment. The European Communities submits that the existence of a potential threat justifies the assessment of risks on a case-by-case basis and special measures of protection based on the precautionary principle.

7.78 The European Communities asserts that the precautionary principle has by now become a fully-fledged and general principle of international law. According to the European Communities, the precautionary principle was first recognised in the *World Charter for Nature*, adopted by the UN General Assembly in 1982, and was subsequently incorporated into various international conventions on the protection of the environment. Furthermore, the *Rio Declaration* that concluded the 1992 Rio Conference on the Environment and Development codified an application of this principle in its Principle 15[255]. Since then, the *United Nations Framework Convention on Climate Change and the Convention of Biological Diversity* have referred to the precautionary principle. More recently, in the

[252] We have no information on whether Argentina and Canada have made their intentions clear after signing the 2000 Protocol as to whether they still wished to become a party to the 2000 Protocol.

[253] We have no information on whether the United States has made its intentions clear as to whether it wishes to become a party to the 2000 Protocol.

[254] We note that it is also not in force for several third parties to this dispute, including Australia, Chile, Honduras, Thailand and Uruguay. *See* http://www.biodiv.org/world/parties.asp.

[255] For the text of Principle 15 of the *Rio Declaration*, *see infra* footnote 263.

specific field of GMOs, the *Biosafety Protocol* has confirmed the key function of the precautionary principle in the decision to restrict or prohibit imports of GMOs in the face of scientific uncertainty.

7.79 The European Communities further points out that in many countries approval systems are based on the need to take precautionary action. As examples, the European Communities cites the Australian Gene Technology Act (2000), the Swiss GMO legislation and the New Zealand Hazardous Substances and New Organisms Act. Additionally, the European Communities notes that the precautionary principle is one of the "salutary principles which govern the law of the environment" in India and has been applied by the Indian Supreme Court.[256]

7.80 The **United States** argues that the European Communities has not identified how a "precautionary principle" would be of relevance to interpreting any particular provision of the *WTO Agreement*. Moreover, the United States notes that in the *EC – Hormones* dispute, the Appellate Body examined at length nearly identical arguments presented by the European Communities regarding the relationship between a purported "precautionary principle" and the *SPS Agreement*. The European Communities has not presented, and cannot argue, that any different results should apply here. The United States considers that as the Appellate Body found it unnecessary and imprudent in the *EC – Hormones* case to make a finding on the status of the precautionary principle in international law, the Panel should have no need to address this theoretical issue.

7.81 The United States nonetheless notes that it strongly disagrees that "precaution" has become a rule of international law. According to the United States, the "precautionary principle" cannot be considered a general principle or norm of international law because it does not have a single, agreed formulation. The United States notes in this regard that, on the contrary, the concept of precaution has many permutations across a number of different factors. Thus, the United States considers precaution to be an "approach", rather than a "principle" of international law.

7.82 Furthermore, the United States submits that if precaution is not a principle of international law, then it is *a fortiori* not a rule of customary international law. The United States submits that precaution does not fulfil any of the requirements to become a rule of customary international law for the following reasons: (i) it cannot be considered a "rule" because it has no clear content and therefore cannot be said to provide any authoritative guide for a State's conduct; (ii) it cannot be said to reflect the practice of States, as it cannot even be uniformly defined by those who espouse it; and (iii) given that precaution cannot be defined and, therefore, could not possibly be a legal norm, one could not argue that States follow it from a sense of legal obligation.

7.83 Finally, the United States argues that even if a precautionary principle were considered a relevant rule of international law under Article 31(3) of the *Vienna Convention*, it would be useful only for interpreting particular treaty terms, and could not override any part of the of the *SPS Agreement*.

7.84 **Canada** argues that while the *Biosafety Protocol* may reflect the "precautionary approach contained in Principle 15 of the *Rio Declaration*", the precautionary principle "finds reflection" in several provisions of the *SPS Agreement*, including Article 5.7. Canada notes that the Appellate Body in *EC – Hormones* has previously held that the precautionary principle cannot be invoked as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of the *SPS Agreement*.

[256] *See T.N. Godavarman Thirumalpad v. Union of India* (2002) 10 SCC 606.

7.85 **Argentina** states that the Appellate Body has addressed the status of this so-called "principle" of precaution in *EC – Hormones*.

7.86 The **Panel** notes the European Communities' contention that the precautionary principle has "by now" become a fully-fledged and general principle of international law. The European Communities has not explained exactly what it means by the term "general principle of international law". We note that this term may be understood as encompassing either rules of customary law or the recognized general principles of law or both.[257] Given this, we are prepared to consider whether the precautionary principle fits within either of these categories. This approach is consistent with the position taken by the European Communities in *EC – Hormones* where the European Communities contended on appeal that the precautionary principle was a general customary rule of international law or at least a general principle of law.[258]

7.87 In its report on *EC – Hormones*, the Appellate Body had this to say in response to the aforementioned contention by the European Communities:[259]

> "The status of the precautionary principle in international law continues to be the subject of debate among academics, law practitioners, regulators and judges. The precautionary principle is regarded by some as having crystallized into a general principle of customary international *environmental* law. Whether it has been widely accepted by Members as a principle of *general* or *customary international law* appears less than clear.[260] We consider, however, that it is unnecessary, and probably imprudent, for the Appellate Body in this appeal to take a position on this important, but abstract, question. We note that the Panel itself did not make any definitive finding with regard to the status of the precautionary principle in international law and that the precautionary principle, at least outside the field of international environmental law, still awaits authoritative formulation.[261]

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[257] *See, e.g.*, Ian Brierly, *Principles of Public International Law*, 5th ed. (Clarendon Press, 1998), pp. 18-19.

[258] Appellate Body Report, *EC – Hormones*, para. 121.

[259] *Ibid*., paras. 123-124.

[260] (*original footnote*) Authors like P. Sands, J. Cameron and J. Abouchar, while recognizing that the principle is still evolving, submit nevertheless that there is currently sufficient state practice to support the view that the precautionary principle is a principle of customary international law. See, for example, P. Sands, *Principles of International Environmental Law*, Vol. I (Manchester University Press 1995) p. 212; J. Cameron, "The Status of the Precautionary Principle in International Law", in J. Cameron and T. O'Riordan (eds.), *Interpreting the Precautionary Principle* (Cameron May, 1994) 262, p. 283; J.Cameron and J. Abouchar, "The Status of the Precautionary Principle in International Law", in D. Freestone and E. Hey (eds.), *The Precautionary Principle in International Law* (Kluwer, 1996) 29, p. 52. Other authors argue that the precautionary principle has not yet reached the status of a principle of international law, or at least, consider such status doubtful, among other reasons, due to the fact that the principle is still subject to a great variety of interpretations. See, for example, P. Birnie and A. Boyle, *International Law and the Environment* (Clarendon Press, 1992), p. 98; L. Gündling, "The Status in International Law of the Precautionary Principle" (1990), 5:1,2,3 *International Journal of Estuarine and Coastal Law* 25, p. 30; A. deMestral (et. al), *International Law Chiefly as Interpreted and Applied in Canada*, 5th ed. (Emond Montgomery, 1993), p. 765; D. Bodansky, in *Proceedings of the 85th Annual Meeting of the American Society of International Law* (ASIL, 1991), p. 415.

[261] (*original footnote*) In *Case Concerning the Gabcíkovo-Nagymaros Project (Hungary/Slovakia)*, the International Court of Justice recognized that in the field of environmental protection "... new norms and standards have been developed, set forth in a great number of instruments during the last two decades. Such new norms have to be taken into consideration, and such new standards given proper weight ...". However, we note that the Court did not identify the precautionary principle as one of those recently developed norms. It also

> It appears to us important, nevertheless, to note some aspects of the relationship of the precautionary principle to the *SPS Agreement*. First, the principle has not been written into the *SPS Agreement* as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of that Agreement. Secondly, the precautionary principle indeed finds reflection in Article 5.7 of the *SPS Agreement*. We agree, at the same time, with the European Communities, that there is no need to assume that Article 5.7 exhausts the relevance of a precautionary principle. It is reflected also in the sixth paragraph of the preamble and in Article 3.3. These explicitly recognize the right of Members to establish their own appropriate level of sanitary protection, which level may be higher (i.e., more cautious) than that implied in existing international standards, guidelines and recommendations. Thirdly, a panel charged with determining, for instance, whether "sufficient scientific evidence" exists to warrant the maintenance by a Member of a particular SPS measure may, of course, and should, bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned. Lastly, however, the precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation in reading the provisions of the *SPS Agreement*."

7.88 The Appellate Body made this statement in January 1998. It appears to us from the Parties' arguments and other available materials that the legal debate over whether the precautionary principle constitutes a recognized principle of general or customary international law is still ongoing. Notably, there has, to date, been no authoritative decision by an international court or tribunal which recognizes the precautionary principle as a principle of general or customary international law.[262] It is correct that provisions explicitly or implicitly applying the precautionary principle have been incorporated into numerous international conventions and declarations, although, for the most part, they are environmental conventions and declarations.[263] Also, the principle has been referred to and applied

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declined to declare that such principle could override the obligations of the Treaty between Czechoslovakia and Hungary of 16 September 1977 concerning the construction and operation of the Gabcíkovo/Nagymaros System of Locks. See, *Case Concerning the Gabcíkovo-Nagymaros Project (Hungary/Slovakia)*, I.C.J. Judgement, 25 September 1997, paras. 140, 111-114.

[262] We note that in the *Southern Bluefin Tuna Cases* brought before the International Tribunal for the Law of the Sea, two judges referred to the precautionary principle in their separate opinions. Judge Treves indicated understanding for "the reluctance of the Tribunal in taking a position as to whether the precautionary approach is a binding principle of customary international law", noting also that "[o]ther courts and tribunals, recently confronted with this question, have avoided to give an answer". Judge Laing considered that it was "not possible, on the basis of the materials available and arguments presented [...], to determine whether [...] customary international law recognizes a precautionary principle", adding that "treaties and formal instruments use different language of obligation; the notion is stated variously (as a principle, approach, concept, measures, action); no authoritative judicial decision unequivocally supports the notion; doctrine is indecisive; and domestic juridical materials are uncertain or evolving". International Tribunal for the Law of the Sea, *Southern Bluefin Tuna Cases* (*New Zealand v. Japan*; *Australia v. Japan*) *(Requests for Provisional Measures)*, 1999, para. 9 (Separate Opinion of Judge Treves) and para. 16 (Separate Opinion of Judge Laing).

[263] We note, by way of example, Principle 15 of the 1992 *Rio Declaration on Environment and Development*:

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

by States at the domestic level, again mostly in domestic environmental law.[264] On the other hand, there remain questions regarding the precise definition and content of the precautionary principle.[265] Finally, regarding doctrine, we note that many authors have expressed the view that the precautionary principle exists as a general principle in international law.[266] At the same time, as already noted by the Appellate Body, others have expressed scepticism and consider that the precautionary principle has not yet attained the status of a general principle in international law.[267]

7.89 Since the legal status of the precautionary principle remains unsettled, like the Appellate Body before us, we consider that prudence suggests that we not attempt to resolve this complex issue, particularly if it is not necessary to do so. Our analysis below makes clear that for the purposes of

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> We also note preambular paragraph 9 of the *Convention on Biological Diversity*, which states:
>
> Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat.
>
> Finally, we note the *Biosafety Protocol*, which states in Article 1:
>
> In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.
>
> Furthermore, Article 10(6) of the *Protocol* states:
>
> Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.

[264] We note, for instance, the European Communities' reference to a decision of the Indian Supreme Court. Another example is provided by Article 1(6) of Colombia's Law 99 of 1993, which provides that "[i]n formulating environmental policy, account shall be taken of the results of the scientific investigation process. However, the environmental authorities and individuals shall apply the precautionary principle according to which, where there are threats of serious and irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" (Panel's translation from Spanish).

[265] This point was made, for instance, by Judge Laing in his previously mentioned separate opinion in the *Southern Bluefin Tuna Cases*.

[266] *See, e.g.*, O. McIntyre/T. Mosedale, "The Precautionary Principle as a Norm of Customary International Law", *Journal of Environmental Law* 9 (1997), pp. 222-223; J. Cameron/W. Wade-Gery/J. Abouchar, "Precautionary Principle and Future Generations", in E. Agius *et al.* (eds.), *Future Generations and International Law*, London, 1998, p. 96; P. Sands, *Principles of International Environmental Law*, 2nd ed. (Cambridge University Press, 2003), p. 279.

[267] *See, e.g.*, L. M. Jurgielewicz, *Global Environmental Change and International Law* (Lanham, 1996), p. 64; P.-M. Dupuy, "Où en est le droit international de l'environnement à la fin du siècle?", *Revue Générale de Droit International Public* 4 (1997), pp. 889-890; J. O. McGinnis, "The Appropriate Hierarchy of Global Multilateralism and Customary International Law: The Example of the WTO", *Virginia Journal of International Law* 44 (2003), pp. 260-261.

disposing of the legal claims before us, we need not take a position on whether or not the precautionary principle is a recognized principle of general or customary international law. Therefore, we refrain from expressing a view on this issue.

(b) Other rules of international law as evidence of the ordinary meaning of terms used in a treaty

7.90 Up to this point, we have examined whether there are other applicable rules of international law which we are required to take into account, in accordance with Article 31(3)(c) of the *Vienna Convention*, in interpreting the WTO agreements at issue in this dispute. We now turn to examine whether other rules of international law could be considered by us in the interpretation of the WTO agreements at issue even if these rules are not applicable in the relations between the WTO Members and thus do not fall within the category of rules which is at issue in Article 31(3)(c).

7.91 The **European Communities** notes in this regard that in *US – Shrimp* the Appellate Body interpreted WTO rules by reference to treaties which were not binding on all parties to the proceedings. More specifically, the European Communities points out that the Appellate Body in that case invoked treaties in support of arguments made by the United States, even though the United States had either not signed or not ratified these treaties. The European Communities notes that one such treaty was the *Convention on Biological Diversity*.

7.92 The **Panel** recalls that pursuant to Article 31(1) of the *Vienna Convention*, the terms of a treaty must be interpreted in accordance with the "ordinary meaning" to be given to these terms in their context and in the light of its object and purpose. The ordinary meaning of treaty terms is often determined on the basis of dictionaries. We think that, in addition to dictionaries, other relevant rules of international law may in some cases aid a treaty interpreter in establishing, or confirming, the ordinary meaning of treaty terms in the specific context in which they are used.[268] Such rules would not be considered because they are legal rules, but rather because they may provide evidence of the ordinary meaning of terms in the same way that dictionaries do.[269] They would be considered for their informative character. It follows that when a treaty interpreter does not consider another rule of international law to be informative, he or she need not rely on it.

7.93 In the light of the foregoing, we consider that a panel may consider other relevant rules of international law when interpreting the terms of WTO agreements if it deems such rules to be informative. But a panel need not necessarily rely on other rules of international law, particularly if it considers that the ordinary meaning of the terms of WTO agreements may be ascertained by reference to other elements.

7.94 This approach is consistent with the Appellate Body's approach in *US – Shrimp*, as we understand it. In that case, the Appellate Body had to interpret the term "exhaustible natural resources" in Article XX(g) of the GATT 1994. The Appellate Body found that this term was by definition evolutionary and therefore found it "pertinent to note that modern international conventions and declarations make frequent references to natural resources as embracing both living and non-

[268] It is useful to note in this context that the Appellate Body has stated that "dictionaries are important guides to, not dispositive statements of, definitions of words appearing in agreements and legal documents". Appellate Body Report, *US – Offset Act (Byrd Amendment)*, para. 248.

[269] A treaty interpreter would have to keep in mind, of course, that other rules of international law may be negotiated rules and, as such, may assign meanings to particular terms which may not be reflective of the ordinary meaning of those terms. We note that this possibility is recognized in Article 31(4) of the *Vienna Convention*, which states that "[a] special meaning shall be given to a term if it is established that the parties so intended".

living resources".[270] Thus, as we understand it, the Appellate Body drew on other rules of international law because it considered that they were informative and aided it in establishing the meaning and scope of the term "exhaustible natural resources".[271] The European Communities correctly points out that the Appellate Body referred to conventions which were not applicable to all disputing parties. However, the mere fact that one or more disputing parties are not parties to a convention does not necessarily mean that a convention cannot shed light on the meaning and scope of a treaty term to be interpreted.[272]

7.95 In the present case, in response to a question from the Panel[273], the European Communities has identified a number of provisions of the *Convention on Biological Diversity* and of the *Biosafety Protocol* which it considers must be taken into account by the Panel.[274] The European Communities has not explained how these provisions are relevant to the interpretation of the WTO agreements at issue in this dispute. We have carefully considered the provisions referred to by the European Communities. Ultimately, however, we did not find it necessary or appropriate to rely on these particular provisions in interpreting the WTO agreements at issue in this dispute.

7.96 Furthermore, we recall that after consulting the Parties, we have requested several international organizations (Codex, FAO, the IPPC Secretariat, WHO, OIE, the CBD Secretariat and UNEP) to identify materials (reference works, glossaries, official documents of the relevant international organizations, including conventions, standards and guidelines, etc.) that might aid us in determining the ordinary meaning of certain terms used in the definitions provided in Annex A to the *SPS Agreement*. The materials we have obtained in this way have been taken into account by us, as appropriate.

B. OVERVIEW OF MEASURES AT ISSUE

7.97 In this section, we provide an overview of the measures at issue in this dispute. We have pointed out earlier that the three Complaining Parties in this dispute have filed legally separate complaints, but that each of these complaints relates to the same matter and that the DSB therefore decided to have them examined by a single panel.

7.98 The specific measures which are being contested in each complaint are indeed quite similar. As the case name suggests, the measures at issue in all three complaints are certain EC measures affecting the approval and marketing of biotech products. More specifically, the Complaining Parties are each challenging three identical categories of EC measures. The categories in question are:

(i) the alleged general EC moratorium on approvals of biotech products (hereafter the "general EC moratorium");

(ii) various product-specific EC measures affecting the approval of specific biotech products (hereafter the "product-specific EC measures"); and

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[270] Appellate Body Report, *US – Shrimp*, para. 130.

[271] We note that the Appellate Body did not suggest that it was looking to other rules of international law because it was required to do so pursuant to the provisions of Article 31(3)(c) of the *Vienna Convention*. Indeed, the Appellate Body did not even mention Article 31(3)(c).

[272] Equally, in a case where all disputing parties are parties to a convention, this fact would not necessarily render reliance on that convention appropriate.

[273] Panel question No. 4.

[274] The European Communities refers to the Preamble and Article 8(g) of the *Convention on Biological Diversity* and Articles 1, 8, 10, 11, 15, 23, 26 and Annex III of the *Biosafety Protocol*.

(iii) various EC member State safeguard measures prohibiting the import and/or marketing of specific biotech products (hereafter the "member State safeguard measures").

7.99 In respect of the first category – the alleged general EC moratorium – we note that it is the only category which consists of one single alleged measure. The Complaining Parties use slightly different language to describe the specific measure at issue, but, as we explain in the relevant section below, we consider that the Complaining Parties are in fact challenging one and the same measure.

7.100 With regard to the second category – the product-specific EC measures – we note that, according to the Complaining Parties, the measures falling within this category are distinct from, albeit related to, the alleged general EC moratorium. As we explain in the relevant section below, the Complaining Parties have defined the measures at issue differently. However, what characterizes each of these measures is that it relates to one specific biotech product, or to be more accurate, an approval procedure concerning a specific biotech product. A total of thirty different products are at issue in this category of measures. In a number of cases, two Complaining Parties are challenging a (differently defined) measure which concerns the same biotech product. But in no case are all three Complaining Parties challenging a measure which concerns the same product.

7.101 Concerning the third category – the member State safeguard measures – we note that this category consists of nine distinct measures taken by six different EC member States, namely, Austria, France, Germany, Greece, Italy and Luxembourg. The Complaining Parties are each challenging a different number of safeguard measures. However, each member State safeguard measure is being challenged by more than one Complaining Party, and two of them are being challenged by all three Complaining Parties. It is important to note that even though the member State safeguard measures were introduced by the relevant member States and are applicable only in the territory of the member States concerned, the European Communities as a whole is the responding party in respect of the member State safeguard measures. This is a direct consequence of the fact that the Complaining Parties have directed their complaints against the European Communities, and not individual EC member States.[275] The European Communities never contested that, for the purposes of this dispute, the challenged member State measures are attributable to it under international law and hence can be considered EC measures. Indeed, it was the European Communities – and it alone – that defended the contested member State safeguard measures before the Panel.[276]

7.102 We address the three categories of measures at issue in this dispute in separate sections below. Thus, in Section D, we examine the alleged general EC moratorium. In Section E, we examine the various product-specific EC measures. Finally, in Section F, we examine the various member State safeguard measures.

C. RELEVANT EC APPROVAL PROCEDURES

7.103 This section describes and analyses the relevant EC procedures for the approval of EC-wide marketing of biotech products. It is useful to do so at the outset, as these procedures are relevant to all

[275] A similar situation has previously arisen in the panel proceedings concerning *EC – Asbestos*, where the European Communities was the responding party, although the measure at issue was being maintained by one member State, namely, France. Panel Report, *EC – Asbestos*, paras. 2.3 and 3.4.

[276] It should be pointed out, however, that representatives of the relevant member States were part of the EC delegations present at the substantive meetings of the Panel with the Parties. Furthermore, as part of its defence of the member State safeguard measures, the European Communities submitted numerous documents which it had obtained from the member States concerned.

three categories of measures which are being challenged by the Complaining Parties. Initially, we provide a factual description of the specific approval procedures at issue in this dispute. We first place them in their historical context, by showing how the EC regime for the approval of biotech products has evolved over time. Then we explain, by reference to the relevant EC legislation, the various stages of the approval procedures at issue. Thereafter, we proceed to a legal analysis of these procedures. It is important to note in this respect that the Complaining Parties are not challenging these procedures as such. What the Complaining Parties are challenging is the European Communities' application of these procedures. In order to assess the legal merits of this challenge, we need to examine, as a threshold matter, whether the WTO agreement on which the Complaining Parties are primarily basing their challenge – the *SPS Agreement* – is applicable to each of these procedures. The European Communities argues that at least in part these procedures fall outside the scope of the *SPS Agreement*.

1. Evolution of the EC regime for the approval of biotech products

7.104 The European Communities' legal regime for the approval of the marketing of biotech products has changed over time, including while these Panel proceedings were ongoing. Since this evolution of the EC approval regime is of some importance in the present dispute, we set out below, in the form of a table, relevant dates and legislative milestones.

Evolution of the EC approval regime for biotech products	
23 April 1990	Adoption of Council Directive 90/220 "on the deliberate release into the environment of genetically modified organisms".
23 October 1991	Entry into force of Council Directive 90/220.
27 January 1997	Adoption of Regulation 258/97 "concerning novel foods and novel food ingredients".
15 May 1997	Entry into force of Regulation 258/97.
23 February 1998	Commission proposal for a European Parliament and Council Directive amending Directive 90/220.
24 and 25 June 1999	2194th Environment Council meeting: Common Position, agreed by the Council on the Commission proposal for a directive amending Directive 90/220, by which the Council reached a political consensus on a number of issues which were still outstanding in the draft legislative text.[277]
12 March 2001	Adoption of Directive 2001/18 of the European Parliament and of the Council "on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC".
17 April 2001	Entry into force of Directive 2001/18.
25 July 2001	Commission proposal for a Regulation of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from

[277] In response to a question from the Panel, the European Communities has explained that in the EC legislative process, a common position of the Council is a political decision by the Council which intervenes after the European Parliament has expressed its opinion on a Commission legislative proposal. It reflects the Council's position on those elements of the European Parliament's opinion with which the Council disagrees and which it cannot approve. *See* the EC reply to Panel question No. 93, Annex D.

Evolution of the EC approval regime for biotech products	
	genetically modified organisms and amending Directive 2001/18.
17 October 2002	Repeal of Council Directive 90/220.
22 September 2003	Adoption of Regulation 1829/2003 of the European Parliament and of the Council "on genetically modified food and feed". Adoption of Regulation 1830/2003 of the European Parliament and of the Council "concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC".
7 November 2003	Entry into force of Regulation 1829/2003, applying as of 18 April 2004. Entry into force of Regulation 1830/2003.

7.105 In connection with the above table, it is useful to recall that it was on 13 May 2003 that the United States and Canada formally initiated the present dispute settlement proceedings by requesting consultations with the European Communities.[278] Argentina requested consultations with the European Communities on 14 May 2003.[279] The United States, Canada and Argentina each requested the establishment of a panel on 7 August 2003.[280] A single panel was established by the DSB on 29 August 2003.[281] The composition of this Panel was determined and announced on 4 March 2004.[282]

2. Description of the relevant EC approval procedures

7.106 For the purposes of this dispute, the legal instruments of primary relevance are those which were in force on or before the date of establishment of this Panel, *i.e.*, on 29 August 2003. They are:

(a) Directive 90/220/EEC (hereafter "Directive 90/220")[283] "on the deliberate release into the environment of genetically modified organisms" (repealed on 17 October 2002),

(b) Directive 2001/18 (hereafter "Directive 2001/18")[284] "on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC",

(c) Regulation 258/97 (hereafter "Regulation 258/97")[285] "concerning novel foods and novel food ingredients".[286]

[278] WT/DS291/1 and WT/DS292/1, respectively.
[279] WT/DS293/1.
[280] WT/DS291/23, WT/DS292/17 and WT/DS293/17, respectively.
[281] WT/DSB/M/155.
[282] WT/DS291/24, WT/DS292/18 and WT/DS293/18.
[283] Published in OJ of the EC N° L 117 of 08.05.1990, p. 15.
[284] Published in OJ of the EC N° L 106 of 17.04.2001, p. 1.
[285] Published in OJ of the EC N° L 43 of 14.02.1997, p. 1.
[286] Under EC law, directives are legislative acts that need to be implemented by EC member States through national legislation. By contrast, regulations are directly applicable in all EC member States and do not require any national implementing legislation.

7.107 Below we provide a brief factual description of Directives 90/220 and 2001/18 as well as Regulation 258/97. We begin with Directives 90/220 and 2001/18.

(a) Deliberate release into the environment of genetically modified organisms: Directives 90/220 and 2001/18

7.108 A fundamental purpose of Directives 90/220 and 2001/18 is to avoid adverse effects on human health and the environment which might arise from the deliberate release into the environment of products consisting of, or containing, genetically modified organisms (hereafter "GMOs"). In the present dispute, Directives 90/220 and 2001/18 are relevant to the extent they regulate the deliberate release of GMOs for placing on the market as or in products.[287]

7.109 Directives 90/220 and 2001/18 lay down administrative procedures for granting consents for the placing on the market of GMOs as or in products. In line with the fact that Directive 2001/18 is a revised version of Directive 90/220, the administrative procedure laid down by Directive 2001/18 has been made more efficient. However, there are more similarities between the two administrative procedures than differences, and so in our description below we deal with them together, while noting important differences. Since the administrative procedures set out in Directives 90/220 and 2001/18 are multi-stage procedures, we have structured our description according to the main procedural stages.

7.110 We note that at the request of the Panel, the European Communities has provided flow charts which illustrate the administrative procedures as described below. These flow charts are reproduced in Annexes A-1 and A-2.

(i) Submission of application by applicant

7.111 Before a GMO as or in a product may be placed on the EC market, the manufacturer or importer of the product (hereafter the "applicant") must submit a notification (hereafter "application") and accompanying dossier to the competent authority of the member State where such a GMO is to be placed on the market for the first time (hereafter the "lead CA").[288] The application and the dossier must include specified information, such as information about the applicant, the nature of the GMO, the commercial names to be used, the intended uses of the product, proposals for labelling or for restrictions on use, and an assessment of any risks for human health and the environment related to the GMO.[289]

(ii) Assessment by lead CA

7.112 On receipt and after acknowledgement of the application, the lead CA must examine the application for compliance with the Directive. To that end, within 90 days after receipt of the application, the lead CA must prepare an assessment report.[290] For the purposes of calculating the 90-day period, any periods of time during which the lead CA is awaiting further information which it may have requested from the applicant shall not be taken into account. If the lead CA's assessment

[287] The deliberate release for research and development purposes, while covered by the Directives, is not at issue in this dispute.
[288] Articles 5 and 11 of Directive 90/220 and Articles 6 and 13 of Directive 2001/18.
[289] Article 11(1) of Directive 90/220 and Article 13(2) and Annexes II, III and IV of Directive 2001/18.
[290] Article 12(1) and (2) of Directive 90/220 and Article 14(1) and (2) of Directive 2001/18.

report concludes that a GMO should not be placed on the market, it rejects the application by a decision that states the reasons, and the procedure is ended.[291]

(iii) Circulation of lead CA assessment report to other member States for comments

7.113 In cases where the lead CA's assessment report concludes that a GMO may be placed on the market, the procedure moves on to the Community level. The lead CA submits the application together with the assessment report to the European Commission (hereafter the "Commission"), which must forward it to the competent authorities (hereafter the "CAs") of all other EC member States.[292] Within a period of 60 days from the date of circulation of the assessment report, a CA of another member State and, in the case of Directive 2001/18, the Commission, may ask for further information, make comments or present reasoned objections to the placing on the market of the GMO in question.

7.114 In the absence of any reasoned objection from the CA of a member State, or in the case of Directive 2001/18, the Commission, within 60 days following the date of circulation of the assessment report, the lead CA must give its consent in writing for placing on the market.[293] Under Directive 2001/18, in cases where the CA of another member State or the Commission raises a reasoned objection, the member States and the Commission may take an additional 45-day period to discuss any outstanding issues with the aim of arriving at an agreement. If outstanding issues are resolved within the prescribed period, the lead CA must give its consent for placing on the market.[294]

(iv) Community-level procedure in case of objections

7.115 In cases where the CA of another member State or, in the case of Directive 2001/18, the Commission, maintains a reasoned objection, the decision on whether to approve the application must be taken at Community level.[295] To that end, the Commission must prepare a draft measure. The Commission begins this process by consulting the relevant EC scientific committee with respect to the objection(s).[296] Once the Commission has prepared a draft measure taking into account the opinion of the relevant EC scientific committee, it must submit it to the appropriate "Regulatory Committee" for a vote.

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[291] Article 12(2)(b) of Directive 90/220 and Articles 14(3)(b) and 15(2) of Directive 2001/18.

[292] Article 13(1) of Directive 90/220 (providing that the Commission must forward the assessment report "immediately") and Article 14(2) of Directive 2001/18, (providing that the Commission must forward the assessment report within 30 days of its receipt).

[293] Article 13(2) of Directive 90/220 and Article 15(3) of Directive 2001/18.

[294] Articles 15(1) and (3) of Directive 2001/18. We note that in accordance with Article 15(1) any periods of time during which further information from the applicant is awaited are not to be taken into account for the purpose of calculating the 45-day period.

[295] Article 13(3) of Directive 90/220 and Articles 18(1) and 30(2) of Directive 2001/18. Article 18(1) of Directive 2001/18 specifies that a decision must be adopted and published within 120 days. For the purposes of calculating the 120-day period, any period of time during which the Commission is awaiting further information which it may have requested from the applicant or is seeking the opinion of an EC scientific committee will not be taken into account.

[296] Under Directives 2001/18 and 90/220, the relevant scientific committee was the Scientific Committee for Plants ("SCP"). The SCP has been replaced by the scientific panel on genetically modified organisms established by the European Food Safety Authority (the "EFSA") which was created pursuant to *Regulation 178/2002*. We note that Article 28 of Directive 2001/18 requires that the Commission consult the scientific committee in case an objection is maintained. According to Article 18(1) of Directive 2001/18, the period of time the Commission is waiting for the scientific committee opinion is not to exceed 90 days. Under Directive 90/220, the Commission was not required to do so, but generally chose to do so.

7.116 The Regulatory Committee is composed of representatives of the member States and chaired by a representative of the Commission.[297] The Regulatory Committee must deliver its opinion on the draft measure within a time limit which the chairman may lay down according to the urgency of the matter.[298] The Regulatory Committee delivers opinions by qualified majority vote. The Commission must adopt the draft measures envisaged if they are in accordance with the opinion of the Regulatory Committee. If the measures envisaged are not in accordance with the opinion of the Regulatory Committee, or if no opinion is delivered, the Commission must, without delay, submit to the Council of Ministers (hereafter the "Council") a proposal relating to the measures to be taken.[299]

7.117 The Council can either adopt or reject the Commission's draft measure by a qualified majority.[300] In either case, it must act within a time-period which shall in no case exceed three months from the date of referral to the Council.[301] If the Council has not acted within that time-period, the Commission must adopt the draft measure it has submitted to the Council.[302]

(v) Member State consent to placing on the market

7.118 Where a favourable decision has been taken at the Community level, whether by the Commission on the basis of a favourable opinion by the Regulatory Committee, by the Council after the submission of a proposal by the Commission, or by the Commission in the event the Council does not act within three months from the date of referral, the lead CA must give consent in writing to the placing on the market of the GMO as or in a product concerned. Such consent is transmitted to the applicant, and the other member States and the Commission must be informed thereof.[303] Once the applicant has received the written consent of the lead CA, it may proceed with the placing on the market. The approved product may be used without further application throughout the Community, subject to any conditions specified in the written consent.[304]

(vi) Transition from Directive 90/220 to Directive 2001/18: Pending applications

7.119 As indicated previously, Directive 90/220 was repealed on 17 October 2002, and EC member States had to implement Directive 2001/18 by the same date. Directive 2001/18 addresses the issue of applications submitted under Directive 90/220 but still pending on 17 October 2002. Thus, Directive 2001/18 makes clear that applications received pursuant to Directive 90/220 and in respect of which the procedures of Directive 90/220 were not completed by 17 October 2002 became subject to the provisions of Directive 2001/18. Furthermore, applicants had until 17 January 2003 to

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[297] Regulatory Committees have their origin in Article 202 of the EC Treaty and act on the basis of Article 5 of Council Decision 1999/468/EC. They assist the Commission in the exercise of the powers delegated to it by the Council for the implementation of its acts.

[298] Article 21 of *Directive 90/220* and Article 30(2) of Directive 2001/18 (referring to Articles 5 and 7 of *Council Decision 1999/468*).

[299] *Ibid*.

[300] Pursuant to Article 148(2) of the *Treaty Establishing the European Community as Amended by Subsequent Treaties*, in force at the time of establishment of this Panel, a qualified majority requires at least 62 votes in favour out of a total of 86 votes. For further details, *see* footnote 580. The Council can also modify the draft measure, albeit by unanimous vote only. Article 250(1) of the *Treaty Establishing the European Community as Amended by Subsequent Treaties*.

[301] According to Article 18(1) of Directive 2001/18, the period of time the Council takes to act is not be taken into account in calculating the 120-day period laid down in Article 18(1).

[302] Article 21 of Directive 90/220 and Article 30(2) of Directive 2001/18 (referring to Articles 5 and 7 of *Council Decision 1999/468*).

[303] Article 13(4) of Directive 90/220 and Article 18(2) of Directive 2001/18.

[304] Article 13(5) of Directive 90/220 and Article 19(1) and (2) 2001 of Directive 2001/18.

complement their applications in accordance with Directive 2001/18.[305] According to the European Communities, this means that pending applications only needed to be updated (complemented), not re-submitted in their entirety. The European Communities has further stated that the new information submitted in relation to the pending applications required a new assessment under the provisions of Directive 2001/18. Thus, irrespective of the procedural stage reached by an application under Directive 90/220, the updated application had to go through all procedural stages provided for in Directive 2001/18, beginning with the initial assessment by the lead CA. However, according to the European Communities, any results and conclusions reached under the procedures of Directive 90/220 on the basis of the then-existing data and information were in principle still relevant under the procedures of Directive 2001/18 and hence did not need to be re-examined.

(vii) Safeguard measures by individual member States

7.120 Where a GMO used as or in a product has been approved for Community-wide marketing under Directives 90/220 or 2001/18, member States ordinarily may not prohibit or restrict trade in, or use of, that product on their respective territories, provided the conditions attached to the marketing approval are being met. Exceptionally, however, member States may provisionally adopt safeguard measures which prohibit or restrict trade in, or use of, biotech products which have been granted Community-wide marketing approval.

7.121 Pursuant to Article 16 of Directive 90/220, a member State may provisionally restrict or prohibit the use and or sale of a product in its territory where it has "justifiable reasons to consider that a product which has been properly notified and has received written consent [...] constitutes a risk to human health or the environment". Article 23 of Directive 2001/18 provides that a safeguard measure may be adopted where, "as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge", a member State has "detailed grounds for considering that a GMO as or in a product [...] constitutes a risk to human health or the environment [...]".

7.122 The safeguard measures taken pursuant to Directives 90/220 and 2001/18 can be maintained only on a provisional basis, pending a full assessment at EC level.[306] The member State adopting a safeguard measure must immediately inform the Commission and other member States of its measure.[307] Upon notification of the safeguard measure, the Commission must take a decision with respect to that measure. Such decision will result either in the modification of the Community-wide marketing approval, or in the termination of the safeguard measure.[308]

7.123 According to the procedure laid down in the relevant provisions of Directives 90/220 and 2001/18, the Commission, when making a decision on a safeguard measure which has been notified, is assisted for this purpose by the Regulatory Committee.[309] The Commission must submit a draft of the measure to be taken to the Regulatory Committee, which shall deliver its opinion on the draft.[310] If the draft measure is in accordance with the opinion of the Regulatory Committee or the Standing

[305] Article 35 of Directive 2001/18.

[306] Article 16(1) of Directive 90/220 and Article 23(1), 3rd paragraph of Directive 2001/18.

[307] Article 16(1) of Directive 90/220 and Article 23(1), 3rd paragraph of Directive 2001/18.

[308] Article 21 of Directive 90/220. Under Directive 90/220, such a decision by the Commission must be taken within a period of three months from the time of notification of the measure.

[309] Articles 21 of Directive 90/220 and 30(2) of Directive 2001/18.

[310] Article 21 of Directive 90/220 and Article 30(2) of Directive 2001/18. Article 30(2) of Directive 2001/18 refers to Articles 5, 7 and 8 of Decision 1999/468. According to the European Communities these provisions are similar to Article 21 of Directive 90/220.

Committee on Foodstuffs, the Commission must adopt the draft measure. However, if the measure is not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission must submit a proposal to the Council on the measure to be taken. The Council must act on the proposal within a period of three months, failing which the Commission must adopt the proposed measure.[311]

(viii) Availability under EC and member State law of procedures for administrative and judicial review

7.124 To the extent that an applicant requesting the approval of a biotech product under Directives 90/220 and 2001/18 is dissatisfied with any act or failure to act by a national authority of a member State or of a Community institution, it has the possibility to seek administrative or judicial review of such acts or omissions at the member State and/or Community level. The law of each member State provides for administrative and/or judicial review of acts or omissions relating to the application at the national level. At Community level, Articles 230 and 232 of the EC Treaty provide that the European Court of Justice has jurisdiction to review the legality of acts, or of the failure to act, by the European Commission.

7.125 The European Communities has stated before the Panel that, in respect of the biotech products which are the subject of these proceedings, it is aware of only one instance where legal proceedings were brought at member State level. Those proceedings concerned a safeguard measure introduced by Italy pursuant to Regulation 258/97. According to the European Communities, no applications have been made to the European Court of Justice challenging any actions, or an alleged failure to act, by the Community institutions in respect of any of the relevant biotech products.

(b) Novel foods and novel food ingredients: Regulation 258/97

7.126 We now turn to address Regulation 258/97. Regulation 258/97 concerns the placing on the market of products to be used as a novel food or a novel food ingredient. These products include foods and food ingredients containing or consisting of GMOs within the meaning of Directives 90/220 and 2001/18. They also include foods and food ingredients produced from, but not containing, GMOs.

7.127 A fundamental purpose of Regulation 258/97 is to ensure that the covered novel foods and food ingredients: (1) not present a danger for the consumer; (2) not mislead the consumer; and (3) not differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous to the consumer.

7.128 Applications for the placing on the market of foods and food ingredients containing or consisting of GMOs are assessed under Regulation 258/97 only. However, where an application concerns a product containing, or consisting of, a GMO and that product is intended for use as food as well as for feed and for cultivation, the application is assessed under Regulation 258/97 in relation to its use as food and under Directive 90/220 or Directive 2001/18 in relation to its use as feed and in relation to cultivation.[312]

7.129 Regulation 258/97 lays down administrative procedures for granting authorizations for the placing on the market of the products at issue in this dispute, *i.e.*, foods and food ingredients containing or consisting of GMOs. These administrative procedures are similar to those described

[311] Article 21 of Directive 90/220 and Article 30 of Directive 2001/18.
[312] Article 9(2) of Regulation 258/97.

above for Directives 2001/18 and 90/220. Our description of the procedures laid down in Regulation 258/97 has been structured according to the main procedural stages.

7.130 As with Directives 90/220 and 2001/18, the European Communities has provided flow charts which illustrate the administrative procedures as described below. These flow charts are reproduced in Annex A-3.

(i) Submission of application by applicant

7.131 Before foods containing or consisting of GMOs may be placed on the EC market, the applicant must submit a request (hereafter "application") and accompanying dossier to the CA of the member State where such a product is to be placed on the market for the first time, *i.e.*, the lead CA.[313] The application must contain the necessary information, including the studies and materials which are available to demonstrate that the food complies with the following requirements: (1) that the food not present a danger for the consumer; (2) that it not mislead the consumer; and (3) that it not differ from foods or food ingredients which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous to the consumer.[314] In addition, the application must contain an appropriate proposal for labelling, in accordance with the requirements of Regulation 258/97, of the relevant food.[315] Where the food contains or consists of a GMO, the application must be accompanied by the information required under Directive 90/220 and Directive 2001/18, including the environmental risk assessment.[316]

(ii) Assessment by lead CA

7.132 Upon receipt of the application, the lead CA is to prepare an initial assessment report within a period of three months from receipt of the application. The assessment report must determine whether the application complies with the relevant requirements and is in accordance with the Commission's published recommendations.[317] The assessment report must also decide whether or not an additional assessment is required.[318]

(iii) Circulation of lead CA assessment report to other member States for comments

7.133 Upon completion of its assessment report, the lead CA must, without delay, forward it to the Commission, which in turn must forward it to the other member States. Within a period of 60 days from the date of circulation of the report by the Commission, a member State or the Commission may make comments or present a reasoned objection to the marketing of the food concerned. Comments or objections shall be forwarded to the Commission, which shall circulate them to member States within the 60-day period.[319]

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[313] Article 4(1) of Regulation 258/97.
[314] Articles 6(1) and 3(1) of Regulation 258/97.
[315] Article 8 of Regulation 258/97.
[316] Article 9 of Regulation 258/97.
[317] Article 6(2) and 6(3) of Regulation 258/97. Also Commission Recommendation of 29 July 1997 "concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under *Regulation No 258/97*".
[318] *Ibid*.
[319] Article 6(4) of Regulation 258/97.

7.134 If the lead CA's assessment report reaches the conclusion that no additional assessment is required, and no reasoned objection has been presented by another member State or the Commission, the lead CA must inform the applicant, without delay, that the food may be placed on the market.[320]

(iv) Community procedure in case an additional assessment is required or an objection is raised

7.135 If the lead CA's assessment report reaches the conclusion that an additional assessment is required, or a reasoned objection has been raised by another member State or the Commission, an authorization decision is to be taken at Community level.[321] To that end, the Commission must prepare a draft measure. The Commission ordinarily begins this process by consulting the relevant EC scientific committee – the Scientific Committee for Food (the "SCF").[322] Once the Commission has prepared a draft measure taking into account the opinion of the SCF, it must submit it to the appropriate Regulatory Committee, the so-called Standing Committee for Foodstuffs for a vote.[323] The Standing Committee for Foodstuffs must deliver its opinion on the Commission's draft measure within a time limit which the Chairman may lay down according to the urgency of the matter. The Standing Committee for Foodstuffs delivers opinions by qualified majority vote. The Commission must adopt the draft measure envisaged if it is in accordance with the opinion of the Standing Committee for Foodstuffs. If the draft measure envisaged is not in accordance with the opinion of the Standing Committee for Foodstuffs, or if no opinion is delivered, the Commission must, without delay, submit to the Council a proposal relating to the measures to be taken.[324]

7.136 The Council can either adopt or reject the Commission's draft measure by a qualified majority.[325] In either case, it must act within a time-period which shall in no case exceed three months from the date of referral to the Council. If the Council has not acted within that time-period, the Commission must adopt the draft measure it has submitted to the Council.[326]

7.137 The Commission must without delay inform the applicant of the decision taken at Community level, which will be published in the Official Journal of the European Communities.[327]

(v) Simplified Procedure

7.138 It should be noted that for novel foods which are "substantially equivalent" to existing foods, Regulation 258/97 provides for a simplified procedure.[328] This includes food products which are produced from, but do not contain, GMOs. "Substantial equivalence" can be demonstrated in two ways: (1) by relying on scientific evidence available and generally recognized or (2) by relying on an opinion delivered by one of the competent food assessment bodies of the member States.[329] In the case of substantially equivalent novel foods, the applicant must "notify" the Commission of the

[320] Article 4(2) of Regulation 258/97.
[321] Article 7 of Regulation 258/97.
[322] Article 11 of Regulation 258/97. Since the entry into force of Regulation 178/2002, the tasks of the SCF have been entrusted to the EFSA.
[323] Article 13(1) of Regulation 258/97.
[324] Articles 13(3) and 13(4) of Regulation 258/97.
[325] The Council may also modify the draft measure, although by unanimous vote only. Article 250(1) of the EC Treaty.
[326] Article 13(4) of Regulation 258/97.
[327] Article 7(3) of Regulation 258/97.
[328] Article 5 of Regulation 258/97.
[329] Article 3(4) of Regulation 258/97.

placing on the market when it does so. Then, the Commission forwards to the member States, within 60 days, a copy of the application.[330]

(vi) Safeguard measures by individual member States

7.139 As with Directives 90/220 or 2001/18, where a biotech product has been approved for Community-wide marketing under Regulation 258/97, member States ordinarily may not prohibit or restrict trade in, or use of, that product on their respective territories, provided the conditions attached to the marketing approval are being met. However, Article 12 of Regulation 258/97 provides that a safeguard measure may be adopted where, "as a result of new information or a reassessment of existing information", a member State has "detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment [...]".

7.140 The safeguard measures taken pursuant to Regulation 258/97 can be maintained only on a provisional basis, pending a full assessment at EC level.[331] The member State adopting a safeguard measure must immediately inform the Commission and other member States of its measure.[332] Upon notification of the safeguard measure, the Commission must take a decision with respect to that measure. Such decision will result either in the modification of the Community-wide marketing approval, or in the termination of the measure.[333]

7.141 According to Article 13 of Regulation 258/97, when making a decision on a safeguard measure which has been notified, the Commission is assisted by the Standing Committee on Foodstuffs. The Commission must submit a draft of the measure to be taken to the Standing Committee on Foodstuffs, which shall deliver its opinion on the draft. If the draft measure is in accordance with the opinion of the Standing Committee on Foodstuffs, the Commission must adopt the draft measure. However, if the measure is not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission must submit a proposal to the Council on the measure to be taken. The Council must act on the proposal within a period of three months, failing which the Commission must adopt the proposed measure.[334]

(vii) Availability under EC and member State law of procedures for administrative and judicial review

7.142 With regard to the availability of procedures for administrative or judicial review under EC law and member State law, we note that the possibility to challenge actions or omissions by member State or Community authorities exists in the same way under Regulation 258/97 as it exists under Directives 90/220 and 2001/18.

7.143 As we have stated earlier, the European Communities has stated before the Panel that, in respect of the biotech products which are the subject of these proceedings, it is aware of only one instance where legal proceedings were brought at member State level. Those proceedings concerned a safeguard measure introduced by Italy pursuant to Regulation 258/97.[335] According to the European

[330] Article 5 of Regulation 258/97.
[331] Article 12(1) of Regulation 258/97.
[332] *Ibid*.
[333] In contrast with Directive 90/220, we note that Regulation 258/97 does not establish a timeframe for a decision by the Commission.
[334] Article 13(4)(b) of Regulation 258/97.
[335] On 13 November 2000 Monsanto Agricoltura Italia SpA and others brought proceedings before the Italian courts challenging the validity of the Italian Decree of 4 August 2000 temporarily suspending trade in

Communities, no applications have been made to the European Court of Justice challenging any actions, or an alleged failure to act, by the Community institutions in respect of any of the relevant biotech products.

(c) GM food and feed and traceability and labelling of GMOs and traceability of food and feed products produced from GMOs: Regulation 1829/2003 and Regulation 1830/2003

7.144 Regulation 1829/2003 "on genetically modified food and feed"[336] (hereafter "Regulation 1829/2003") and Regulation 1830/2003 "concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC"[337] (hereafter "Regulation 1830/2003") are not directly relevant to this dispute. While there are frequent references to these Regulations in the Panel record, the Parties have provided little information on their content and purpose. Accordingly, we provide merely a very basic description of these most recent legislative instruments concerning the approval of biotech products.

7.145 Regarding Regulation 1829/2003, we note that it replaced Regulation 258/97, although Regulation 258/97 remains applicable to novel foods other than GM foods. Regulation 1829/2003 lays down streamlined Community procedures for the approval of GM food and feed as well as new provisions for the labelling of GM food and feed. Notably, it establishes the "one door-one key" principle whereby the approval of a biotech product which is for use as food and feed and for cultivation can be requested in one single application filed exclusively under Regulation 1829/2003. It appears, however, that the applicant also has the choice of submitting an application both under Directive 2001/18, insofar as the application is for the deliberate release of the relevant product into the environment, and under Regulation 1829/2003, insofar as the application is for the use of the product as or in a food product.

7.146 Regarding Regulation 1830/2003, we note that it applies to all products containing or consisting of GMOs irrespective of their use (*i.e.*, food and feed as well as cultivation). Regulation 1830/2003 provides a Community framework for the traceability of products consisting of or containing GMOs, and food and feed produced from GMOs with the objectives of facilitating accurate labelling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products. Directive 2001/18 already requires member States to take measures to ensure traceability of authorized GMOs at all stages of their placing on the market. However, it does not contain a definition of traceability for GMOs, and it does not include the objectives of traceability or a complete approach for its implementation. Regulation 1830/2003 therefore amends Directive 2001/18 in relevant part. Regulation 1830/2003 sets up a harmonized Community system for the labelling of all products consisting of or containing GMOs and imposes additional labelling requirements for these products.

3. Applicability of the *SPS Agreement*

7.147 The Complaining Parties all allege that the above-mentioned EC approval procedures concerning the deliberate release of biotech products into the environment (Directive 90/220 and subsequently Directive 2001/18) and concerning novel foods and novel food ingredients

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and use of certain novel foods within Italy (issued pursuant to Article 12 of Regulation 258/97), and seeking compensation for loss claimed to result from the Decree. These proceedings are still pending.

[336] Published in OJ N° L 268, 18/10/2003, p. 1.

[337] Published in OJ N° L 268, 18/10/2003, p. 24.

(Regulation 258/97) are SPS measures within the scope of the *SPS Agreement*. The European Communities maintains that the EC approval procedures fall in part within the scope of the *SPS Agreement*, and in part outside of scope of the *SPS Agreement*. In this section, the Panel will determine whether the relevant EC approval procedures are SPS measures which fall to be assessed under the *SPS Agreement*.

7.148 We note that Annex A(1) of the *SPS Agreement* provides the following legal definition of the term "SPS measure":

DEFINITIONS[338]

> *Sanitary or phytosanitary measure* - Any measure applied:
>
> (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
>
> (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
>
> (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
>
> (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.
>
> Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

7.149 Annex A(1) indicates that for the purposes of determining whether a particular measure constitutes an "SPS measure" regard must be had to such elements as the purpose of the measure, its legal form and its nature. The purpose element is addressed in Annex A(1)(a) through (d) ("any measure applied to"). The form element is referred to in the second paragraph of Annex A(1) ("laws, decrees, regulations"). Finally, the nature of measures qualifying as SPS measures is also addressed in the second paragraph of Annex A(1) ("requirements and procedures, including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; [etc.]").

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[338] (*original footnote*) For the purpose of these definitions, "animal" includes fish and wild fauna; "plant" includes forests and wild flora; "pests" include weeds; and "contaminants" include pesticide and veterinary drug residues and extraneous matter.

(a) Whether a law, or a requirement contained therein, may be deemed to embody an SPS measure as well as a non-SPS measure

7.150 Before examining in detail whether the relevant EC approval procedures are SPS measures which are to be assessed under the provisions of the *SPS Agreement*, it is necessary to address an issue put before us by the European Communities. The issue is whether a law, or a requirement contained therein, may, if it meets the applicable conditions, be considered to incorporate an SPS measure as well as a distinct measure which falls to be assessed under a WTO agreement other than the *SPS Agreement*, such as the *TBT Agreement*.

7.151 The **European Communities** argues that the *SPS Agreement* has a limited scope of application and that the scope is defined by reference to the objective, or purpose, of the measure at issue, that is the reasons justifying the measure. The European Communities considers that if a WTO Member acts for two different reasons, one of which falls within the scope of the *SPS Agreement*, and the other of which does not, there are in effect two different measures for WTO purposes. According to the European Communities, this is so even if the two different objectives are sought to be achieved by a measure reflected in a single document. The measure (or part thereof) taken for any of the reasons enumerated in the *SPS Agreement* falls within the scope of that *Agreement*. The measure (or part thereof) taken for other reasons falls outside the scope of the *SPS Agreement*.

7.152 The European Communities argues that there is nothing in the *SPS Agreement* or in any other WTO agreement that obliges a WTO Member to refrain from adopting in its domestic jurisdiction a single act, incorporating two or more measures regulated by more than one WTO agreement or provision. The European Communities submits that this situation is very common in the context of the WTO, and the issue with which the Panel is confronted is thus a horizontal one.

7.153 The European Communities considers that where a Member's regulation pursues an SPS objective and also a non-SPS objective, and that regulation is found by a panel to fall within the scope of the *SPS Agreement* and to be inconsistent with it (because the way in which the SPS objective is dealt with conflicts with the rules in the *Agreement*), the most that the panel could properly find is that the regulation includes an SPS measure and that the SPS measure in the regulation is inconsistent with the *SPS Agreement*. The panel's recommendation could only be that the Member take the measures necessary to bring the SPS measure in the regulation into conformity with the *SPS Agreement*. The European Communities submits that the panel could not make any recommendation in relation to the regulation as a whole, unless it also considered and made findings in relation to the measures in the regulation that fall outside the scope of the *SPS Agreement*. Consequently, when it would come to implementation, the Member concerned would be under an obligation to bring the SPS measure into conformity with the *SPS Agreement*, by removing the SPS objective and the elements of the measure that derive therefrom, but the Member in question would not be under an obligation to remove the regulation.

7.154 In relation to the present dispute, the European Communities submits that the environmental and related objectives of its legislation for the approval of biotech products and of measures taken thereunder which are not governed by the *SPS Agreement* may have to be assessed by reference to the *TBT Agreement*. The European Communities considers that the addition of an SPS objective to a measure does not exclude the application of the *TBT Agreement* to non-SPS aspects of that measure. In such a case, the *SPS Agreement* would apply to the extent that SPS objectives are pursued and the *TBT Agreement* would apply to the extent that non-SPS objectives are pursued.

7.155 The European Communities points out that it is aware of Article 1.5 of the *TBT Agreement*, which provides that:

> "The provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures."

7.156 According to the European Communities, Article 1.5 of the *TBT Agreement* means that a single measure that, at the same time, falls within the scope of the *SPS Agreement* and within the scope of the *TBT Agreement* falls to be considered only under the *SPS Agreement*. Article 1.5 does not mean that an act that contains both an SPS measure and a TBT measure (*i.e.*, a measure falling under the *TBT Agreement* but not under the *SPS Agreement*) falls to be considered only under the *SPS Agreement* and not at all under the *TBT Agreement*. If that were true, it would allow Members to camouflage TBT measures behind the *SPS Agreement*, which is in certain respects less strict than the *TBT Agreement*, by simply adding an SPS aspect to the act. Conversely, it would also lead to the bizarre result that a perfectly lawful TBT measure might suddenly become unlawful, just because it is in the same act as an SPS measure, and happens not to comply with a provision of the *SPS Agreement*. Furthermore, 99 percent of an act might be a TBT measure and 1 percent of the act an SPS measure, and yet the whole act would fall to be considered only under the *SPS Agreement*, and the *TBT Agreement* would not apply at all. In the European Communities' view, that cannot be right.

7.157 The **United States** notes that the European Communities has not disputed that both its novel foods regulation and deliberate release directives are covered within the scope of the *SPS Agreement*. Furthermore, with regard to the member State measures, the European Communities acknowledges that each of the member State measures was adopted for "some reasons" that fall within the scope of the *SPS Agreement*. The United States considers that the European Communities' agreement that its measures were adopted for "some reasons" that fall within the scope of the *SPS Agreement* is more than sufficient to bring those measures with the scope of that Agreement.

7.158 Article 1.5 of the *TBT Agreement* is quite clear in stating that the provisions of the *TBT Agreement* "do not apply" to SPS measures as defined in Annex A of the *SPS Agreement*. Annex A makes clear that "any measure" applied to protect against one of the enumerated risks falls within the scope of the *SPS Agreement*. The Annex does not state that the measure needs to be exclusively applied to protect against only the enumerated risks. Nor does the *SPS Agreement* say that an SPS measure – meaning a measure addressing a risk enumerated in Annex A – somehow loses its status as an SPS measure if the adoption of the measure is also supported by other rationales. Thus, for example, even if the European Communities' deliberate release directives could be construed to cover some risks outside the scope of the *SPS Agreement*, these directives would still be SPS measures, and subject to the disciplines under the *SPS Agreement*.

7.159 **Canada** notes that Article 1.5 of the *TBT Agreement* states that it does not apply to SPS measures as defined in Annex A of the *SPS Agreement*. According to Canada, this does not assist in resolving the more discrete question of whether a single or "indivisible" measure taken for both SPS and non-SPS reasons can be considered as both an SPS measure and a non-SPS measure, or whether, as the European Communities contends, it must be considered to be a series of measures. On balance, Canada is of the view that a hermetic approach to the *SPS Agreement* and the *TBT Agreement*, respectively, is probably neither valid from an interpretive standpoint, nor useful from a practical perspective. A Member's measure is an SPS measure to the extent that it addresses SPS risks; to the extent that it addresses other risks or policy objectives, it is another type of measure, including, possibly, a TBT measure. Whether a measure that addresses both SPS risks and other types of risks or policy objectives should be considered a single measure or a series of measures is purely semantic.

7.160 Canada notes that, in any event, the European Communities has conceded that its measures are at least in part SPS measures. All Parties agree that a measure taken for reasons having to do with

the definition of an SPS measure in Annex A(1) must be examined in the light of the requirements of the *SPS Agreement*. As a consequence, if that measure does not meet those requirements, it gives rise to a violation of one or more of the provisions of the *SPS Agreement*. The fact that the measure might also have a TBT dimension and may even be TBT-consistent would be entirely beside the point because consistency with one Agreement cannot operate to excuse or remedy a violation under another Agreement.

7.161 **Argentina** argues that the European Communities admits that the measures at issue in this dispute which affect the approval and marketing of biotech products are partially covered by the *SPS Agreement*. According to Argentina, the *SPS Agreement* is the agreement to be applied, since it refers to the protection against certain risks and not against certain products. Argentina further submits that in accordance with Article 1.5 of the *TBT Agreement* the *SPS Agreement* and the *TBT Agreement* are mutually exclusive. Finally, Argentina contends that, by definition, a measure cannot be a series of measures.

7.162 The **Panel** considers that the issue raised by the European Communities is best analysed using a hypothetical example. Thus, assume that a Member imposes two identical requirements with regard to a particular product, and that each of the two requirements is laid down in a separate law. The law containing the first requirement states that that requirement is applied for one of the purposes enumerated in Annex A(1) of the *SPS Agreement*. The law containing the second requirement states that the second requirement is applied exclusively for a different purpose, one which is not covered by Annex A(1). Clearly, the first requirement would qualify as an SPS measure, as it meets the form (law), nature (requirement) and purpose (one of the enumerated purposes) elements of the definition of the term "SPS measure" as provided in Annex A(1). Equally clearly, the second requirement would not qualify as an SPS measure. While it would meet the form (law) and nature (requirement) elements of the definition of an SPS measure, it would not satisfy the purpose element, as it is not applied for one of the purposes enumerated in Annex A(1). Needless to say, however, the second requirement would also constitute a measure for WTO purposes. For simplicity, we refer to it here as the "non-SPS measure".

7.163 Now assume that the Member concerned decides to consolidate the two separate laws which contain the identical requirements into one single law. Since the two requirements in question are identical, the relevant requirement is included only once in the consolidated law. As the two independent purposes of the requirement in question remain as valid as before, the consolidated law specifies that the requirement is applied for both purposes. The issue now arises whether the requirement in the consolidated law (hereafter "the requirement at issue") constitutes an SPS measure or a non-SPS measure, or both.

7.164 According to the United States' and Argentina's view, the requirement must be considered an SPS measure, and an SPS measure alone, because it meets all elements of the definition of an SPS measure. It undoubtedly meets the form and nature elements; and since the requirement is at least in part applied for one of the purposes enumerated in Annex A(1), the United States' and Argentina's position is that it also meets the purpose element of the definition of an SPS measure. The European Communities rejects this view, arguing that the requirement at issue should be considered (i) an SPS measure to the extent it is applied for one of the purposes enumerated in Annex A(1) and (ii) a non-SPS measure to the extent it is applied for a purpose which is not covered by Annex A(1).[339]

[339] Canada has stated that a hermetic approach to the *SPS Agreement* and the *TBT Agreement*, respectively, is probably neither valid from an interpretative standpoint, nor useful from a practical perspective. According to Canada, a requirement is an SPS measure to the extent it addresses SPS risks; to the extent that it

7.165 In our assessment, the better and more appropriate view is that of the European Communities. Hence, we consider that to the extent the requirement in the consolidated law is applied for one of the purposes enumerated in Annex A(1), it may be properly viewed as a measure which falls to be assessed under the *SPS Agreement*; to the extent it is applied for a purpose which is not covered by Annex A(1), it may be viewed as a separate measure which falls to be assessed under a WTO agreement other than the *SPS Agreement*. It is important to stress, however, that our view is premised on the circumstance that the requirement at issue could be split up into two separate requirements which would be identical to the requirement at issue, and which would have an autonomous raison d'être, *i.e.*, a different purpose which would provide an independent basis for imposing the requirement.

7.166 We recognize that, formally, the requirement at issue constitutes one single requirement. However, neither the *WTO Agreement* nor WTO jurisprudence establishes that a requirement meeting the condition referred to in the previous paragraph may not be deemed to embody two, if not more, distinct measures which fall to be assessed under different WTO agreements. We note that Annex A(1) of the *SPS Agreement*, which defines the term "SPS measure", refers to "[a]ny measure" and to "requirements". But these references do not imply that a requirement cannot be considered to embody an SPS measure as well as a non-SPS measure.

7.167 We note the United States' and Argentina's argument that Article 1.5 of the *TBT Agreement* supports a different conclusion. To recall, Article 1.5 states that the provisions of the *TBT Agreement* "do not apply" to SPS measures as defined in Annex A(1) of the *SPS Agreement*. The operation of Article 1.5 is best illustrated by reference to the specific case of our hypothetical requirement contained in the consolidated law. To that end, we assume that the consolidated law qualifies as a technical regulation within the meaning of Annex 1(1) of the *TBT Agreement*.[340] We have stated above that to the extent the requirement in the consolidated law is applied for one of the purposes enumerated in Annex A(1) of the *SPS Agreement*, it can be viewed as an SPS measure. As such, it falls to be assessed under the *SPS Agreement*, provided the measure may affect international trade.[341] Article 1.5 makes clear that to the extent the requirement at issue qualifies as an SPS measure, the provisions of the *TBT Agreement* would "not apply", even though the requirement at issue is contained in a law which meets the definition of a technical regulation. We have also said that to the extent the requirement at issue is applied for a purpose not covered by Annex A(1) of the *SPS Agreement*, it can be viewed as embodying a non-SPS measure. By its terms, Article 1.5 is not applicable to non-SPS measures. However, given that the requirement is assumed to be part of a technical regulation, it falls to be assessed under the *TBT Agreement*, to the extent it embodies a non-SPS measure.[342] As the foregoing considerations demonstrate, our view that a requirement may in

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addresses other risks or policy objectives, it is another type of measure, including, possibly, one to be assessed under the *TBT Agreement*. Canada considers that the issue of whether a requirement that addresses both SPS risks and other types of risks or policy objectives should be considered a single measure or a series of measures is purely semantic.

[340] Annex 1(1) defines a technical regulation as a "[d]ocument which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is necessary". Annex 1(1) further specifies that a technical regulation "may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method".

[341] Articles 1.1 and 1.2 of the *SPS Agreement* make clear that the *SPS Agreement* applies to all measures which (i) meet the definition of an SPS measure provided in Annex A(1) and (ii) may affect international trade.

[342] We note that according to Article 1.4 of the *SPS Agreement*, "[n]othing in this Agreement shall affect the rights of Members under the [*TBT Agreement*] with respect to measures not within the scope of this Agreement".

certain cases incorporate more than one measure is consistent with, and gives meaning and effect to, the provisions of Article 1.5. Therefore, we do not agree that Article 1.5 compels a different view.

7.168 In addition to the foregoing considerations, there is another consideration which we think militates against treating the requirement at issue as constituting only an SPS measure. To see this, it should first of all be recalled that, as a general matter, Members impose requirements because they consider it necessary to do so.[343] If they do deem it necessary to impose a particular requirement, it is only logical that they also seek to minimize the risk of a successful legal challenge, whether before a domestic court or at the WTO. In the case of our hypothetical example, the Member concerned would face the risk – for instance, due to uncertainties as to the correct interpretation or application of relevant WTO provisions – that a WTO panel would find the requirement at issue to be WTO-inconsistent as an SPS measure but WTO-consistent as a non-SPS measure, or vice versa, or that a panel would find the requirement to be WTO-inconsistent either as an SPS or as a non-SPS measure.

7.169 If the view were taken that the requirement at issue would constitute an SPS measure only, the Member concerned would have to defend that requirement as an SPS measure. In view of the possibility that the requirement at issue might withstand scrutiny by a WTO panel as a non-SPS measure, but not as an SPS measure, it is reasonable to assume, however, that, *ex abundanti cautela*, the Member concerned would not want to forgo the opportunity of defending the requirement at issue also as a non-SPS measure. The Member concerned could prevent this by enacting the requirement at issue twice, either in different laws with a statement of the appropriate purpose or in the same law as separate provisions with a statement of their different purpose. However, a Member might face substantial difficulties in convincing its legislators of the need for enacting the same requirement twice, whether it be in different laws or as separate provisions in the same law. Moreover, pursuing this option might run counter to many Members' basic legislative objectives and requirements. It is axiomatic that the primary objective of legislation is to communicate directives to those affected by it in a manner that is clear, easily understandable and reduces uncertainties. By enacting the same requirement twice, in different laws or as separate provisions in the same law, a Member would arguably reduce clarity and create a potential for confusion and uncertainty among those affected by the law. Also, if the same requirement were enacted twice in different laws, the result would be a more fragmented domestic legal order.

7.170 Thus, if we were to embrace the view that the requirement in the consolidated law must be considered to constitute an SPS measure only, we would effectively impose an unwanted choice on the Member concerned. The Member could either choose to enact the requirement at issue twice and thus possibly act inconsistently with sound legislative objectives. Or it could choose not to enact the requirement twice and thus expose itself to potential legal risks. We think it would be ill-advised to put Members in a situation where they effectively have to make this kind of choice, particularly when it is not imposed by WTO rules. As we have said, we are unaware of a directive in the *WTO Agreement* which says that a requirement can never be deemed to embody two or more distinct measures which fall to be assessed under different WTO agreements.

7.171 To be clear, we are not saying that Members cannot, or should not, enact the same requirement twice if they see fit to do so. Plainly, Members may do so. Our concern is with those Members, and the European Communities appears to be among them, that see fit not to do so. We consider that we should not interpret the *WTO Agreement* in a manner which would effectively require Members to choose between enacting a requirement twice, which may be inconsistent with

[343] Article 2.1 of the *SPS Agreement* provides that "Members have the right to take "[SPS] measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of [the *SPS Agreement*]".

their internal laws or their legitimate preference, and exposing themselves to potential legal risks, which may be imprudent.

7.172 Turning now to the specific case before us, we note the European Communities' assertion that the EC approval legislation which sets out the relevant approval procedures is applied in part for purposes which are identified in Annex A(1) of the *SPS Agreement* and in part for other purposes. The European Communities submits that to the extent the relevant EC approval legislation is applied for purposes which are identified in Annex A(1), it is governed by the *SPS Agreement*; to the extent the legislation is applied for other purposes, it falls within the scope of another WTO agreement, possibly the *TBT Agreement*. Since, as we will see, the approval procedures are conducted for a number of purposes (namely, to avoid various adverse effects), our analysis above suggests that it may conceivably be warranted to view each of the relevant EC approval procedures as incorporating an SPS measure as well as a non-SPS measure.

7.173 Given this, it is pertinent to recall that, according to the European Communities, the question of whether the measures at issue in this dispute are SPS measures or non-SPS measures, or both, may have implications for the implementation of a possible adverse DSB ruling in this dispute, and that, in the European Communities' view, it is therefore important for the Panel appropriately to circumscribe the focus and scope of its findings. We also note that two Complaining Parties, Argentina and Canada, have presented claims under the *TBT Agreement*. Argentina has indicated that its claims under the *TBT Agreement* are made in the alternative, in case we reject its claims under the *SPS Agreement*. Canada, however, has stated that if the Panel were to determine that parts of the measures at issue are covered by the *TBT Agreement* in addition to the *SPS Agreement*, Canada's claims under the *TBT Agreement* are to be considered cumulative rather than alternative *vis-à-vis* its claims under the *SPS Agreement*. In the light of these elements, and in the interests of effective dispute resolution, we find it appropriate to analyse for each of the relevant EC approval procedures whether it is an SPS measure, and if so, whether it is an SPS measure only, or whether it may be considered to embody an SPS measure as well as a non-SPS measure. This analysis will also facilitate a similar inquiry to be carried out by us in Section F below, where we examine the Complaining Parties' complaints in respect of the member State safeguard measures.

7.174 Accordingly, we now proceed to examine whether the EC approval procedures are SPS measures within the meaning of Annex A(1) of the *SPS Agreement*. To that end, we will consider one by one the definitional elements of the term "SPS measure" and then will draw appropriate conclusions on whether the EC approval procedures are SPS measures, and if so, on whether they are SPS measures only.

(b) Whether the EC approval procedures are SPS measures in terms of their purpose

7.175 We first analyse whether the EC approval procedures are SPS measures in terms of the purpose element of the Annex A(1) definition of the term "SPS measure". As we set out to determine whether the European Communities is correct in arguing that each of the EC approval procedures can be viewed as embodying both an SPS measure and a non-SPS measure, we consider all relevant purposes for which the EC approval procedures are applied. As always, we begin our analysis with a summary of the Parties' arguments.

7.176 The **United States** argues that the approval regime is unquestionably an SPS measure. It notes that Directive 90/220 states that one of its objectives is "to protect human health and the environment" from, among other things, the "placing on the market [of] genetically modified

organisms as or in products within the Community".[344] The same objective is stated in Directive 2001/18.[345] Regulation 258/97 states that "foods and food ingredients falling within the scope of the Regulation must not present a danger for the consumer" or be "nutritionally disadvantageous".[346]

7.177 According to the United States, the EC approval regime requires consideration of specific risks that fall within the definition of an SPS measure as set out in Annex A(1) to the *SPS Agreement.* Thus, concerns that a biotech product might lead to an allergic or toxic reaction on the part of certain animals or concerns that some biotech plant varieties could harm beneficial organisms as well as target organisms, fall within the definition of Annex A(1)(a). Concerns that a biotech product might lead to an allergic or toxic reaction on the part of consumers or regarding unacceptable levels of pesticide residue in pesticide-producing plant varieties, fall within the definition of Annex A(1)(b). Similarly, concerns that widespread consumption of varieties containing antibiotic resistance marker genes might lead to the development of antibiotic resistant strains of bacteria also fall under the definition of Annex A(1)(b). Such concerns have been characterized as food safety issues. Thus, according to the United States, a measure based on these concerns is a measure designed to protect "human or animal life or health" from "disease-causing organisms" in "foods, beverages or feedstuffs."

7.178 The United States further argues that concerns regarding the cross-contamination (or transfer) of biotech products to non-target organisms, *e.g.*, concerns that herbicide tolerance could be transferred from a biotech variety to a wild variety, fall within the scope of Annex A(1)(d). The United States points out in this regard that Annex A defines "pests" to include weeds, and weeds are defined as "plant[s] that grow[]… where [they are] not wanted."[347]

7.179 **Canada** argues that the central purpose of Directive 2001/18 is to protect against the kinds of risks identified in paragraph 1 of Annex A of the *SPS Agreement*. Directive 2001/18 requires that an environmental risk assessment be conducted and lists the following "potential adverse effects" of biotech products that should be addressed:[348]

- diseases to humans including allergenic or toxic effects;
- diseases to animals and plants including toxic, and where appropriate allergenic effects;
- effects on the dynamics of populations of species in the receiving environment and on genetic diversity of each of these populations;
- altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors.

Canada argues that Annex A(1) defines the purpose of an SPS measure as being to address, *inter alia*, these potential adverse effects.

7.180 Canada further notes that the Directive identifies as a potential concern the "*spread* of GMO(s) in the environment."[349] In this context, according to Canada the Directive requires, where

[344] Article 1 of Directive 90/220.
[345] Article 1 of Directive 2001/18.
[346] Article 3(1) of Regulation 258/97.
[347] *The New Shorter Oxford English Dictionary,* L. Brown (ed.) (Clarendon Press, 2002), Vol. 2, p. 2171.
[348] Annex II C.2.1. of Directive 2001/18.
[349] *Ibid*, emphasis added by Canada.

appropriate, the submission of information in the application for approval relating to the "likelihood of the GMO [becoming] persistent and invasive in natural habitats…"; "any selective advantage or disadvantage conferred to the GMO and the likelihood of this becoming realised…"; and the "potential … environmental impact of the direct and indirect interactions between the GMO with non-target organisms, including impact on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens".

7.181 Canada also maintains that the requirement in Directive 2001/18 for information regarding "possible…effects on animal health and consequences for the feed/food chain resulting from the consumption of the GMO and any product derived from it, if it is intended to be used as animal feed" is further evidence that Directive 2001/18 is an SPS measure with the objective of addressing concerns identified in Annex A(1) of the *SPS Agreement*.[350]

7.182 Concerning Directive 90/220, Canada notes that similar to its successor Directive, the central objective of Directive 90/220 was "to protect human health and the environment…when placing on the market products containing, or consisting of, genetically modified organisms intended for subsequent deliberate release into the environment."[351] Moreover, information similar to that identified under Directive 2001/18 was also to be included in notifications under Directive 90/220.[352] Therefore, according to Canada, Directive 90/220 was also an SPS measure as defined in Annex A(1) of the *SPS Agreement*.

7.183 Regarding Regulation 258/97, Canada argues that the central purpose of Regulation 258/97 is to protect against risks identified in paragraph 1(b) of Annex A of the *SPS Agreement*. Furthermore, Commission Recommendation 97/618 sets out the type of scientific information necessary to support applications for the placing on the market of novel foods and novel food ingredients under Regulation 258/97.[353] Canada notes that, pursuant to Commission Recommendation 97/618, safety assessments conducted under Regulation 258/97 should include an assessment of contaminants, toxins and disease-causing organisms resulting from the novel elements of the novel food or food ingredient in question. These are among the risks explicitly identified in Annex A(1)(b). The Commission Recommendation states that the safety assessment should address only "[c]hemical or microbiological *contaminants* of novel foods…specifically related to the novelty…" and "the presence of microbial *toxins* and microbial or *viral infective agents*…[when] this is a consequence of the novelty."[354] Canada also points out that Part XIII of the Commission Recommendation sets out the type of toxicological information that should be included in an assessment for novel foods under Regulation 258/97, including *toxicity*, mutagenicity and allergenicity studies.[355]

7.184 **Argentina** maintains that the European Communities' approval procedures are SPS measures, because their stated purpose is to determine, by means of case-by-case assessment, the presence or absence of "additives", "contaminants" or "toxins" in foods, beverages or feedstuffs and the risks to human life and health resulting from their presence. The risks to which the EC legislation refers, and the risks which have been evaluated by the respective EC scientific committees, fall within the scope of Annex A(1) of the *SPS Agreement* because they refer to or deal with, *inter alia*, risks such as toxic or

[350] Annex II D.1. of Directive 2001/18.
[351] Article 1 of Directive 90/220.
[352] Annex II, Part IV of Directive 90/220.
[353] Commission Recommendation of 29 July 1997 concerning the scientific aspects of the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97, Commission Recommendation 97/618, (Exhibit CDA-24).
[354] *Ibid*, Art. 5 (emphasis added by Canada).
[355] *Ibid*, p. 14, Part XIII.

allergic effects in humans and animals, the growth of antibiotic-resistant bacteria and cross-contamination.

7.185 The **European Communities** argues that the *SPS Agreement* applies to measures taken to prevent an exhaustive list of narrowly defined risks and that the provisions of the *SPS Agreement* are specifically designed to regulate such measures. However, the issues arising out of the existence of GMOs and the issues addressed by Directives 90/220 and 2001/18 as well as by Regulation 258/97, go beyond the risks envisaged and regulated by the *SPS Agreement*. Thus, according to the European Communities, the *SPS Agreement* does not provide a sufficient legal framework for the examination of the EC measures at issue.

7.186 The European Communities maintains that the *SPS Agreement* is relevant only to some of the issues examined by EC authorities in the course of GMO approval procedures, but does not cover all of the issues of concern. Thus, while Annex A(1)(b) of the *SPS Agreement* concerns certain things "in foods, beverages or feedstuffs", according to the European Communities, a GMO seed destined to be planted in the ground, not eaten by humans or fed to animals cannot be considered to be a "food, beverage or feedstuff". Similarly, a *GM crop* or plant is not in itself necessarily a food, although it may be processed into something that becomes a food. Furthermore, a crop or plant is not necessarily a "feedstuff" for animals – that depends on whether or not it is destined for such use, and whether or not the crop will first be processed.

7.187 The European Communities further argues that while the term "disease" appears in both Annex A of the *SPS Agreement* and the EC legislation, a GMO is not infected or an infection and is not, in itself, a "disease" within the meaning of Annex A(1).[356] Nor is a GMO a "disease-carrying organism" or generally considered a "disease-causing organism" within the meaning of Annex A. Furthermore, with regard to the term "pest" as used in the definition in Annex A(1), the European Communities maintains that, in light of the definition of a pest in the 1997 *International Plant Protection Convention* (hereafter the "IPPC")[357], in order for a GMO to be a pest within the meaning of the *SPS Agreement*, the relevant GMO would have to be "pathogenic" or "injurious" – that is, it would have to do more than merely interact in some way with humans, animals or plants.

7.188 The **Panel** will determine below whether the specific risks or concerns identified in Directives 90/220 and 2001/18 and in Regulation 258/97 are risks that fall within the scope of the definition of an SPS measure in Annex A(1). For this purpose, the Panel will consider separately the approval legislation concerning the deliberate release of biotech products, established by Directive 90/220 and subsequently by Directive 2001/18, and that concerning novel foods established by Regulation 258/97.

(i) Directives 90/220 and 2001/18

7.189 Directive 90/220 indicates that a central purpose of the Directive is "to protect human health and the environment [...] when placing on the market products containing, or consisting of, genetically modified organisms intended for subsequent deliberate release into the environment".[358]

[356] The European Communities makes reference to the OIE definition of a disease by the World Organization for Animal Health (OIE) as "the clinical and/or pathological manifestation of infection", International Animal Health Code, 2002.

[357] The European Communities refers to the *International Plant Protection Convention* (IPPC) 1997, which defines the term "pest" as "[a]ny species, strain or biotype of plant, animal or pathogenic agent injurious to plants and plant products", *International Plant Protection Convention*, FAO, Rome 1997.

[358] Article 1.1, second tiret, of Directive 90/220.

Directive 90/220 also states that "Member States shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or placing on the market of GMOs."[359] Although Directive 90/220 does not explicitly identify what potential risks for human health and the environment must be assessed prior to a release of GMOs into the environment, it does identify the information required in an application for marketing approval. Thus, information to be provided by applicants relating to the characteristics of the final GMO includes, *inter alia*, toxic or allergenic effects, information on pathogenicity, communicability, host range, and antibiotic resistance patterns.[360] Information to be provided by applicants relating to the potential environmental impact of the GMOs includes information on:[361]

- potential for excessive population increase in the environment;
- competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s);
- anticipated mechanism and result of interaction between the released GMOs and the target organism;
- identification and description of non-target organisms which may be affected unwittingly;
- likelihood of post-release shifts in biological interactions or in host range;
- known or predicted effects on non-target organisms in the environment, impact on population levels of competitors: preys, hosts, symbionts, predators, parasites and pathogens;
- known or predicted involvement in biogeochemical processes;
- other potentially significant interactions with the environment.

7.190 Turning to Directive 2001/18, we note that as with Directive 90/220, a central purpose of the Directive is to protect human health and the environment when placing on the market genetically modified organisms as or in products.[362] Article 4 further clarifies that the purpose of Directive 2001/18 is to "avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs."[363] Like Directive 90/220, Directive 2001/18 does not explicitly identify what potential risks for human health and the environment must be assessed prior to a release of GMOs into the environment, but identifies the information to be provided by applicants in their applications for marketing approval. The information which we have said was to be provided by applicants under Directive 90/220 is also to be provided under Directive 2001/18.[364] Unlike Directive 90/220, however, Directive 2001/18 also addresses the methodology to be followed to perform an environmental risk assessment. In this context, Annex II.C.2.1 of the Directive mentions that potential adverse effects of GMOs vary from case to case and may include:

- disease to humans including allergenic or toxic effects;
- disease to animals and plants including toxic, and where appropriate, allergenic effects;

[359] Article 4(1) of Directive 90/220.
[360] Annex II.II.C.2(i). The chapeau to the Annex states, *inter alia*, that "[n]ot all the points included will apply to every case. It is to be expected, therefore, that individual notifications will address only the particular subset of considerations that are appropriate to individual situations."
[361] Annex II.IV.C of Directive 90/220.
[362] Article 1, second tiret, of Directive 2001/18.
[363] Article 4(1) of Directive 2001/18.
[364] Annexes IIIA and IIIB.

- effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these – changes in populations and in genetic diversity brought about by effects on life/health which may have more deleterious effects on one species than another, hence changing population dynamics;
- altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors;
- compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine;
- effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material.

7.191 The Directive states that adverse effects may occur directly or indirectly through mechanisms which may include the spread of the GMO(s) in the environment; the transfer of the inserted genetic material to other organisms or the same organism; phenotypic and genetic instability; interactions with other organisms; and changes in management, including, where applicable, in agricultural practices.[365]

7.192 Furthermore, and again in addition to the provisions of Directive 90/220, Annex II.D.1 of Directive 2001/18 identifies concerns that are to be considered in the case of GMOs other than higher plants, while Annex II.D.2 identifies concerns to be considered in the case of genetically modified higher plants (hereafter "GMHP"). With respect to GMHP, the products at issue in this dispute[366], the following issues are to be considered:

- likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats;
- any selective advantage or disadvantage conferred to the GMHP;
- potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species;
- potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids, and pathogens (if applicable);
- possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens;
- possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into contact with or in the vicinity of the GMHP release(s);
- possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed;

[365] Annex II.C.2 of Directive 2001/18.

[366] Annex III of Directive 2001/18 indicates that "higher plants" means plants which belong to the taxonomic group Spermatophytae (Gymnospermae and Angiospermae). The products at issue in this dispute are all Angiospermae.

- possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s);
- possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.

7.193 The Panel notes that in replacing Directive 90/220, Directive 2001/18 was presented as an improvement over the previous Directive, providing, *inter alia*, clarification of the scope of Directive 90/220.[367] Indeed, as we have indicated, Directive 2001/18 specifies or amplifies in its annexes some of the potential risks from GMOs from which protection of human health and the environment is to be provided. In view of the fact that Directive 2001/18 clarifies rather than expands the scope of Directive 90/220, we believe that we can presume that any potential adverse effect within the scope of Directive 2001/18 was also covered by Directive 90/220.

7.194 We note that, according to the European Communities, the EC approval legislation has the objective of addressing concerns relating to:

- herbicide tolerance in GM plants (agricultural persistence of the GM plant and cross-breeds; natural persistence resulting in damage to the ecological balance or biodiversity; effects on human or farm animal health from the modified gene in foodstuffs, from allergens or from increased herbicide use; impact on wild flora and fauna from herbicide use; effects of cross-breeding on wild flora);
- insecticidal properties of GM plants (agricultural insect resistance; spread of insect resistance trait into wild flora; effects on human or farm animal health, including allergies; effects on human or farm animal health from increased insecticide use; effects on wild fauna of the toxin in the GM plant; effect on wild fauna from increased insecticide use); and
- antibiotic resistance.

We consider that these are not concerns *in addition* to those identified in the Directives themselves (see paragraphs 7.189-7.192 above), but rather a different way of describing the concerns contained therein.

7.195 As a result, and given the greater degree of specificity of the relevant provisions of Directive 2001/18 compared to those of Directive 90/220, for the purposes of our analysis, we will focus on the potential adverse effects identified in Directive 2001/18. We are aware that Annex II.C.2 to Directive 2001/18 by stating that "adverse effects *may include*" (emphasis added) is not intended to be a closed list of the possible adverse effects of GMOs on human health and the environment. Therefore, we will also consider the additional possible adverse effects which have been identified by the European Communities in the case at hand. The fact that we address the potential adverse effects of GMOs mentioned in Directive 2001/18, or mentioned separately by the European Communities, should not be construed to mean that we necessarily agree that all GMOs, or even specific GMOs, actually or potentially give rise to such effects.

7.196 Having determined that the purpose of Directives 90/220 and 2001/18 is to protect human health and the environment from adverse effects on human health and the environment which might

[367] 1st and 2nd preambular paragraphs of Directive 2001/18.

result from the deliberate release of GMOs into the environment, we now proceed to examine whether that purpose is covered by the various sub-paragraphs of Annex A(1) to the *SPS Agreement*.

Protection of the environment

7.197 The Panel will first consider the general purpose of protection of the environment as stated in Directives 90/220 and 2001/18.

7.198 The **European Communities** observes that Directives 90/220 and 2001/18 repeatedly state that one of the purposes of these pieces of legislation is to protect the environment. The European Communities contrasts this with Annex A of the *SPS Agreement* which it claims does not address environmental protection, unlike Article 2.2 of the *TBT Agreement*, for example, which expressly refers to "the environment". According to the European Communities, it is clear that when the drafter of an international agreement uses a term in one instrument but not in another, the drafter intended to exclude that term from the latter instrument. The European Communities concludes from this that the *SPS Agreement* was not intended to address the prevention of risks to the environment.

7.199 The European Communities contends that this is also clear from the negotiating history of the *SPS Agreement*. In this context, the European Communities refers to a 1993 Uruguay Round GATT Secretariat background paper on the proposed *SPS Agreement*, wherein it is stated that "[m]easures for environmental protection, *per se*, […] are not covered by the proposed [*SPS*] *Agreement*".[368] The European Communities also refers to the "Cover note to the SPS Decision circulated on 20 December 1990 (also known as the 'Dunkel text')"[369]. However, the European Communities is mistaken in referring to the Dunkel text. The European Communities meant to refer to the cover note to the *Draft Text on Sanitary and Phytosanitary Measures* circulated on 20 November 1990 (not 20 December 1990, as the European Communities contends) by the Chairman of the Working Group on Sanitary and Phytosanitary Measures. The European Communities points out that the cover note at issue addressed certain bracketed elements in the draft text which included a reference to "the environment". The European Communities notes that, according to the cover note, the relevant brackets are "linked to the question of whether or not this agreement should apply to measures taken for the protection of animal welfare and the environment […]".[370] The European Communities further notes that this bracketed text was not retained in the final text of the *SPS Agreement*. The European Communities deduces from this that environmental damage *per se* does not fall within the scope of the *SPS Agreement*.

7.200 The European Communities contends that the ordinary meaning of the word "environment" is broad and includes the protection of biodiversity; it does not focus on a short-term risk to the life or health of a particular animal or plant. Furthermore, according to the European Communities, negative effects on biodiversity may occur without negatively affecting the wild flora and fauna or an area. In the European Communities' view, such effects could result from positive effects on wild fauna and/or flora that disrupt the ecological equilibrium; negative effects on soil or water micro-organisms;

[368] Quoted in EC second written submission, footnote 35.
[369] EC reply to Panel question No. 120(c).
[370] Uruguay Round document MTN.GNG/NG5/WGSP/7, p. 1 (reference identified by Panel).

modification of interactions between two organisms, including through trophic interactions[371]; and negative effects on the biogeochemical processes of an ecosystem.[372]

7.201 The **United States** argues, in contrast, that a biotech plant can only damage biodiversity or the ecological balance through its ability to adversely affect, directly or indirectly, the wild flora or fauna of the area. Any damage would occur due to alterations in the invasiveness or persistence of certain plant species, causing changes in the abundance of different plant species and secondary negative impacts on animal life.

7.202 The United States considers that the European Communities' citation to the negotiating history is incomplete and misleading, and in no way supports the European Communities' contention. The United States notes that the "bracketed text" referred to by the European Communities is actually two different bracketed phrases.. Both of these phrases are contained in the concluding paragraph of the Annex A(1) definition of "SPS measure" (that is, in the paragraph following lettered paragraphs a to d) – a paragraph which (in its final form) describes types of measures – such as labelling and quarantines – as opposed to describing particular types of risks. One of the bracketed phrases would have expressly included animal welfare, environment, and consumer interests and concerns. The second bracketed phrase would have expressly excluded those issues.

7.203 The United States points out that the final text of the *SPS Agreement* drops both the proposal for an explicit inclusion and the proposal for an explicit exclusion of environmental and animal welfare concerns. Thus, contrary to the European Communities' assertions, this change is not the least bit instructive on whether the drafters of the agreement intended to include or exclude environmental issues. On the other hand, this change could support an interpretation that the drafters decided to leave the last paragraph of Annex A(1) to describe types of measures (such as labelling and quarantine) and to place the types of covered risks within the lettered paragraphs a to d.

7.204 The United States argues, moreover, that the European Communities does not make note of a more relevant and significant change between the late 1990 draft text and the final *SPS Agreement*. The late 1990 draft text did not include footnote 4, which defines "animal" to include "wild fauna" and "plant" to include "wild flora". The fact that these clarifications were added to the text means that the issue of environmental damage was in fact considered by the drafters, and that the drafters purposely and specifically decided to include damage to wild flora and fauna within the scope of the *SPS Agreement*. Thus, contrary to the European Communities' assertions, the negotiating history of the *SPS Agreement* provides no support for the European Communities' contention that the *SPS Agreement* was not intended to cover damage to the environment.

7.205 **Canada** argues that the *SPS Agreement* explicitly covers wild flora and fauna. Canada maintains that the term "fauna" encompasses both macrofauna and microfauna, whereas the term "flora" includes also microflora. The types of risk related to the environment that are addressed in Directives 90/220 and 2001/18 are those that ultimately pertain to animal or plant life or health. Nothing in the *SPS Agreement* limits SPS measures to short-term risks. "Biological diversity" is

[371] *The New Shorter Oxford English Dictionary* defines "trophic" as "of or pertaining to nutrition" L. Brown (ed.) (Clarendon Press, 2002), Vol. 2, p. 3403.

[372] In response to a question by the Panel, Dr. Snow, one of the experts consulted by the Panel, indicated that: "The biogeochemical cycle refers to the cycling of nutrients and carbon in any type of ecosystem including a farmer's field. People are asking questions about whether the biotech crop might affect nutrients that come out of the dead materials from the crop and are recycled into the soil so it could affect soil fertility and things like that and just the rate at which nutrients are cycled locally. So biogeochemical, if that is clear enough, nutrients and carbon cycling in the form of organic matter and then back to their original components in an ecosystem. ", Annex J, para. 305.

defined in the *Convention on Biological Diversity* as "the variability among living organisms from all sources…".[373] In the context of this case, any harm to biodiversity or the ecological balance of an area arising from biotech products is through harm to plants and animals, as defined by the *SPS Agreement*. Canada considers that the materials from the negotiating history to which the European Communities refers do not indicate whether WTO Members intended for all types of environmental measures to be excluded; indeed, the more plausible reading of those materials is that the WTO Members intended for more general types of environmental measures, such as those relating to air and water quality, waste management, and the like, to be excluded from the coverage of the *SPS Agreement*, but that environmental effects related to SPS-type risks would remain within the scope of that agreement.

7.206 **Argentina** argues that since humans, animals and plants comprise the universe of living things, and since biodiversity is concerned with the diversity of living things, biodiversity is necessarily related to human, animal or plant life or health. In Argentina's view, the most likely way in which biotech products could damage biodiversity or the ecological balance of an area is through negatively affecting wild flora and/or fauna. A measure taken to protect biodiversity would therefore be covered by the definition of an SPS measure contained in Annex A(1).

7.207 The **Panel** recalls that Directives 90/220 and 2001/18 serve to protect human health and the "environment". It is clear from the Directives that as part of the purpose of protecting the "environment" they address the protection of the health of animals or plants. Indeed, Article 2(8) of Directive 90/220 states that the term "environmental risk assessment" as used in the Directive "means the evaluation of the risk to human health and the environment (*which includes plants and animals*) …" (emphasis added). Among the information required with the submission of an application under Directive 90/220, in the context of "Information on the environment", is information on flora and fauna, including crops, livestock and migratory species.[374]. Directive 2001/18 refers to assessing the accumulated effects of consents for placing on the market on "human health and the environment, including *inter alia* flora and fauna, ... animal health...".[375] We note that in accordance with Annex A(1)(a) and (b) of the *SPS Agreement*, the *SPS Agreement* covers measures applied to protect animal and plant life or health from certain risks. Thus, to the extent Directives 90/220 and 2001/18 are applied to protect animals and plants as part of their purpose of protecting the environment, they are not *a priori* excluded from the scope of application of the *SPS Agreement*.

7.208 The European Communities argues, however, that negative effects on the environment may occur without there being negative effects on wild flora and fauna. The European Communities refers to adverse effects on biodiversity as a relevant example. The European Communities implies that to the extent Directive 90/220 and 2001/18 are applied to protect the environment from such adverse effects, the Directives fall outside the scope of the *SPS Agreement*. We will address this argument below in the context of our analysis of Directives 90/220 and 2001/18 under Annex A(1)(d) of the *SPS Agreement*. Annex A(1)(d) refers to measures applied to prevent or limit "other damage within the territory" from risks associated with "pests". As we will explain, we consider that Annex A(1)(d) covers measures applied to prevent or limit certain forms of damage to the environment. At this point, we need only observe that neither the *TBT Agreement* nor the GATT Secretariat background paper referred to by the European Communities, nor the Working Group

[373] The *Convention on Biological Diversity* defines "biological diversity" in Article 2 as "the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems." *Convention on Biological Diversity* (CBD) done in Rio de Janeiro, 5 June 2002.

[374] Annex II.III.B.9 of Directive 90/220.

[375] Chapeau to Annex II of Directive 2001/18.

Chairman's *Draft Text on Sanitary and Phytosanitary Measures* supports the view that all measures applied to protect from risks to the environment other than risks to the life or health of animals or plants fall outside the scope of application of the *SPS Agreement*.

7.209 Regarding the European Communities' reliance on the *TBT Agreement*, we do not consider that the fact that the *TBT Agreement* refers to "the environment", and that Annex A(1) does not, precludes us from interpreting the term "other damage" in Annex A(1)(d) to encompass also certain damage to the environment other than damage to the life or health of animals or plants. The fact that the term "other damage" is broad and unqualified suggests to us that it is intended to ensure coverage of a residual category of damage, which, as we will see, is not limited to environmental damage. Therefore, we do not find it surprising that the drafters omitted a reference to "the environment" in Annex A(1)(d).

7.210 As far as the the 1993 GATT Secretariat background paper is concerned, we consider that it merely intended to clarify that the purpose of environmental protection, *per se*, is not sufficient to bring a measure within the scope of application of the *SPS Agreement*, even if the measure otherwise meets the definition of an SPS measure (*e.g.*, in terms of its form and nature). To provide an example, a measure to reduce air pollution may be applied to protect the life or health of plants (to the extent that high levels of air pollution could result in certain plant species lacking sufficient sunlight for them to exist and survive), and hence to protect the environment, but it would nonetheless not be a measure applied for one of the purposes enumerated in Annex A(1) of the *SPS Agreement* (in that the measure would not be applied to protect plant life or health from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms, or to prevent other damage from the entry, establishment or spread of pests).

7.211 Finally, we turn to the 1990 *Draft Text on Sanitary and Phytosanitary Measures* circulated by the Chairman of the Working Group on Sanitary and Phytosanitary Measures. We note that the draft text contained bracketed text the acceptance of which would have meant that "measures for the protection of animal welfare and of the environment, as well as of consumer interests and concerns" are "SPS measures" within the meaning of the Annex A(1) definition.[376] However, the Annex A(1) definition in the Chairman's draft text also contained bracketed text which stated that "[r]equirements concerning quality, composition, grading, [consumer preferences, [...], the environment or ethical and moral considerations] are *not* included in the definition of sanitary or phytosanitary measures".[377] Neither of the two bracketed texts was included in the final text of the *SPS Agreement*. Since according to one of the two bracketed texts measures taken for the protection of the environment would have been covered by the *SPS Agreement*, while according to the other bracketed text such measures would not have been covered, and since neither text was included in the final text of the *SPS Agreement*, we cannot draw the inference that the European Communities asks us to draw – that the removal of the bracketed text which would have meant that measures taken for the protection of the environment are SPS measures implied a decision that such measures should not be covered by the *SPS Agreement*. In view of the fact that neither of the two bracketed texts was included in the final text of the *SPS Agreement*, we consider that the Working Group Chairman's draft text does not assist us in determining whether all measures applied to protect from risks to the environment other than risks to the life or health of animals or plants fall outside the scope of application of the *SPS Agreement*.

[376] Uruguay Round document MTN.GNG/NG5/WGSP/7, p. 8.
[377] *Ibid*. (emphasis added).

Annex A(1)(a) to the *SPS Agreement:* Protection of animal or plant life or health from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms

7.212 As indicated, we will now analyse whether Directives 90/220 and 2001/18 can be considered as measures applied for one of the purposes identified in sub-paragraphs (a) through (d) of Annex A(1) of the *SPS Agreement*. We begin this analysis with Annex A(1)(a). Annex A(1)(a) makes clear that the *SPS Agreement* is applicable to measures applied "to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms".

7.213 In order for us to determine whether Directives 90/220 and 2001/18 fall within the scope of Annex A(1)(a), we need to consider the meaning and scope of some of the terms and phrases used in Annex A(1)(a) and address whether certain potential effects of GMOs identified in the Directives meet the definition of these terms and phrases. Accordingly, we have structured our analysis below according to certain terms and phrases used in Annex A(1)(a), including "animal or plant life or health", "risks arising from", "entry, establishment or spread", "pests" and "diseases, disease-carrying organisms or disease-causing organisms." We note that one specific concern which has been identified in Directives 90/220 and 2001/18 relates to potential adverse effects of GMOs resulting from the use of antibiotic resistance marker genes. A separate subsection addresses whether this concern can be considered to relate to the risks covered in Annex A(1)(a).

"animal or plant life or health"

7.214 The **United States** argues that the EC approval regime requires consideration of, *inter alia*, concerns that a biotech product might harm beneficial organisms as well as target organisms. According to the United States, these are concerns relating to potential risks to animal or plant life or health.

7.215 **Canada** observes that Annex A of the *SPS Agreement* defines plants and animals to include wild flora and wild fauna, which are integral parts of what is commonly understood as "the environment". Furthermore, Canada maintains that the term "fauna" as used in the *SPS Agreement* encompasses both macrofauna and microfauna, whereas the term "flora" includes also microflora. Contrary to the arguments of the European Communities, according to Canada nothing in the *SPS Agreement* limits measures to those that address short-term risks to plant or animal life or health.

7.216 **Argentina** argues that the most likely way in which biotech products could damage biodiversity or the ecological balance of an area is through negatively affecting wild flora and/or fauna. Annex A of the *SPS Agreement* explicitly states that the term "animals" includes wild fauna and the term "plants" includes wild flora.

7.217 The **European Communities** argues that GMOs could affect micro-organisms that are specialized in biophysical or biochemical processes in the soil, or aquatic micro-organisms, and thus affect ecosystems without affecting plant or animal health.

7.218 The **Panel** understands the European Communities to argue that a measure taken to address any adverse effects biotech products might have on soil or aquatic micro-organisms would not be a

measure applied to protect "animal or plant life or health". In considering this argument, it should be recalled that the footnote to the definitions provided in Annex A of the *SPS Agreement* states that:[378]

> "For *the* purpose of these definitions, 'animal' includes fish and wild *fauna*; 'plant' includes forests and wild *flora*; 'pests' include weeds; and 'contaminants' include pesticide and veterinary drug residues and extraneous matter."

7.219 The term "fauna" is commonly defined as "the animals or animal life of a given area, habitat, or epoch"[379], whereas the term "flora" is commonly defined as "plants or plant life of a given area, habitat, or epoch".[380] The clarification provided in the footnote to Annex A that the terms "animal" and "plant" include "wild fauna" and "wild flora" indicates to us that the scope of the phrase "animal or plant life or health" is meant to be comprehensive in coverage. Moreover, we note that, textually, the unqualified terms "animal" and "fauna", on the one hand, and "plant" and "flora", on the other, can encompass macro- and micro-fauna, on the one hand, and macro- and micro-flora, on the other. We also consider that the terms "animal" and "plant" can encompass both target and non-target fauna and flora. By "non-target" fauna and flora, we mean plants and animals (including insects) which are not themselves the organisms farmers seek to control or eliminate through the cultivation of GM crops, but which are affected by the cultivation of the GM crop, including through consumption of components of the GM plants (*e.g.*, pollen). In the light of this, we consider that non-target micro-organisms, such as soil or aquatic micro-organisms, are "animals" or plants" within the meaning of Annex A(1).[381]

7.220 We note that Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material".[382] We understand that this concern relates to the potential introduction of transgenes into the soil via the roots of GM plants (*e.g.*, in the case of Bt-producing plants) or through the decomposition of GM plants. This may potentially pose a threat to non-target soil micro-organisms. Presumably the same products of decomposition could be introduced to bodies of water through run-off, and hence pose potential threats to non-target water micro-organisms. We consider that to the extent Directives 90/220 and 2001/18 could be used to protect the life or health of non-target micro-organisms from risks covered by Annex A(1)(a), the Directives would fall within the scope of this Annex.

"risks arising from"

7.221 The **United States** considers that the phrase "arising from" does not require a demonstration that the risk be direct or immediate. Although there may be intermediate effects that occur before the effect of concern appears, the risks nonetheless "arise from" the organism in that it is the presence of the organism that triggers the necessary sequence of events. The United States maintains, for example, that adverse effects on plant and animal health due to the use of more powerful pesticides to control insects or weeds which have developed herbicide resistance as a result of the planting of herbicide-resistant biotech crops would be "risks arising from" the establishment or spread of a pest.

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[378] Emphasis added.

[379] *The Shorter Oxford English Dictionary*, L. Brown (ed.) (Oxford University Press, 2002), Vol. 1, p. 931.

[380] *Ibid*., p. 979.

[381] We note that the common definition of an "organism" is: "an organized living body; esp. (the material structure) of an individual animal, plant, bacterium, etc.". *The Shorter Oxford English Dictionary*, L. Brown (ed.) (Oxford University Press, 2002), Vol. 2, p. 2019.

[382] Tiret 6 of Annex II C.2 of Directive 2001/18.

7.222 **Canada** also argues that the phrase "arising from" does not require that the risk be immediate or direct. If, for example, a biotech product qualifies as a "pest" that needs to be controlled with herbicides, any resulting risks to wild flora and/or fauna "arise from" the pest. This includes a situation where a pest management strategy is no longer effective because the target pest has developed resistance, resulting in health risks to wild fauna from increased or altered use of pesticides.

7.223 The **European Communities** argues that the use of the phrase "arising from" indicates a requirement of causality; that is, the measure must be applied with the objective of preventing certain risks "arising from" a certain situation.

7.224 The **Panel** notes that the dictionary defines the phrasal verb "to arise from" as meaning "occur as a result of".[383] Thus, the phrase "risks arising from" indicates that the relevant risks to animal or plant life or health must occur as a result of some event, substance, condition, etc. In the specific context of Annex A(1)(a), the phrase "risks arising from" implies that the risks to animal or plant life or health must occur as a result of a pest, disease, disease-carrying organism or disease-causing organism.

7.225 Article 4 of Directives 90/220 and 2001/18 makes clear that these Directives are measures applied to protect human health and the environment from adverse effects "which might arise from" the deliberate release of GMOs into the environment. Thus, like Annex A(1)(a), the Directives use the phrasal verb "to arise from". We recognize that Annex A(1) uses the phrase "arising from", not "which might arise from". However, the phrase "arising from" is broad and unqualified. We therefore think that Annex A(1) brings within the scope of the *SPS Agreement*, not just measures which are applied to protect against risks which invariably and inevitably arise from, *e.g.*, the spread of a pest, but also measures applied to protect against risks which might arise from, *e.g.*, the spread of a pest.

7.226 We note that Annex II of Directive 2001/18 indicates that direct, indirect, immediate and delayed adverse effects are to be considered in the assessment of GMOs. Here again, we note that the phrase "arising from" in Annex A(1) is broad and unqualified. There is nothing in Annex A(1)(a) which indicates that potential risks to animal or plant life or health must necessarily be the direct or immediate result of, *e.g.*, the spread of a pest. Notably, Annex A(1) does not say that only risks "arising directly and immediately from", *e.g.*, the spread of a pest, are covered. We therefore do not consider that measures taken to protect animal or plant life or health from risks that arise indirectly or in the longer term from pests, diseases, disease-carrying organisms or disease-causing organisms fall outside the scope of Annex A(1)(a). Accordingly, the reference in Annex II of Directive 2001/18 to indirect and delayed adverse effects does not, by itself, remove that Directive from the scope of Annex A(1)(a).

"entry, establishment or spread"

7.227 The **European Communities** argues that concerns regarding the potential development of resistance in target pests are not a question of "establishment or spread" of a pest. The pest, that is, the insect of concern, already exists and will not spread to other areas. Rather the problem relates to the treatment of the pest, and the need to use additional insecticides in order to get rid of the pest.

7.228 The **United States** disagrees, arguing that the concern about the potential development of resistant target insects *is* that those individuals carrying the resistance trait could become established

[383] *The Concise Oxford Dictionary*, 10th edn, J. Pearsall (ed.) (Oxford University Press, 1999), p. 71.

and spread throughout the population. As more insect populations become resistant, more toxic chemical pesticides may need to be applied, causing greater environmental damage.

7.229 **Canada** observes that if a pest management strategy is no longer effective because the target pest has developed resistance, an alternative pest management strategy would still have the objective of addressing risks "arising from" the establishment or spread of the resistant pest.

7.230 **Argentina** notes that if a pest management strategy is no longer effective because the target pest has developed resistance, the "risks arising from the entry, establishment or spread" of that pest have not disappeared. The concern remains that the target pest may become established or spread.

7.231 Before addressing the European Communities' specific argument on resistance in target pests, it is useful to consider more generally whether Directives 90/220 and 2001/18 are concerned with the "entry, establishment or spread" of pests, diseases, etc. The **Panel** recalls in this regard that the purpose of Directive 2001/18 is to avoid adverse effects arising from the "deliberate release into the environment" of GMOs.[384] The term "deliberate release" is defined as "any intentional *introduction* into the environment of a GMO".[385] Annex II.C.2.1 to Directive 2001/18 specifies that potential adverse effects of GMOs may include disease to animals and plants. It is clear to us that the purpose of avoiding disease in general includes the purpose of avoiding, more specifically, the "entry, establishment or spread" of "diseases". Furthermore, Annex C.2.1 specifies that effects on the dynamics of populations of species and genetic diversity of populations are relevant adverse effects. These effects relate to potential "pest effects" of GMOs which could occur, *inter alia*, through the spread of pollen from genetically modified plants to other plants ("out-crossing")[386], or through the development of persistence or "invasiveness" of the GMO or GM plant due to a selective advantage.[387] We think that the purpose of avoiding "pest effects" of GMOs includes the purpose of avoiding the "entry, establishment or spread" of GMOs as "pests". We also note that Annex II.C.2.1 of Directive 2001/18 specifically states that adverse effects may occur through the "spread of GMO(s) in the environment". In the light of this, we are satisfied that Directives 90/220 and 2001/18 can be considered to constitute measures applied to protect against risks arising from the "entry, establishment or spread" of, *inter alia*, disease and "pest effects" which may be caused by GMOs.

7.232 We now turn to the European Communities' argument that possible concerns regarding the potential development of resistance in target pests (*e.g.*, insects) are not concerns regarding the "establishment or spread" of a pest. It appears that the effect of the development of resistance in target pests may be a potential adverse effect of GMOs which Directives 90/220 and 2001/18 seek to avoid.[388] We are not persuaded, however, that in terms of Annex A(1) risks associated with the development of resistance would not be risks arising from the "establishment or spread" of the target pest. Even if, as the European Communities argues, the target pest may have existed in a particular area before, if the pest develops resistance, it may be that thanks to the resistance trait the pest can not only exist in the area in question, but also become established and thus become more of a problem.

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[384] Article 4 of the Directives.

[385] Article 2(3) of Directive 2001/18 (emphasis added).

[386] The Panel understands the term "out-crossing" or "cross-breeding" to refer to the unintentional breeding of a cultivated plant, in this case a GM plant, with another cultivated or wild plant, in this case a "conventional" or non-GM, plant.

[387] The Panel understands selective advantage to refer to the enhanced ability of a particular trait to survive in a population, thus leading to a change in the composition of traits within the population. In this case, the spread of herbicide resistance may allow plants with that trait to out-compete other plants for water, nutrients, space, etc.

[388] *See, e.g.*, Annex II.iv.C.4 of Directive 90/220 and Annex IIIA.iv.B.11 and Annex II.D.1.4 of Directive 2001/18.

Similarly, the resistance trait may allow the pest to spread to areas it has not entered before, *e.g.*, because of a pest management strategy which was effective prior to the development of resistance in the relevant pest.

"pests"

7.233 The **United States** notes that the ordinary meaning of the term "pest" is "any thing or person that is noxious, destructive or troublesome".[389] The United States further argues that the IPPC definition of a pest, as contained in the International Standard for Phytosanitary Measures Number 11, *Pest Risk Analysis for Quarantine Pests, including Analysis of Environmental Effects and Living Modified Organisms* (hereafter ISPM No. 11) supports the view that the scope of IPPC also extends to organisms which may directly affect uncultivated and/or unmanaged plants, indirectly affect plants, or indirectly affect plants through effects on other organisms.[390] While the United States does not contend that this is dispositive of the term "pest" under the *SPS Agreement*, the specific inclusion of such damage in ISPM No. 11, by the body explicitly recognized by the *SPS Agreement* as responsible for international standards for plant health, is additional evidence that the ordinary meaning of the term "pest" includes a biotech plant that cross-breeds with existing flora, and consequently, adversely affects biological diversity.

7.234 **Canada** argues that the use of the term "pest" in Annex A(1)(a), (c) and (d) suggests that in the context of the *SPS Agreement*, "pest" should be defined as "any species, strain or biotype of plant, animal or pathogenic agent injurious to plants, plant products, animals or humans." In Canada's view, the biotech products at issue in this dispute can be viewed as a potential "pest" to plants, including "wild flora", or a potential "pest" to animals, including "wild fauna".

7.235 **Argentina** recalls that the *International Plant Protection Convention* of 1997 has defined a "pest" to be "[a]ny species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products." Argentina argues that the phrase "injurious to plants and plant products" should be

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[389] *The Shorter Oxford English Dictionary*, L. Brown (ed.) (Oxford University Press, 2002), Vol. 2, p. 2171.

[390] The United States notes that the FAO's *International Plant Protection Convention* of 1997 defines the term "pest" as "[a]ny species, strain or biotype of plant, animal or pathogenic agent *injurious* to plants or plant products". The IPPC's 2004 revisions to ISPM No. 11, which modified the existing standard specifically to address risks from a particular category of GM crops ("living modified organisms", or "LMOs"), identifies among the potential phytosanitary risks for LMOs:

> c. Adverse effects on non-target organisms including, for example:
>
> - changes in host range of the LMO, including the cases where it is intended for use as a biological control agent or organism otherwise claimed to be beneficial
> - <u>effects on other organisms, such as biological control agents, beneficial organisms, or soil fauna and microflora, nitrogen-fixing bacteria, that result in a phytosanitary impact (indirect effects)</u>
> - capacity to vector other pests
> - <u>negative direct or indirect effects of plant-produced pesticides on non-target organisms beneficial to plants</u>." (emphasis added by the United States)

International Standard for Phytosanitary Measure No. 11, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks*, FAO, Rome, 2004 (adopted April 2004), Annex 1 "Comments on the scope of the IPPC in regard to environmental risks".

interpreted broadly, as is evidenced by the broad interpretation given in the context of ISPM No. 11[391] and that the term "pests" in the *SPS Agreement* should be given a similarly broad interpretation. An organism is a "pest" for the purposes of the *SPS Agreement* and ISPM No. 11 if it is "injurious to plants or plant products" in the sense of causing damage to plant life or health. According to Argentina, any undesirable cross-breed of plants could be considered a "pest"; for instance when a herbicide-tolerance gene is transferred to a crop's weeds. Argentina argues that the *SPS Agreement* covers risks arising from a biotech product that becomes a weed, that is, a persistent and invasive plant that grows in environments where it is not wanted and overtakes other plant species, raising broader ecological concerns.

7.236 The **European Communities** argues that the IPPC definition may provide relevant context for the purposes of interpreting the term "pest" in Annex A(1) of the *SPS Agreement*. In particular, the European Communities insists that (1) a pest must be a living organism, and so isolated strands of modified DNA cannot be, in and of themselves, injurious to human, animal or plant life or health; and (2) the organism must cause injury to a plant. The mere presence of a transgene may be undesirable but it need not present any phytosanitary risk. The European Communities contends that a cross-breed that harms biodiversity, micro-organisms, animals or the environment is not a pest.

7.237 The European Communities maintains that a crop that is resistant to a herbicide is not a pest if it is growing in the right place at the right time. However, in the wrong place (such as a neighbouring field) or at the wrong time (such as the following year in the same field sown with a different crop) the plant may be unwanted. The unwanted plant may compete with other crops, and its herbicide resistant trait could give it a selective advantage. It might choke or stunt other crop plants. It could thus adversely affect or injure other crops. It could therefore become a pest, and a measure taken to control it could be within the scope of the *SPS Agreement*.

7.238 The **Panel** notes at the outset that three of the sub-paragraphs of Annex A(1) to the *SPS Agreement*, namely, Annex A(1)(a), A(1)(c) and A(1)(d), identify "pests" as a possible source of risks. The word "pest" ordinarily means "a troublesome, annoying or destructive person, animal, or thing".[392] In applying this definition to Annex A(1), we find two contextual elements in particular to be noteworthy. The first is the previously mentioned footnote to the definitions provided in Annex A of the *SPS Agreement*. It specifies that, for the purposes of the *SPS Agreement*, the term "pest" includes weeds. Weeds are plants. Therefore, we consider that the term "pest" in Annex A(1) must be understood to cover plants in addition to animals.

7.239 The other element which we find instructive are the references in Annex A(1)(a) and A(1)(c) to "animal or plant life or health" and "human life or health" as well as the reference in Annex A(1)(d) to "other damage". It is apparent from these references that the *SPS Agreement* is intended to be applicable, not just to measures taken to protect against risks which pose a threat to the life, and thus the very existence, of animals, plants or humans, but also to measures taken to protect against risks to the "health" of animals, plants or humans, and to measures taken to prevent other "damage" within the territory of a Member. In the light of this, we consider that the term "pest" should be interpreted to cover "destructive" animals or plants – that is animals or plants which destroy the life and threaten the very existence of other animals, plants or humans. Equally, however, we think that, for the purposes of the *SPS Agreement*, the term "pest" should be interpreted to cover animals and plants which cause

[391] International Standard for Phytosanitary Measure No. 11, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks*, FAO, Rome, 2004 (adopted April 2004), Annex 1, p. 34.

[392] *The New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. 2 p. 2174.

other, less serious, deleterious effects, namely, animals and plants which cause harm to the health of animals, plants or humans or which cause other harm.

7.240 Consistent with the foregoing considerations, it may thus be said that in the context of the *SPS Agreement* the term "pest" should be understood as referring to an animal or plant which is destructive, or causes harm to the health of other animals, plants or humans, or other harm, or a troublesome or annoying animal or plant.

7.241 We note that the 1997 IPPC defines the term "pest" as "[a]ny species, strain or biotype of plant, animal or pathogenic agent *injurious* to plants or plant products".[393] We agree that plants, or animals, which are "injurious" to other plants or plant products constitute "pests" within the meaning of Annex A(1). Indeed, we have said that, in our view, the term "pest" in Annex A(1) encompasses destructive animals or plants, or animals or plants which cause harm to the health of animals or plants. However, we have determined that the term "pest" in Annex A(1) also encompasses animals or plants which cause other harm, and troublesome or annoying animals or plants. The IPPC definition of the term "pest" does not specifically bear out the second part of our interpretation. We recognize that the definition of the term "pest" in the IPPC may in some respects be informative to, and hence aid, an interpreter of the *SPS Agreement*. But the negotiated IPPC definition is not dispositive of the meaning and scope of the term "pest" as it appears in Annex A(1).[394] Therefore, we do not consider that the IPPC definition of "pest" detracts from our view that plants may be considered as "pests" even if they are not injurious to other plants.

7.242 The Parties have presented various arguments which suggest that GM plants could be considered "pests" within the meaning of Annex A(1) in each of the following three situations: (a) situations where GM plants grow where they are undesired, *e.g.*, as a result of seed spillage or persistence or invasiveness; (b) situations of unintentional gene flow or transfer from a GMO plant ("out-crossing"), leading to cross-breeds between GM plants and other plants, whether conventional crops or wild flora, which have undesired introduced traits (such as herbicide or insect resistance) and may establish or spread; and (c) situations where pesticide-producing (*e.g.*, insecticide-producing) GM plants increase the potential for the development of pesticide-resistance in target organisms, notably insects.[395] We will address these three situations below, as necessary. In addition, in sub-section (d), we will address concerns that GM plants might act as "pests" in other situations, specifically concerns regarding potential adverse effects of GMOs on non-target organisms and on biogeochemical cycles.

GM plants growing where they are undesired

7.243 We first turn to examine whether GM plants which grow where they are undesired can be considered as "pests". The European Communities argues that they can. The United States also argues that a GM plant that might potentially establish or spread into new areas and out-compete and

[393] FAO *International Plant Protection Convention*, 1997, Article II, No. 1 (emphasis added). We note that the 1997 Convention was not in force on the date of establishment of this Panel. However, Article II.2 of the FAO's 1979 *International Plant Protection Convention* defined the term "pest" in very similar terms, stating that the term "pest" includes "any form of plant or animal life, or pathogenic agent, injurious or potentially injurious to plants or plant products".

[394] It is important to note in this context that unlike the *SPS Agreement*, the IPPC is concerned only with plant pests, not animal pests.

[395] The Panel will use the term "pesticide" to encompass both insecticides and herbicides. One of the experts advising the Panel, Dr. Snow, indicated that herbicide resistance can develop from selection of naturally occurring herbicide tolerant plants, but this has only been shown to occur in a few instances. It is much more likely for this trait to be passed due to out-crossing. (Annex H, para. 153.)

displace wild flora thereby potentially altering the availability of resources such as food and shelter used by wild fauna would be considered to be a "weed". Canada and Argentina as well argue that if a GM plant becomes a persistent and invasive plant that grows in environments where it is not wanted and overtakes other plant species, it becomes a weed or a "pest" in the context of the *SPS Agreement*.

7.244 We recall our view that the term "pest" in Annex A(1) refers to a plant which is destructive, or causes harm to the health of other animals, plants or humans, or other harm, or a plant which is troublesome or annoying. It is clear to us that a plant which grows where it is not wanted may, for that reason, be destructive, cause harm to the health of other organisms or other harm, or be troublesome or annoying. For instance, an unwanted plant in a cultivated field may necessitate control or eradication efforts by a farmer (*e.g.*, in the case of weeds) or diminish the economic value of the crop the farmer is seeking to grow (*e.g.*, because his/her market is non-GMO with low or little tolerance for impurities). We also recall that the footnote to Annex A specifically indicates that "pests" include weeds. A weed is defined as a "wild plant growing where it is not wanted and in competition with wild plants".[396] Thus, the footnote supports the view that plants growing where they are undesired can be considered as "pests".

7.245 An important implication of the view that plants growing where they are undesired may be considered as "pests" is that even a cultivated plant or crop may in some situations be or become a "pest". Whether that is so would depend on the relevant circumstances, and notably where it grows and the perspective of the user of the land where the plant grows. The Panel therefore agrees with the observation of the European Communities that plants which in one situation may be desirable and hence cultivated (i.e., cultivated sunflowers growing in a field of sunflowers), in another context may be considered "pests" (i.e., sunflowers accidentally growing in a soybean field). Similarly, a GM plant cultivated expressly in a particular field would not qualify as a "pest", whereas volunteer[397] GM plants growing in fields of conventional plants might be considered to be undesirable plants and hence "pests", or "weeds", from the perspective of the farmer seeking to grow a crop other than the unwanted GM crop.[398]

7.246 Turning to Directives 90/220 and 2001/18, we note that the Directives seek to avoid adverse effects on the environment which might arise from the deliberate release of GMOs. More specifically, Directive 2001/18 specifies that adverse effects of GMOs include "effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these"[399], which in turn include the potential of the GM plant for excessive population increase in the environment and any competitive advantage of the GMOs in relation to the unmodified recipient or parental organisms.[400] Along similar lines, Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "[l]ikelihood of [GM plants] becoming more

[396] *The Concise Oxford Dictionary*, 10th edn, J. Pearsall (ed.) (Oxford University Press, 1999), p. 1623.

[397] Volunteer GM plants are GM plants growing unexpectedly from seeds sown through natural processes, *e.g.*, by wind, animals or birds, or from seeds which were accidentally dropped as they were transported between locations.

[398] This view is also supported by the experts advising the Panel. Dr. Squire, for example, defines volunteer plants as "plants that originate from seed or vegetative material shed or left by a crop, and that inhabit fields, usually emerging as a *weed* within a crop" (emphasis added). Although Dr. Squire uses the term "feral" to describe plants that originate from seed or vegetative material left by crops and that exist outside fields, in waysides and the margins of agriculture, he observes that some authors use the term feral for plants descended from a crop whether they are found inside or outside fields. (Annex H, para. 45.)

[399] Annex II.C.2.1 of Directive 2001/18.

[400] Annex IIIA.IV.B.8 and 9 of Directive 2001/18.

persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats" and "[a]ny selective advantage or disadvantage conferred to the [GM plant]".[401]

7.247 We consider that these potential effects of GM plants relate to situations where GM plants grow where they are undesired. In such situations, due to a potential competitive advantage, persistence and invasiveness, GM plants may crowd out or eliminate other plants. Competitive pressure from GM plants may also affect the genetic diversity of remaining plant populations, putting at risk the survival of certain plant species. As these potential effects of GM plants impact negatively on the ability of other plants to exist and survive in the affected area, we think they can be considered to cause harm to the "life or health" of other plants. In other words, we think that by causing harm in the aforementioned ways, GM plants would act as "pests" within the meaning of Annex A(1)(a).[402] Therefore, to the extent Directives 90/220 and 2001/18 are applied to avoid the adverse effects identified in the previous paragraph, they can, in our view, be considered as measures applied "to protect [...] plant life or health […] from risks arising from the entry, establishment or spread" of GM plants *qua* "pests".

unintentional gene flow or transfer from a GM plant to other plants

7.248 We next consider the situation where a GM plant cross-breeds with other plants, whether conventional crops or wild flora (out-crossing[403]). The issue is whether in such a situation the GM plant could be considered a "pest" within the meaning of Annex A(1). We first recall the main arguments.

7.249 The **United States** argues that any undesirable cross-breeding of a plant would render the plant a "pest". The United States considers that this view is supported by the Annex to ISPM No. 11 which extends the IPPC definition of a pest to organisms which may directly affect uncultivated and/or unmanaged plants, indirectly affect plants, or indirectly affect plants through effects on other organisms.[404]

7.250 **Canada** notes that the focus of inquiry in terms of pest characteristics in the context of Directive 2001/18 is the plant containing the transgene, not the modified DNA itself. Canada considers that an undesirable cross-breed of a plant would be considered a "pest" under the *SPS Agreement* to the extent that the undesirable cross-breed of the plant harms "animal or plant life or health" (Annex A(1)(a)) or "human life or health" (Annex A(1)(c)) or causes "other damage" (Annex A(1)(d)). According to Canada, the risks associated with insecticidal crops, such as those producing Bt, arise from their potential impact on insect populations, whether target insects or

[401] Annex II.D.2.1 and D.2.2.of Directive 2001/18.

[402] If it were considered, contrary to our view, that the adverse effects in question do not cause harm to the "life or health" of other plants, we think they would need to be considered to cause "other damage" within the meaning of Annex A(1)(d).

[403] As previously noted, we use the term "out-crossing" or "cross-breeding" to refer to the unintentional breeding of a cultivated plant, in this case a GM plant, with another cultivated or wild plant, in this case a "conventional" or non-GM, plant. Out-crossing could result in the transfer of characteristics of GM plants, such as herbicide resistance or the production of Bt toxin, into conventional or wild plant populations. The experts advising the Panel indicated that the likelihood of out-crossing depends on the species of plant. Dr. Squire, for example, indicates that in Europe oilseed rape plants are more likely to out-cross with susceptible wild species than cotton or corn plants. He states, however, that the fact that a plant is a GM plant should not markedly affect the likelihood of out-crossing, unless the genetic modification changes the male fertility of the plant. (*See* Annex H, paras. 145-148.)

[404] International Standard for Phytosanitary Measure No. 11, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks*, FAO, Rome, 2004 (adopted April 2004), Annex 1, p. 34.

otherwise. To the extent that insecticidal crops harm insects, they can be considered "pests" to wild fauna. If insecticidal crops increase the potential for the development of resistance to other biological control agents, such as Bt, this may have a corresponding indirect effect on plants. Canada also refers to the statement in ISPM No. 11 that the scope of the IPPC also extends to organisms which are pests because they indirectly affect plants through effects on other organisms.

7.251 **Argentina** considers that any undesirable cross-breed could be considered a "pest"; for instance when a herbicide-tolerance gene is transferred to a crop's weeds.

7.252 The **European Communities** argues that (1) a pest must be a living organism, i.e. isolated strands of modified DNA cannot be, in and of themselves, injurious to human, animal or plant life or health; and (2) the organism must cause injury to a plant. The mere presence of a transgene may be undesirable but not present any phytosanitary risk; plants do not injure flora by cross-breeding with them, and for that reason cannot be considered "pests". Furthermore, the European Communities argues that the transfer of herbicide resistance from genetically modified plants into wild flora could result in the development of a herbicide-resistant wild population which could become invasive and could result in damage to biodiversity, however the European Communities considers that the novel herbicide-resistant wild plant would not be a pest as defined by the IPPC, since it would primarily affect insects and other organisms of the trophic chain.[405]

7.253 The **Panel** notes that according to Annex 3 of FAO's ISPM No. 11, a living modified organism (hereafter an "LMO") may be deemed to be a "pest" if the LMO is associated with "[a]dverse effects of gene flow or gene transfer including, for example [...] transfer of pesticide or pest resistance genes to compatible species".[406] Annex 3 of ISPM No. 11 further states in this regard that:

> "In cases of phytosanitary risks related to gene flow, the LMO is acting more as a potential vector or pathway for introduction of a genetic construct of phytosanitary concern rather than as a pest in and of itself. Therefore, the term "pest" should be understood to include the potential of an LMO to act as a vector or pathway for introduction of a gene presenting a potential phytosanitary risk."[407]

7.254 Annex 3 of ISPM No. 11 suggests that contrary to what the European Communities contends in paragraph 7.236 above, an unwanted transgene in a cross-breed between a GM plant and other plants may be considered to present a potential phytosanitary risk. As none of the Parties has argued that a transgene presenting a potential phytosanitary risk should be considered as a "pest" within the meaning of Annex A(1), we see no need to address this issue. We merely note that Annex 3 of ISPM No. 11 does not suggest that the transgene should or could be viewed as a "pest" in its own right. Rather, it states that the LMO which potentially transfers the transgene should be viewed as a "pest".

7.255 Along the lines of the above-quoted statement in Annex 3 of ISPM No. 11, it could be argued that the term "pest" as it appears in Annex A(1) of the *SPS Agreement* should be understood to include GMOs which could act as vectors or pathways for the introduction into the same or another

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[405] *See supra*, footnote 371.

[406] International Standard for Phytosanitary Measure No. 11, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks*, FAO, Rome, 2004 (adopted April 2004), Annex 3, p. 36. The European Communities has pointed out that the 1997 IPPC on the basis of which ISPM No. 11 was published had not been ratified by the European Communities on the date of establishment of this Panel. We note in this regard that we are neither applying ISPM No. 11 as such nor treating it as dispositive of the meaning of terms used in Annex A(1) of the *SPS Agreement*. However, we think we may refer to it if we find that it is informative and aids us in establishing the meaning and scope of the terms used in Annex A(1).

[407] *Ibid*, Annex 3, p. 37.

plant of a gene presenting a risk for the life or health of other plants or for animals. However, for the purposes of the present dispute, we need not take a position on whether a GM plant which cross-breeds with other plants could be viewed as a "pest" within the meaning of Annex A(1). We are satisfied that even if a GM plant which cross-breeds with other plants were not itself viewed as a "pest", the cross-breeds could be regarded as "pests" for the purposes of Annex A(1), to the extent they have undesired introduced traits (such as herbicide or insect resistance) and harm animal, plant or human life or health or result in other damage. For instance, the herbicide resistant trait might be conferred to a cross-breed plant, which could give it a selective advantage when the relevant herbicide is used. In other words, the cross-breed could become persistent or invasive and thus pose a risk to the life or health of wild flora or fauna.

7.256 Another concern arising from cross-breeds that have acquired herbicide resistance is that they may lead to the need for an increased use of the same herbicides, or for the use of more toxic herbicides, to control the resistant weeds.[408] We recall that the United States points out that section 2.3.1.2 of ISPM No. 11 mentions as an indirect effect of a "pest" "environmental and other undesired effects of control measures".[409] The United States appears to argue on this basis that if a cross-breed plant has acquired herbicide resistance and this necessitates the use of more or different herbicides, any undesired effect of this pesticide use on non-target flora and fauna would qualify as an indirect and undesired effect of the herbicide resistant GMO or cross-breed on non-target flora and fauna. On the other hand, the European Communities argues that potential risks to animal or plant life or health would be the result, not of the spread of resistant cross-breeds, but of steps taken to prevent the spread of resistant crossbreeds, *i.e.*, of the change in the use of pesticides. We accept that any injury to animals or plants would be a direct result of the pesticide use. Nonetheless, any injury to animals or plants would be an indirect result of the entry, establishment or spread of resistant cross-breeds. The harmful pesticide use would not be necessary if the herbicide resistance trait had not been conferred on these cross-breeds by the GM plant. We therefore consider that risks to animal or plant life or health resulting from a change in pesticide use may be viewed as arising indirectly from the entry, establishment or spread of cross-breeds *qua* relevant pest. We note that this view is also

[408] Dr. Andow, for example, has indicated that "[t]here is abundant evidence that repeated use of a given biotech herbicide tolerant crop would likely result in the evolution of resistance in weeds to the herbicide. [...] Adverse effects on non-target flora and fauna could arise directly from transgene products, directly from the herbicide compounds, or indirectly through the effects of the transgenic crop or the herbicide on the environment. [...] Gene flow from a GMHT crop to a weedy relative can create weeds that are more difficult to control with herbicides." (excerpts from Annex H, paras. 170-172.) Dr. Snow has indicated that "[f]requencies of specific crop genes in free-living plant populations depend on their rates of introduction and also their effects on plant fitness (i.e, relative survival and reproduction). Unlike some types of nontransgenic herbicide tolerance, the transgenes that confer tolerance to glyphosate and glufosinate are not expected to have any negative effects on crop yields or the fitness of crop relatives [...] In the absence of exposure to the herbicide in question, herbicide-tolerant plants will not have any selective advantage over their non-transgenic counterparts. But when the herbicide is used repeatedly, it will select very quickly for plants that are resistant to the herbicide. The scientific literature in weed science is full of examples of rapid evolution and spread of herbicide resistant weeds [...] In principal, the potential for the establishment and spread of herbicide-tolerant plants is similar for nontransgenic vs. transgenic crops that have genes for these traits. [...] The more the herbicide is used, the stronger the selection pressure favoring herbicide-resistant weeds. [...] Another method for suppressing populations of herbicide-resistant weeds is to use several types of herbicides in tank-mixes each year, before or after a crop is grown, to kill off resistant plants. Management options become more challenging and more complicated when the pest population has genes for several types of herbicide resistance. In some cases, it may be necessary to revert to the use of herbicides that have greater toxicity and longer persistence in the environment (*e.g.*, 2,4-D)." (excerpts from Annex H, paras. 150-155)

[409] International Standard for Phytosanitary Measure No. 11, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks*, FAO, Rome, 2004 (adopted April 2004), Section 2.3.1.2.

consistent with the aforementioned section 2.3.1.2 of ISPM No. 11, which specifically states that indirect pest effects include environmental and other undesired effects of pest control measures.

7.257 Having regard to Directives 90/220 and 2001/18, we recall, first of all, that they seek to avoid adverse effects on the environment which might arise from the deliberate release of GMOs. We also note that Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "potential for gene transfer to the same or other sexually compatible plant species […] and any selective advantage or disadvantage conferred to those species"[410], and "possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms [...]."[411] In the light of this, we think Directives 90/220 and 2001/18 can be considered as measures applied to protect animal or plant life or health from risks arising directly (*e.g.*, through changes in selective advantage) or indirectly (*e.g.*, through changes in the use of pesticides) from the entry, establishment or spread of cross-breeds with undesired traits (such as herbicide or insect resistance) resulting from transfer of genetic material from a GM plant.

7.258 We recognize that Directives 90/220 and 2001/18 are measures applied in respect of, and primarily concerned with, GMOs rather than their cross-breeds. Nonetheless, we think the Directives can be viewed as measures protecting from risks arising from cross-breeds of GM plants, given that the relevant cross-breeds would be an effect of the deliberate release of GM plants into the environment. As noted, Directives 90/220 and 2001/18 seek to avoid adverse effects of the release of GMOs into the environment, including those resulting from gene transfer. Hence, there is a rational relationship between controlling the release into the environment of GM plants which might cross-breed with other plants and the purpose of protecting animal or plant life or health from risks arising from the entry, spread or establishment of cross-breads with undesired traits. Also, there is nothing in the text of Annex A(1) to suggest that the product subject to an SPS measure – in this case, a GM plant to be released into the environment – need itself be the pest which gives rise to the risks from which the measure seeks to protect.

development of pesticide-resistance in target and non-target organisms

7.259 We address next the situation where pesticide-producing (*e.g.*, insecticide-producing) GM plants increase the potential for the development of pesticide-resistance in target and non-target organisms, notably insect populations, and where this leads to negative environmental effects. As in the gene flow situation, the issue is whether in the situation where resistance develops in target and non-target organisms, the GM plant could be considered a "pest" within the meaning of Annex A(1).

7.260 The Panel understands from the evidence provided by the Parties and from the expert advice that resistance in insect populations to pesticides may develop due to frequent exposure to pesticides.[412] This is the case whether the insect is the target of a GM insecticide-producing plant or a

[410] Annex II.D.2.3 of Directive 2001/18.

[411] Annex II.D.2.5 of Directive 2001/18.

[412] One of the experts advising the Panel, Dr. Andow, states that "[t]here is strong evidence that resistance will develop in the field to any insecticide applied uniformly over wide areas for a long enough period of time. This has been a scientific consensus since the 1980s", and further expressed the view that "[...]of all of the potential environmental risks of transgenic Bt crops, it can be said that resistance in the target pests is a real, tangible risk, while risks associated with gene flow and risks to non-target organisms are mostly only potential risks" (Annex H, paras. 92 and 96, respectively). Another expert, Dr. Squire, states that "[t]he emergence of resistance by pest insects to pesticides differs widely from context to context depending on factors such as the exposure to and strength of the toxin, the movement of insect populations from areas where the pesticide is not applied, and the genetics and mating system of the insect. Resistance to Bt crops has occurred and is influenced

non-target insect. We further understand that if high levels of resistance were to develop in insect populations, it is possible that pesticides might be needed where none were applied before, or that increased volumes of the same pesticides or more toxic chemical pesticides might be needed, to control the resistant insects, which might potentially cause greater environmental damage. It is also possible that the resistant insect population would gain a selective advantage with negative consequences for other flora and fauna, or that the development of resistance in the insect population could have deleterious effects on predators of the resistant insects, including on other predator insects, birds or mammals. The Panel further understands that potential impacts of the development of insect resistance include ecosystem effects. Ecosystem effects include negative effects on animal or plant life or health.

7.261 The European Communities argues that the concerns in this situation are not with the GMO as a pest, but with changes in the characteristics or the genetic make-up of the target organisms. According to the European Communities, the potential risks to animal or plant life or health do not arise from the "establishment" or "spread" of the target organisms, since the target organisms already existed before the introduction of the GMO. Furthermore, the European Communities argues that it is the use of the additional pesticides used to control the target organism which may cause adverse environmental effects, not the pest itself. The European Communities does not in this context explicitly address the issue of development of resistance in non-target insect populations.

7.262 The United States argues that the language used in ISPM No. 11 regarding pests, such as "indirectly affect plants […] by other processes such as competition" and "significant reduction, displacement, or elimination of other plant species"[413] clearly includes all reasonably foreseeable injuries that an organism might cause to plant life or health. Annex I of ISPM No. 11 explicitly provides that the scope also extends to those injuries caused by organisms that indirectly affect plant species or health, through effects on other organisms in the ecosystem. The United States appears to argue on this basis that if an insect population develops resistance to a pesticide produced by a GM plant, and this necessitates the use of more or different pesticides, any undesired effect of this pesticide use on non-target flora or fauna would qualify as an indirect and undesired effect of the plant-produced pesticide on non-target flora or fauna. Consequently, in the United States' view, the "pest" would be the pesticide-producing GM plant.

7.263 For the purposes of the present dispute, it is not necessary for us to take a position on whether a GM plant to which target or non-target organisms (*i.e.*, insect populations) develop resistance, with the result that more or different pesticides need to be used to control the resistant organisms and that other non-target organisms are negatively affected by the pesticide use, could be viewed as a "pest" within the meaning of Annex A(1). Even if a GM plant to which insect populations develop resistance were not viewed as a "pest", we think the resistant target or non-target organisms (*i.e.*, the resistant insects) could be regarded as "pests" within the meaning of Annex A(1), inasmuch as they present a risk to animal, plant or human life or health or result in other damage. In fact, pesticide-producing or pesticide-resistant GM plants are cultivated precisely because the target organisms are considered "pests".

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by the "dose" of toxin delivered to the pest and the genetic nature of the pest, among other factors. [...] The processes involved in Bt resistance and its management are generally appreciated by scientists, and mitigation strategies that have a strong scientific basis have been considered." (Annex H, para. 105.)

[413] International Standard for Phytosanitary Measure No. 11, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks*, FAO, Rome, 2004 (adopted April 2004), Article 2.3.1.1 and Annex 1, p.34.

7.264 Turning to Directives 90/220 and 2001/18, we again recall that the Directives seek to avoid adverse effects on the environment which might arise from the deliberate release of GMOs. We also note that Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the [GM plant] and target organisms".[414] Similarly, Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the [GM plant] and non-target organisms.[415] In the light of this, we think Directives 90/220 and 2001/18 can be considered as measures applied to protect animal or plant life or health from risks arising, directly or indirectly, from the entry, establishment or spread of target or non-target organisms which have developed, or might develop, resistance to a pesticide as a result of interactions with GM plants producing that pesticide.

7.265 We have noted earlier that Directives 90/220 and 2001/18 are measures applied in respect of, and primarily concerned with, GMOs. We have also pointed out, however, that Directives 90/220 and 2001/18 seek to avoid adverse effects of the release of GMOs into the environment, including those resulting from the interactions between pesticide-producing GM plants and target organisms. We have explained that the kind of adverse effects on animal or plant life or health which are at issue in the situation we are considering would be indirect effects of the GMO-induced development of resistance in target and non-target organisms. Hence, there is a rational relationship between controlling the release into the environment of pesticide-producing GM plants and the purpose of protecting animal or plant life or health from risks arising indirectly from the entry, spread or establishment of resistant target or non-target organisms.[416] Also, as we have previously stated, there is nothing in the text of Annex A(1) to suggest that the product subject to an SPS measure – in this case, a pesticide-producing GMO to be released into the environment – need itself be the pest which gives rise to the risks from which the measure seeks to protect.

7.266 The European Communities argues that potential risks to animal or plant life or health would be the result, not of the spread of resistant target organisms, but of steps taken to prevent the spread of resistant target organisms, *i.e.*, of the change in the use of pesticides. We accept that injury to animals or plants could be a direct result of the pesticide use. Nonetheless, as we have said, any injury to animals or plants would be an indirect result of the entry, establishment or spread of resistant insects. Without the development of resistance in the target (or non-target) organisms, the more harmful pesticide use would not be necessary. We therefore consider that risks to animal or plant life or health resulting from a change in pesticide use may be viewed as arising indirectly from the entry, establishment or spread of resistant target (or non-target) organisms *qua* relevant pest. We note that this view is also consistent with the aforementioned section 2.3.1.2 of ISPM No. 11, which specifically states that indirect pest effects include environmental and other undesired effects of pest control measures.

7.267 The European Communities further argues that potential risks to animal or plant life or health would in any event not arise from the "establishment" or "spread" of the target organisms, given that the target organisms already existed, but from a change in the characteristics, or the genetic make-up,

[414] Annex II.D.2.4 of Directive 2001/18.
[415] *Ibid*.
[416] We note that in addressing the issue of resistance in target or non-target organisms all Parties have been assuming that the resistant organisms would be controlled through the use of more or different pesticides and that this could adversely affect wild flora and/or fauna.

of the target organisms. We are not persuaded by this argument. In our view, there could be a legitimate concern that the target (or non-target) organisms would establish or spread. Indeed, were it otherwise, there would be no need to proceed to any change in the control of the resistant insect populations. Moreover, if, as the European Communities asserts, the resistant target (or non-target) insects had characteristics or a genetic make-up different from previous generations of these insects, it would seem that this might be the difference that would allow the resistant insect populations to become established or spread.

effects on non-target organisms and biogeochemical cycles

7.268 Before leaving the issue of "pests", we need to address whether other potential adverse effects than the ones we have already considered could also be viewed as effects of GMOs *qua* "pests" on animal or plant life or health. We note in this respect that Directive 2001/18 specifies that adverse effects of GMOs include "effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these"[417], which in turn include adverse effects of the release of GMOs on non-target organisms.[418] Similarly, Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "[p]ossible immediate and/or delayed environmental impact resulting from direct and indirect interactions of [GM plants] with non-target organisms (also taking into account organisms which interact with target organisms) [...]".[419] Furthermore, Directive 2001/18 refers to possible adverse "effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material"[420], and "[p]ossible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of GMO release(s)".[421]

7.269 Having regard to effects on non-target organisms, we consider that to the extent that GM plants may result in changes in animal or plant populations (including in target organism populations), this may increase or decrease the food available for particular non-target animal populations and thus enhance, or detract from, the fitness and health of these animal populations, which in turn may have a deleterious effect on the life or health of plants, *e.g.*, by affecting their ability to reproduce, etc. These effects would thus impact on the genetic diversity of an ecosystem, including populations of species.[422] In our view, by causing harm to the life or health.[423] In our view, by causing harm to the health of animals or other plants in this way, GM plants would act as "pests" within the meaning of

[417] Annex II.C.2.1 of Directive 2001/18.
[418] Annex IIIA.IV.B.12 of Directive 2001/18.
[419] Annex II.D.2.5 of Directive 2001/18.
[420] Annex II.C.2.1 of Directive 2001/18.
[421] Annex II.D.2.8 of Directive 2001/18.
[422] We recall the comment of one of the experts advising the Panel, Dr. Andow, that "[...]of all of the potential environmental risks of transgenic Bt crops, it can be said that resistance in the target pests is a real, tangible risk, while risks associated with gene flow and risks to non-target organisms are mostly only potential risks" (Annex H, para. 96). Dr. Andow further indicated that "[to] my knowledge there are no reports of adverse effects on soil micro- or macro-flora or fauna separate from those in the UK-FSE trials. Nor are there any reports of adverse effects on soil dwelling bacteria, algae, or protozoa. However, to my knowledge there have not been any studies of any of these possible effects. The Panel should not infer that the absence of information implies an absence of effect." (Annex H, para. 174)
[423] Even if it were considered that adverse effects on genetic diversity of ecosystems, including populations of species, would not be damage to the life or health of these populations and hence would fall outside the scope of Annex A(1)(a), these effects could in our view be considered to constitute "other damage" within the territory of a Member and hence would fall within the scope of Annex A(1)(d).

Annex A(1).[424] We note that in relation to potential adverse impacts on plant life or health, this view is consistent with Annex 3 of ISPM No. 11. Annex 3 states that LMOs may be considered as "pests" if they are associated with adverse effects on non-target organisms, including "effects on other organisms, such as biological control agents, beneficial organisms, or soil fauna and microflora, nitrogen-fixing bacteria, that result in a phytosanitary impact (indirect effects)". In the light of these elements, we think Directives 90/220 and 2001/18 can be considered as measures applied to protect the life or health of non-target organisms, whether animals or plants, from risks arising from the entry, establishment or spread of GM plants *qua* "pests".

7.270 Regarding effects on biogeochemistry, it is useful to distinguish between direct and indirect potential effects of GMOs. To the extent that GMOs might affect the life or health of non-target soil microfauna or –flora, Directives 90/220 and 2001/18 could, as we have indicated earlier, be considered as measures applied to protect the life or health of soil microfauna or –flora from risks arising from the entry, establishment or spread of GM plants *qua* "pests".[425] To the extent that GMOs might adversely affect soil microfauna or –flora, or nitrogen-fixing bacteria, and this would have an adverse effect on the life or health of other plants or animals, we think Directives 90/220 and 2001/18 could be considered as measures applied to protect the life or health of animals or plants from risks arising indirectly from the entry, establishment or spread of GM plants *qua* "pests".[426]

7.271 We note that Directive 2001/18 also specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "[p]ossible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs".[427] The European Communities has argued that the use of GM crops as opposed to conventional crops may have adverse effects on the agro-ecological environment and on biodiversity. In this context, the European Communities has referred to research on the effect, if any, that the management practices associated with genetically modified herbicide tolerant crops might have on farmland wildlife, when compared with weed control used with non-GM crops.[428]

7.272 The concern referred to by the European Communities pertains to changes in weed control practices – specifically, changes in herbicide use – that may be associated with the introduction of herbicide tolerant GM crops.[429] In relation to this scenario, there is no doubt in our minds that the

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[424] International Standard for Phytosanitary Measure No. 11, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks*, FAO, Rome, 2004 (adopted April 2004), Annex 3, p. 36.

[425] We understand that such direct risks may arise, for example, through the exposure of soil microfauna to Bt toxins in the roots of Bt-producing GM plants, or through the decomposition and absorption into the soil of other transgenes.

[426] We note that in relation to potential adverse impacts on plant life or health, this view is consistent with Annex 3 of ISPM No. 11, which refers to effects on soil fauna and microflora, and nitrogen-fixing bacteria, which might result in a phytosanitary impact. International Standard for Phytosanitary Measure No. 11, *Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental Risks*, FAO, Rome, 2004 (adopted April 2004), Annex 3, p. 36.

[427] Paragraph 9 of Annex II.D.2. of Directive 2001/18.

[428] UK Department for Environment Food and Rural Affairs, "GM crops: Effects on farmland wildlife", October 2003 (Exhibit EC-38). These studies are referred to as the "Farm Scale Evaluation".

[429] The European Communities addresses specifically changes in herbicide use, and has not provided any information about other potential changes in weed control practices related to the introduction of GM crops as compared to non-GM crops.

weeds against which the herbicide is used qualify as "pests" within the meaning of Annex A(1).[430] The herbicide use, for its part, constitutes a pest control measure. In the scenario posited by the European Communities, potential risks to the environment, including to non-target organisms such as farmland wildlife, would be the result of a change in weed control practices, *i.e.*, the application of a herbicide, the increased application of a herbicide, or the application of a different, more harmful herbicide. Indirectly, however, any environmental risks would be the result of the entry, establishment or spread of the relevant weeds. Given this, we consider that risks to the environment resulting from the use of a herbicide, or of a different herbicide, may be viewed as arising indirectly from the entry, establishment or spread of weeds *qua* relevant pests. We note that this view is consistent with the previously mentioned section 2.3.1.2 of ISPM No. 11, which specifically states that indirect pest effects include environmental and other undesired effects of pest control measures.

7.273 Regarding the link to GM plants, we note that Directives 90/220 and 2001/18 seek to avoid adverse effects of the release of GMOs into the environment, including those resulting from a change in management practices in the wake of the introduction of herbicide tolerant GM plants. Based on the evidence before us, we understand that herbicide tolerant GM plants are linked to the herbicide to which they are tolerant. Indeed, the herbicide-tolerance trait of these GM plants is the reason why these plants have been genetically modified in the first place. In other words, these GM plants have been developed so that farmers can use the relevant herbicide to protect the plants against competition from particular weeds. Moreover, the herbicide to which GM plants are tolerant has been developed to help control and/or eradicate the relevant weeds. Thus, it is clear that, *via* the relevant herbicide, the GM plants in question are also linked to the weeds, and hence the pests, to be controlled.

7.274 As the GM plants, the herbicide and the weeds are interlinked in the aforementioned ways, we consider that there is a rational relationship between controlling the release into the environment of herbicide tolerant GM plants and the purpose of protecting the environment from risks arising indirectly from the entry, spread or establishment of weeds. Also, we recall our earlier statement that there is nothing in the text of Annex A(1) to suggest that the product subject to an SPS measure – in this case, a herbicide tolerant GM plant to be released into the environment – need itself be the pest which gives rise, directly or indirectly, to the risks from which the measure seeks to protect.

7.275 In the light of the foregoing, to the extent that Directives 90/220 and 2001/18 seek to avoid adverse effects on the environment which involve adverse effects on the life or health of non-target organisms (animals and plants) and which arise from the management techniques associated with GMOs, we consider that the Directives can be viewed as measures applied to protect the life or health of animals or plants from risks arising indirectly from the entry, establishment or spread of weeds *qua* "pests".[431]

"diseases, disease carrying organisms or disease-causing organisms"

7.276 The **European Communities** notes that the World Organization for Animal Health (OIE) defines a disease as: "the clinical and/or pathological manifestation of infection".[432] A GMO is not infected or an infection, and is not, in itself, a disease, a disease-carrying organism, nor generally considered a disease-causing organism.

[430] We note that a particular herbicide may target a specific weed or a broad spectrum of weeds. For simplicity, we hereafter refer to "weeds" in the plural.

[431] We will consider this scenario further as part of our discussion of Annex A(1)(d) below.

[432] *International Animal Health Code*, 2002.

7.277 The **Panel** observes that the common definition of the term "disease" as it appears in Annex A(1)(a) is "a disorder of structure or function in an animal or plant of such a degree as to produce or threaten to produce detectable illness or disorder".[433] The World Health Organization (hereafter the "WHO") defines disease as "[a] pathological condition of the body that presents a group of clinical signs, symptoms, and laboratory findings peculiar to it and setting the condition apart as an abnormal entity differing from other normal or pathological conditions (CMD 1997)".[434] Regarding the term "disease-carrying organisms" and "disease-causing organisms" in Annex A(1)(a), we note that the WHO defines a disease-carrying organism as a "vector" and a disease-causing organism as a "pathogen".[435]

7.278 The European Communities contends that GMOs *per se* are neither infected nor infections, nor diseases, nor disease-carrying or disease-causing organisms. We note that we do not need to determine in the abstract whether GMOs are diseases, disease-carrying organisms, etc. Rather, we need to determine whether the adverse effects which might arise from the deliberate release of GMOs into the environment and which Directives 90/220 and 2001/18 seek to avoid are covered by Annex A(1). In this regard, we note that Directive 2001/18 specifies that potential adverse effects of GMOs include disease to animals and plants, and altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors.[436] Directives 90/220 and 2001/18 thus seek to prevent GM plants from introducing or spreading diseases, and from altering the susceptibility of animals or plants to pathogens, which might facilitate the introduction or spread of disease-causing organisms (that is, pathogens) or create new disease-carrying organisms (vectors). In the light of this, we think that Directives 90/220 and 2001/18 can be considered as measures applied to protect animal or plant life or health from risks arising from the entry, establishment or spread of diseases, disease-carrying organisms (*e.g.*, vectors) and disease-causing organisms (*e.g*, pathogens).

antibiotic resistance marker genes

7.279 The **European Communities** observes that the risks of concern regarding antibiotic resistance marker genes (hereafter "ARMG") are that the ARMG could be transferred from the plant to bacteria in the digestive tract of humans or animals, and that this might negatively impact on the use of antibiotics in clinical or veterinary medical treatments. The European Communities argues that it is not the plant DNA, but a separate pathogen, that causes the disease; the plant DNA merely contributes to the development of antibiotic resistance, and therefore such effects fall outside of the scope of the *SPS Agreement*. Another concern, according to the European Communities, relates to the risk that persistence of plant-derived DNA in soil residues could transfer antibiotic resistance to microbial pathogens which would otherwise be treatable by the antibiotic at issue if the pathogens should infect and cause disease in humans or animals.

7.280 The **United States** argues that it is not necessary for plant DNA to be an organism for measures taken to protect against any increased risk of antibiotic resistance to fall within the scope of the *SPS Agreement*. Concerns relating to effects of plant DNA are essentially concerns about the potential effects of the altered plant, which is an organism within the scope of Annex A(1)(a). The text of this provision requires only that the measure be adopted to protect against the risks…arising from the establishment or spread of diseases…or disease-causing organisms. The United States notes

[433] *The Shorter Oxford English Dictionary*, L. Brown (ed.) (Oxford University Press, 2002), Vol. 1, p. 698.
[434] *See* http://www.who.int/docstore/peh/Vegetation_fires/Health_Guidelines_final_AnnC.pdf.
[435] *Ibid*.
[436] Annex II.C.2.1 of Directive 2001/18.

that for an animal infected with the pathogen that would ordinarily be treated with the antibiotic to which the pathogen had become resistant, the transfer of the resistance gene would contribute to the establishment and spread of disease--the disease caused by the now resistant pathogen—a risk that clearly falls within Annex A(1)(a). If an altered plant contributes to the spread of the disease, a measure taken for the purposes of controlling such a plant is a measure taken to protect against the 'risks arising from the spread of...disease-causing organisms." The fact that the altered plant is not the sole cause of the disease does not change this conclusion.

7.281 The **Panel** considers that the concern raised by the European Communities relates to the potential transfer to pathogens of ARMG present in certain GMOs. If pathogens were to become resistant to certain antibiotics in this manner, this might lessen the effectiveness of medical treatments involving these antibiotics and hence might pose a risk to the life or health of animals infected with the resistant pathogen.[437]

7.282 The European Communities argues that neither the GM plant nor the ARMG can be considered a disease-causing organism. We find it unnecessary to take a position on whether the GM plant or the ARMG could be viewed as a disease-causing organism within the meaning of Annex A(1). We are satisfied that even if the GM plant or the ARMG were not viewed as a "disease-causing organisms" in and of themselves, the pathogen which develops resistance to the antibiotic in question could be regarded as a "disease-causing organism" for the purposes of Annex A(1).

7.283 Having regard to Directives 90/220 and 2001/18, we recall that the Directives seek to avoid adverse effects on the environment which might arise from the deliberate release of GMOs. We also note that Directive 2001/18 specifies that potential adverse effects of GMOs include "compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine".[438] In the light of this, we think that Directives 90/220 and 2001/18 can be considered as measures applied to protect animal life or health from risks arising from the entry, establishment or spread of disease-causing organisms which have or might become resistant to antibiotics due to the transfer of ARMG from a GM plant. Similarly, the Directives can, in our view, be considered as measures applied to protect animal life or health from risks arising from the entry, establishment or spread of diseases due to the reduced effectiveness of antibiotics used to treat the pathogens which have become resistant to these antibiotics through gene transfer.

7.284 We recognize, as we have done earlier, that Directives 90/220 and 2001/18 are measures applied in respect of, and primarily concerned with, GMOs. We have also pointed out earlier, however, that Directives 90/220 and 2001/18 seek to avoid adverse effects of the release of GMOs into the environment, including those resulting from the transfer to pathogens of genes conferring antibiotic resistance. The potential risks to animal life or health which are at issue in the situation we are considering would be the direct or indirect result of pathogens which have or might become resistant to antibiotics due to the transfer of genetic material from a GM plant containing an ARMG.

[437] We note, however, that according to the experts advising the Panel, the risk of transferral of the antibiotic resistance marker gene is negligible. Dr. Nutti, for example, described the steps that would be necessary for such a transfer to occur, and stated that "[t]here have been numerous experiments aimed at evaluating the possibility of transfer of plant DNA to microbes and mammalian cells. To date, there are no reports that marker genes in plant DNA transfer to these cells." (Annex H, para. 1123) Dr. Andow stated that "[t]o my knowledge, all reports have not found adverse effects on flora or fauna from antibiotic resistance genes or gene products. Extensive studies on nptII did not find any adverse effects, and found that any undetected adverse effects would likely be several orders of magnitude smaller than naturally occurring phenomena." (Annex H, para. 175)

[438] Annex II.C.2.1 of Directive 2001/18.

Hence, there is a rational relationship between controlling the release into the environment of GM plants containing an ARMG and the purpose of protecting animal life or health from risks arising from the entry, spread or establishment of disease-causing organisms and diseases. Also, we recall that there is nothing in the text of Annex A(1) to suggest that the product subject to an SPS measure – in this case, a GM plant containing an ARMG to be released into the environment – need itself be the disease-causing organism, or the disease, which gives rise to the risks from which the measure seeks to protect.

Preliminary conclusions concerning Annex A(1)(a)to the SPS Agreement

7.285 In light of the above considerations, we are of the view that, of the potential adverse effects of GMOs identified in Annex II.C.2.1 of Directive 2001/18, the following fall within the scope of Annex A(1)(a) of the *SPS Agreement*:

– disease to animals and plants including toxic, and where appropriate, allergenic effects[439];
– effects on the dynamics of populations of species in the receiving environment and the genetic diversity of each of these;
– altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors;
– compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine;
– effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material.

This does not exclude, however, that, depending on the circumstances, some of these potential adverse effects may also fall within the scope of other sub-paragraphs of Annex A(1).

7.286 Similarly, with respect to the concerns identified in Annex D.2 of Directive 2001/18 with respect to genetically modified higher plants (GMHP), we consider that the following fall within the scope of Annex A(1)(a), while recognizing that, depending on the circumstances, some may also fall within the scope of other sub-paragraphs of Annex A(1):

– likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats;
– any selective advantage or disadvantage conferred to the GMHP;
– potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species;
– potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids, and pathogens (if applicable);
– possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens;

[439] We address potential allergenic effects below, in the context of our analysis of Annex A(1)(b) and in footnote 495.

– possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s);
– possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.

Annex A(1)(b) to the *SPS Agreement*: Protection of human or animal life or health from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs

7.287 We now turn to analyse whether Directives 90/220 and 2001/18 fall within the scope of Annex A(1)(b) of the *SPS Agreement*. As we have done above with regard to Annex A(1)(a), we will structure our analysis below according to certain terms and phrases used in Annex A(1)(b), including "foods, beverages or feedstuffs", "additives", "contaminants" and "toxins". The Parties have also addressed concerns relating to potential effects of allergens on human and animal health in the context of Annex A(1)(b), hence we will also consider these concerns below.

"foods, beverages or feedstuffs"

7.288 The **European Communities** notes that a food is something that is intentionally ingested by a human for nutritional purposes; a beverage is something that is drunk; and a feedstuff is something that farmed animals are intentionally permitted to ingest for nutritional purposes. Annex A(1)(b) does not encompass products that are not "foods, beverages or feedstuffs". A GM seed to be used in agriculture is not a "food, beverage or feedstuff". It is destined to be planted in the ground, not eaten by humans or fed to animals. Therefore, according to the European Communities, a GM sowing seed cannot fall within Annex A(1)(b). Similarly, a crop or plant is not in itself necessarily a food. It may be processed into something that becomes a food, but that does not make the crop or plant itself a food. A GM crop or plant does not therefore necessarily fall within sub-paragraph (b). However, the European Communities notes that Annex A(1)(b) may cover the risk of a modified gene in food, beverages or feedstuffs causing disease in humans or animals.

7.289 The European Communities further argues that a crop or plant is not necessarily a "feedstuff" for animals – that depends on whether or not it is destined for such use, and whether or not the crop will first be processed. Finally, the impact of a GMO on wild flora and fauna does not fall within sub-paragraph (b), because it does not relate to foods, beverages or feedstuffs. The GM crop is not a "feedstuff" vis-à-vis the pest. The same is true in respect of non-target organisms, since the crop is not a "feedstuff" vis-à-vis such organisms.

7.290 The **Complaining Parties** argue that "foods, beverages or feedstuffs" encompass genetically modified plants intended for use in foods, including processed foods. The gene or DNA which is inserted into a GM plant can be considered to be an additive or a disease-causing organism. Proteins which are expressed due to the changes generated during genetic modification can be considered to be contaminants or toxins depending upon their food safety effects.

7.291 The **Panel** notes that the common definition of a "food" is a substance taken into the body to maintain life and growth.[440] Thus, we consider that a substance which a human being or an animal consumes for nutritional reasons may be classified as a "food". A "feedstuff" on the other hand is

[440] *The Shorter Oxford English Dictionary*, L. Brown (ed.) (Oxford University Press, 2002), Vol. 1, p. 1001.

defined as fodder[441], and "fodder" is defined as "food for cattle, horses, etc., and more specifically as dried food, as hay, straw, etc., for stall-feeding".[442]

7.292 Applying these definitions in the context of this dispute, we consider that a GM crop grown for the explicit purpose of providing food to animals, and in particular to farmed animals, would qualify as a "feedstuff". A GM crop that has been grown for a different purpose, but is eaten by animals, including wild fauna[443], can be considered to be a "food" for that animal. This would include, for example, pollen of the GM crop which is consumed by insects and GM plants consumed by non-target insects, deer, rabbits or other wild fauna. Contrary to the European Communities, we think GM seeds used for sowing purposes could also be considered animal "food", for instance if these seeds are spilled next to a field or on a farm and are subsequently eaten by birds, etc.

"additives"

7.293 The **United States** claims that certain types of genes, such as the ARMG, fall within the definition of an additive under the *SPS Agreement*. According to the United States, this is further supported by the Codex definition of an additive, which does not exclude genetic inserts or constructs added to food crops.[444] Thus, consistent with the Codex definition, the ARMG is a component of the food from the biotech plant; is not normally consumed as a food by itself; is not normally used as a typical ingredient of the food; and is intentionally added to the plant (and thus the food from the plant), for a technological purpose in the manufacture of the food. Protection against any associated human or animal health risks, such as either the development of antibiotic resistance or the development of the disease the antibiotics would be used to treat, falls within Annex A(1)(b). For the same reason, products that contain ARMG are also covered by the *SPS Agreement*.

7.294 **Canada** considers that an ARMG is a "substance" in the basic sense of that term, and nothing in the Codex definition would exclude the possibility that an ARMG could be considered an additive.

7.295 The **European Communities** notes that the Codex provides a relevant definition for the purposes of determining the meaning of "additive" in Annex A(1)(b). Codex defines an additive as a substance which is added to "food", not a substance which is added to plants and which may find its way into food. The European Communities argues that the GMO products relevant in this dispute are not "additives" within the Codex definition. Nor is a gene an additive – whether introduced by recombinant DNA technology or by conventional breeding. Genes are not substances, but rather instructions for the creation of substances.

7.296 According to the European Communities, the definition of "additive" proposed by the United States would encompass any gene, whether introduced by recombinant DNA technology or by conventional breeding. Furthermore, the European Communities argues that the risks of concern regarding ARMG fall outside of the scope of the *SPS Agreement*. In particular, ARMG or food produced with GM plants which contain ARMG do not cause disease.

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[441] *Ibid*., p. 937.
[442] *Ibid*., p. 997.
[443] The Panel recalls its view that the *SPS Agreement* explicitly covers risks to wild fauna and distinguishes neither among categories of animals (such as insects, birds, and mammals) nor between "target" and "non-target" species.
[444] Art. 2a, Codex Procedural Manual 14th edition (Reference A), p. 43.

7.297 The **Panel** notes that the *New Shorter Oxford English Dictionary* defines "additives" as "a substance added to another so as to give it specific qualities".[445] Given that Annex A(1)(b) is concerned with additives in foods, we also find informative that Codex defines a "food additive" as:

> "Food additive means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include 'contaminants' or substances added to food for maintaining or improving nutritional qualities."[446]

7.298 The Panel is not convinced by the European Communities' categorical assertion that genes cannot be considered substances. A "substance" is defined as the "real physical matter of which a person or thing consists".[447] It is our understanding that genes may be considered as "real physical matter". We do not dispute that genes contain and encode instructions for the creation of various substances. However, this does not exclude that genes may themselves constitute substances.

7.299 We note that the Codex definition of "food additives" refers to additions made "in the manufacture" of the food in question or at subsequent stages of food production. In the present dispute, the Panel considers that "food" encompasses GM plants that are eaten as such or processed into products that are eaten. We note that the concept of "manufacture" does not fit well with the first situation where plants are grown for food purposes (*e.g.*, sweet maize for fresh consumption). As we see it, the farmer cannot add substances to a plant for a technological purpose in the same way that a manufacturer can add substances to a food product for a technological purpose (*e.g.*, colouring to match the flavour of a yoghurt). If farmers wish to add a substance of the relevant type, we think they effectively have to do so at the stage of developing and producing the seeds of the plant. Therefore, we think that in the special case of "plant production", substances intentionally added at the stage of seed development and production could be reasonably considered to be substances added in the manufacture of the food plant, if the substances are present in the harvested plant as a component or affect the characteristics of the harvested plant.

7.300 In any event, the Codex definition is not dispositive of the meaning of the term "additives" as it appears in Annex A(1)(b). We are aware that pursuant to Article 3(1) of the *SPS Agreement* Members are to base their SPS measures on "international standards, guidelines and recommendations", where they exist, and that in accordance with Annex A(3)(a) of the *SPS Agreement*, Codex standards relating to food additives are relevant "international standards" within the meaning of Annex A(3)(a).[448] However, unlike Article 3(1) and Annex A(3), Annex A(1) makes no reference to "international standards, guidelines and recommendations". Had the drafters of

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[445] *The Shorter Oxford English Dictionary*, L. Brown (ed.) (Oxford University Press, 2002), Vol. 1, p. 25.

[446] Codex Procedural Manual 14th edition (Reference A), p. 43. The same definition of an additive is contained in Section 2(a), Codex General Standard for Food Additives (Codex Stan 192-1995) (Rev.6-2005).

[447] *Concise Oxford Dictionary*, Judy Pearsall (ed.) (Oxford University Press, 1999), p. 1429.

[448] It is useful to recall that the Appellate Body has established that for an SPS measure to be "based on" an international standard the measure need not necessarily "conform to", or comply with, that standard. Appellate Body Report, *EC – Hormones*, para. 163. Therefore, even if the meaning and scope of the term "additives" as it appears in the *SPS Agreement* and in the Codex standard did not correspond exactly, it would still be possible for Members to "base" their SPS measure on the Codex standard.

the *SPS Agreement* intended for terms like "additives" to have the meaning given to them by definitions contained in relevant international standards, etc., we think Annex A(1) would have made this clear.[449] Looking at the text of Annex A(1)(b), we note that it broadly, and simply, refers to "additives" "in foods". The ordinary meaning of the term "additives" read in the context of Annex A(1)(b) does not suggest that for an added substance to qualify as an "additive" in a food, the substance needs to have been added at a particular stage prior to the consumption of the food in question.

7.301 In the light of the foregoing, the Panel is of the view that genes, intentionally added for a technological purpose to GM plants that are eaten or being used as an input into processed foods, can be considered "additives in foods" within the meaning of Annex A(1)(b). This should not be construed to mean, however, that all genes of a plant that is eaten or being used as input into processed foods could be classified as "additives".

7.302 We note that Directive 2001/18 specifies that potential adverse effects of GMOs include "compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine".[450] The Parties disagree whether ARMG should be considered as "additives" within the meaning of Annex A(1)(b).

7.303 Based on the explanations given by the Parties, we understand that ARMG are genes used in genetic engineering to detect whether cells into which another foreign gene is inserted have actually taken up that gene.[451] While the ARMG are needed only in the genetic engineering process, the marker genes remain in the GM plant. We recognize that ARMG may not be the kinds of substances that are normally considered to be "additives", *e.g.*, they do not enhance the flavour, appearance or preservation of a product. However, the ARMG is deliberately added in the production of a GM product that is consumed as food, for a specific technological purpose (*e.g.*, to permit the tracing of successful gene transfers), is a component of the GM plants which are processed into food products and remains in the product that is finally consumed. In the light of this, we are of the view that in the context of an approval procedure assessing the safety of specific food products ARMG may be considered to constitute food "additives" within the meaning of Annex A(1)(b).

7.304 We note that the potential adverse effect referred to in Directive 2001/18 is primarily associated with the transmission of antibiotic resistance from the marker genes present in GM plants to the digestive gut of animals or humans. The concern is that this might result in humans or animals developing antibiotic resistance.[452] The development of antibiotic resistance can be considered a risk to human or animal life or health, in that it may compromise the effectiveness of medical or veterinary treatments for diseases. Any potential increase in the population of antibiotic resistant bacteria could also facilitate the dissemination of infectious diseases, as antibiotic treatment would not be effective in stopping the spread of such diseases. Another potential risk is that new reservoirs of diseases could

[449] We find instructive in this regard the provisions of Article 1.1 of the *TBT Agreement*. Article 1.1 provides that "[g]eneral terms for standardization and procedures for assessment of conformity shall normally have the meaning given to them by definitions adopted within the United Nations system and by international standardizing bodies taking into account their context and in the light of the object and purpose of this Agreement".

[450] Annex II.C.2.1 of Directive 2001/18.

[451] For example, we understand that scientists attach these ARMG to the gene which they are seeking to introduce into plant cells. After these linked genes have been inserted into plants, the plant cells are grown in a substance which has been treated with the antibiotic. Only cells which contain the antibiotic resistance, and thus the gene of interest, will survive.

[452] *See supra*, para. 7.303.

be created in humans or animals where resistant bacteria have failed to be eliminated by antibiotic treatments. In the light of this, Directives 90/220 and 2001/18 can, in our view, be considered as measures applied to protect human or animal life or health from risks arising indirectly, namely *via* the potential transfer to humans or animals of marker genes conferring resistance to antibiotics used in human or veterinary medicine, from additives in foods or feedstuffs.

"contaminants"

7.305 The **European Communities** argues that concerns related to higher levels of toxins or contaminants in food, beverages or feedstuffs as a result of increased use of herbicides due to the introduction of herbicide-resistant crops may fall within Annex A(1)(b) of the *SPS Agreement*. However, the European Communities argues that a foreign gene intentionally introduced into a plant through genetic modification techniques is not a contaminant within the meaning of either Annex A(1)(b) of the *SPS Agreement* or the Codex General Standard for Contaminants and Toxins in Food (hereafter, Codex Standard 193). The Codex defines a contaminant as:

> "any substance *not intentionally* added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination."[453]

7.306 The European Communities maintains that both the GMOs and the proteins produced by the GMOs with which this case is concerned will be intentionally present in food. Thus they cannot fall within the Codex definition of contaminant.

7.307 Finally, the European Communities argues that the phrase in Codex Standard 193 "as a result of the production … of such food" refers to the process of food production, not to the more fundamental process of genetic engineering or design. Similarly, the common and ordinary meaning of the words "crop husbandry" refers to what happens on the farm, not what happens in the laboratory. Furthermore, if the Codex definition of contaminant covered any substance unintentionally present as a result of the production of the plant, and included the modification created by gene transfers, or the resulting protein, then most genes and proteins in conventional plants would be "contaminants".

7.308 **Canada** considers that the modification or reaction created by gene transfer, or the expressed protein, could be considered a "contaminant" as that term is defined in Codex Standard 193. While the insertion of the transgene is intentional, that insertion may have unintended effects, one of which could be the creation or expression of an unintended substance. This unintended substance could be considered a contaminant, rather than the transgene itself.

7.309 Furthermore, Canada argues that Codex Standard 193 sets out guidelines for the establishment of the maximum level and guideline levels for contaminants in food or feed, a process that requires an assessment of the "effects" of a contaminant on human and animal health. Codex Standard 193 recognizes that there may be substances that fall within the Codex definition of "contaminant" but are nonetheless excluded from the scope of the Codex Standard because they have "no public health significance".[454] Accordingly, whether a substance falls within Codex Standard 193

[453] Art. 1.2.3, Codex General Standard for Contaminants and Toxins in Food (Codex Stan 193-1995) (Rev.1-1997) (emphasis added).

[454] *Ibid.*, p. 1, Art. 1.2.2. Moreover, Standard 193 provides on p. 3:

is closely tied to the risks to public health associated with that substance, or in other words, the "effects" of the substance.

7.310 Canada notes that the Codex definition requires that the substance must be "present in food as a result of production". One of the examples of production cited is "operations carried out in crop husbandry." Crop husbandry includes the development of seeds. Much of modern crop husbandry is carried out both on the farm and in the laboratory, as an interactive, iterative process between scientist and farmer. Regardless of where selective breeding activities take place, these activities are part of crop husbandry. According to Canada, it therefore logically follows that an unintended substance arising from the genetic modification or reaction by gene transfers is "present in food as a result of production". This type of unintended substance could be considered a "contaminant" for the purposes of Codex Standard 193.

7.311 **Argentina** argues that the gene transfers used in the development of agricultural biotechnology products could generate effects similar to "contaminants".

7.312 The **Panel** notes that the common meaning of a contaminant is "a substance which pollutes, corrupts or infects".[455] We also note that the footnote to Annex A to the *SPS Agreement* states in relevant part that "[f]or purposes of these definitions […] 'contaminants' include pesticide and veterinary drug residues and extraneous matter". These definitions have in common the fact that they refer to substances which are not intentionally added to food. This view is consistent with the above-mentioned Codex definition of "contaminant", which refers to any substance not intentionally added to food, and which is present in such food as a result of the production, processing, packaging, etc, or as a result of environmental contamination.[456]

7.313 Based on the above elements, and noting that the term "contaminants" must be interpreted so as to have a meaning that differs from the meaning of the term "additive" which also refers to substances, we consider that a critical element for determining whether a substance can be considered to be a "contaminant" is that the presence of the substance which is said to "infect or pollute" be unintentional. For this reason, we consider that genes intentionally added to GM plants that are eaten or used as inputs into processed foods would not be "contaminants" in and of themselves. Furthermore, we think that substances such as proteins which are produced by GM plants, and which are *intended*, should not be considered to be "contaminants". However, we agree with Canada that proteins produced through the *unintended* expression of modified genes in agricultural crops may be considered "contaminants" within the meaning of Annex A(1)(b), if these proteins "infect or pollute" the food product.

7.314 The European Communities argues, based on the Codex definition of the term "contaminant", that a protein unintentionally expressed as a result of a genetic modification of a plant should not be considered a "contaminant". The European Communities considers that for the unwanted substance

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> When there are indications that *health hazards* may be involved with consumption of foods that are contaminated, it is necessary that a risk assessment is made. When *health concerns* can be substantiated, a risk management policy must be applied, based on a thorough evaluation of the situation. Depending on the assessment of the problems and the possible solutions, it may be necessary to establish maximum levels or other measures governing the contamination of foods. In special cases, it may also have to be considered to give dietary recommendations, when other measures are not sufficiently adequate to exclude the possibility of *hazards to health*. (emphasis added)

[455] *The New Shorter Oxford English Dictionary*, L. Brown (ed.) (Oxford University Press, 2002), Vol. 1, p. 499.

[456] Codex Procedural Manual, 14th Edition, (Reference A), Rome, 2004, pg. 43.

to qualify as a "contaminant", it would need to be present as a result of the production of the food, and not as a result of the genetic engineering, or the design, of the plant which is used as an input into the processed food. It is correct that the Codex definition of "contaminants" refers to substances which are present in food as a result of the production (including operations carried out in crop husbandry) of the food in question. We recall, however, that we are concerned here with GM plants that are eaten or used as inputs into processed foods. It seems to us that in circumstances where a substance would be created or expressed unintentionally in the process of cultivation of GM plants, *i.e.*, in the process of the production of the plants, it can be reasonably said that the relevant substance is present in the food "as a result of the production" of that food. In any event, the Codex definition is not dispositive of the meaning of the term "contaminant" as it appears in Annex A(1)(b).[457] Annex A(1)(b) broadly, and simply, refers to "contaminants" "in foods". It does not suggest that for a substance present in food to qualify as a "contaminant", the substance needs to have been added at a particular stage prior to the consumption of the food in question.

7.315 We note that Directive 2001/18 specifies that potential adverse effects of GMOs include "disease to humans including allergenic or toxic effects" and "disease to animals [...] including toxic, and where appropriate, allergenic, effects".[458] Furthermore, Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "[p]ossible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed".[459] The Parties have not addressed how contaminants in food or feedstuffs could give rise to disease and hence health problems in humans or animals. To the extent that such risks exist, we think that Directives 90/220 and 2001/18 could be considered as measures applied to protect human or animal life or health from risks arising from contaminants in foods or feedstuffs, namely from proteins unintentionally produced in GM plants which are eaten or used in the production of food or feedstuffs.

7.316 We note the European Communities' argument that the introduction of herbicide-resistant GM crops might lead to a higher level of contaminants, specifically herbicide residues, in foods or feedstuffs, inasmuch as the herbicide-resistance of GM crops might allow for and entail an increased use of herbicides in the field.[460] We would agree that the term "contaminants" in Annex A(1)(b) could encompass herbicide residues present in foods or feedstuffs, and that they may pose risks to human or animal life or health.[461] It is not clear to us from reading Directives 90/220 and 2001/18 whether they are applied, *inter alia*, to avoid disease to humans or animals resulting from herbicide residues in GM plants used as food or feedstuff. To the extent they could be so applied, however, we would agree that the Directives can be seen as measures applied to protect human or animal life or health from risks arising from pesticide residues, and hence contaminants, in GM plants used as or in foods or feedstuffs.

[457] We have addressed earlier, in the context of our discussion of the term "additives", the fact that the *SPS Agreement* in provisions other than Annex A(1) refers to "international standards".

[458] Annex II.C.2.1 of Directive 2001/18.

[459] Annex II.D.2.7 of Directive 2001/18.

[460] We recall that one of the experts advising the Panel, Dr. Snow, noted that "[a]pplication rates of glufosinate and glyphosate are expected to increase greatly if these herbicide-tolerant crops are adopted by farmers". (Annex H, para. 1115)

[461] The United States has pointed out, for instance, that pesticide residues in biotech crops might conceivably have allergenic effects and thus present dietary risks.

"toxins"

7.317 The **European Communities** notes that a toxin can be defined as "a poisonous substance produced during the metabolism and growth of certain micro-organisms and some higher plant and animal species."[462] The European Communities considers that the unintentional production of a poisonous substance during the metabolism and growth of either GM or non-GM plants may be considered as a toxin in the context of Annex A of the *SPS Agreement*. However, the toxic characteristics of seeds or crops, or their effects on non-target organisms, do not fall within SPS Annex A(1)(b) unless the GMO is a "food, beverage or feedstuff."

7.318 The European Communities maintains, furthermore, that the potential toxins created as a result of the *intentionally* introduced specific genetic modification would not be covered by Annex A of the *SPS Agreement*. For example, the toxic effect of an insecticidal crop on the target pest itself cannot fall under Annex A(1)(b), since it is not possible to seek to kill target pests and at the same time seek to protect the life and health of those very same pests.

7.319 The **United States** argues that one food safety-related concern regarding all new plant varieties, developed through modern biotechnology or otherwise, is the unintentional production of a toxin in the food. Toxins introduced into foods by way of biotech or conventional breeding are encompassed by the term "toxins" in the context of Annex A(1)(b). There is nothing in the *SPS Agreement* to indicate that "risks arising from … toxins … in foods, beverages or feedstuffs" should not apply to risks arising from toxins that are in food as a result of breeding changes introduced into the food plant.

7.320 **Canada** agrees that the genetic modification of a plant might unintentionally result in the production of a toxin. The same is true of products from traditionally-bred plants. Canada argues that, apart from potential effects on non-target organisms, the "toxic characteristics of seeds or crops" are only assessed if these products are used for human or animal consumption, not, for example, when these products are for industrial purposes (*e.g.* the oil from oilseed rape used in lubrication or as crude oil).

7.321 The **Panel** notes that common definitions of a "toxin" are "a poison produced by a micro-organism or other organism and acting as an antigen in the body"[463] or "any poisonous antigenic substance produced by or derived from micro-organisms, which causes disease when present at low concentration in the body"[464]. Codex Standard 193 defines two types of toxins in the context of describing the general standard for contaminants and toxins in foods. One is a mycotoxin defined as "a toxicant that is produced as a toxic metabolite of certain microfungi that are not intentionally added to food."[465] The other is a microbial toxin defined as "toxicants that are produced by algae and that may be accumulated in edible aquatic organisms such as shellfish."[466] FAO defines a toxin as "a compound produced by one organism, which is deleterious to the growth and/or survival of another organism of the same or different species".[467] We note that these definitions do not suggest that toxins

[462] *See* http://www.biology-online.org/dictionary.asp as of 15 June 2004.

[463] *Concise Oxford Dictionary*, 10th Edition, Judy Pearsall (ed.) (Oxford University Press, 1999), p. 1517.

[464] *The Shorter Oxford English Dictionary*, L. Brown (ed.) (Oxford University Press, 2002), Vol. 2, p. 3312.

[465] Codex Standard 193 – 1995, General Standard for Contaminants and Toxins in Foods, (Rev.1-1997), p. 1.

[466] *Ibid*, p. 1.

[467] FAO Glossary of Biotechnology for Food and Agriculture, A. Zaid, H.G. Hughes, E. Porceddu and F. Nichols (eds.) (FAO, Rome, 2001), p. 285.

in foods are inherently substances which have been unintentionally added to foods.[468] To be sure, every effort is ordinarily made to avoid the presence of toxins in foods. Nonetheless, a toxin specific to a particular pest is sometimes deliberately added to a food for the purpose of controlling or eradicating that target pest.

7.322 The European Communities argues that the toxins produced by insecticidal GM plants to kill the target insect are not "covered" by Annex A(1)(b) since the production by the GM plant of the toxins is intentional and since it is not possible to kill the target insect and at the same time seek to protect the life and health of those very insects. In our view, the mere fact that the toxin is intentionally produced in the GM plant would not necessarily remove any concerns relating to the toxic effect on the target insect from the scope of Annex A(1)(b). For it could be argued, not implausibly, that the insecticide-producing GM plant constitutes a "toxin" in the food of the target insect which poses a risk to the life and health of the target insect. However, the target insect in the European Communities' example is assumed to be a recognized pest. Accordingly, the release of insecticide-producing GM plants into the environment would normally be controlled, not to protect the life or health of the target insect from risks arising from the release of the GM plant, but to protect the life or health of non-target organisms, etc., from any risks arising from the release of the GM plant.[469] We note that in the present case, the European Communities does not argue that Directives 90/220 and 2001/18 are measures applied to protect target pests, such as insects, from risks arising from the release into the environment of pesticide-producing GM plants.

7.323 We agree with the Parties that a poisonous substance which is produced during the metabolism or growth of a GM crop could qualify as a "toxin" within the meaning of Annex A(1)(b). We also agree with the European Communities that for an SPS measure to be covered by Annex A(1)(b), the toxin which gives rise to risks for human or animal life or health would have to be present in "foods, beverages or feedstuffs". However, we recall that a GM plant which is grown in a field may be eaten as food by wild fauna.[470]

7.324 We note that Directive 2001/18 specifies that potential adverse effects of GMOs include "disease to humans including allergenic or toxic effects" and "disease to animals [...] including toxic, and where appropriate, allergenic, effects".[471] Furthermore, Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "[p]ossible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed".[472] In the light of this, Directives 90/220 and 2001/18 can, in our view, be considered as measures applied to protect the life or health of humans or animals (not including target organisms) from risks arising from toxins produced in GM plants which are foods or feedstuffs.

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[468] We note that the Codex definition of "mycotoxins" refers to the unintentional presence in food of the microfungi, not the unintentional presence of the toxins they may produce.

[469] We refer in this context to our previous discussion of potential risks to animal or plant health arising from the development of resistance in target insects to the insecticide produced by GM plants.

[470] If a GM plant produces a poisonous substance which could adversely affect the health of non-target organisms even if the non-target organisms do not eat the GM plant, or parts thereof, *e.g.*, through exposure other than through ingestion as food, we think the GM plant might qualify as a "pest" within the meaning of Annex A(1)(a).

[471] Annex II.C.2.1 of Directive 2001/18.

[472] Annex II.D.2.7 of Directive 2001/18.

allergens

7.325 The **European Communities** notes that genetic modification may lead to the production of novel proteins or to the increased production of known proteins which may induce an allergic reaction. According to the European Communities, an allergen is defined as "pertaining to antigens that induce an allergic response in an organism or any substance that can cause an allergy."[473] Allergenic responses are only provoked in certain individuals that exhibit sensitivity to the allergen. On the other hand, a toxin is "a poisonous substance produced during the metabolism and growth of certain micro-organisms and some higher plant and animal species."[474] Hence, according to the European Communities, a food allergen cannot be considered to be a toxin. The European Communities argues that it is questionable to describe allergies as diseases; they are better described as medical conditions. In addition, the risk is not so much that the GMO will cause an allergy (which would already be present in the subject), but that it would provoke the allergic reaction.

7.326 The European Communities further notes that potential allergenic effects arising from GM plants may occur as a result of exposure other than through food. Consequently, the issue of allergenicity is not confined to food safety. Rather, the potential presence of allergens in the environment as a result of the release of GM plants may be considered a broader environmental issue, not included in the scope of Annex A(1) of the *SPS Agreement*.

7.327 The **United States** argues that the concern that a biotech product might lead to an allergic reaction on the part of consumers, *e.g.*, concerns regarding allergic reactions based on consumption of a biotech variety that incorporates a genetic trait that can lead to such reactions, falls within the definition of Annex A(1)(b). An allergen would generally fall within the definition of a toxin. A "toxin" is generally defined as "a poison."[475] A "poison" is in turn defined as "any substance which, when introduced into or absorbed by a living organism, destroys life or injures health….".[476] Food allergens clearly fall within the description of a substance that "destroys life or injures health". According to the United States, the allergenicity concern relating to the products at issue in this dispute is that a protein produced in the plant could be allergenic. Or in other words, it is a substance that "destroys life or injures health," or a "poisonous substance," produced during the metabolism and growth of a plant.

7.328 The United States maintains that one exception to this general rule is that when the allergen is itself a pesticide residue, or is a component of a pesticide residue, it would fall within the definition of a contaminant, pursuant to footnote 4 of Annex A(1). Any dietary risks that pesticide residues of GM crops might present would be "risks arising from ... contaminants in foods," including the risk of an allergic reaction from consuming the food.

7.329 The United States argues, in addition, that Annex A(1)(b) is not restricted to dietary risks, but includes any measure taken to protect human or animal life or health from "risks arising from ... toxins ... in foods ... or feedstuffs." Measures taken to protect against occupational exposures from the Bt toxin in the GM plants would fall within this description.

7.330 **Canada** claims that in the context of biochemistry, a "toxin" is defined as "any of the various poisonous substances produced by certain plant and animal cells, including bacterial toxins,

[473] The European Communities notes that antigens are defined as substances that are recognized by the immune system and induce an immune reaction.
[474] *See* http://www.biology-online.org/dictionary.asp [last visited on 15 June 2004].
[475] *The Compact Oxford English Dictionary*, Oxford University Press, 1971, 24th Printing, p. 2224.
[476] *Ibid.*, p. 3367.

phytotoxins and zootoxins."[477] "Toxic" means "relating to a harmful effect by a poisonous substance on the human body by physical contact, ingestion, or inhalation".[478] A "poison" can be defined as "a substance that in relatively small doses has an action that either destroys life or impairs seriously the functions of organs or tissues".[479] Hence, Canada argues that for the purposes of the *SPS Agreement*, allergens in food and feedstuffs can be considered toxins because allergens, in some circumstances, can destroy life or impair seriously the functions of organs or tissues for people with immunological sensitivities to that allergen.

7.331 **Argentina** also argues that the risks arising from a food allergen are comparable to the risks arising from "toxins" or "disease-causing organisms". Allergens, toxins and disease-causing organisms all pose risks to health, even if allergens may affect just a sub-set of the population, instead of the population as a whole. Argentina agrees that a measure to protect humans against occupational exposures from Bt toxins in corn, which is consumed as either a food or feedstuff, is subject to the *SPS Agreement* since Annex A(1)(b) does not specify or restrict the mode of exposure.

7.332 The **Panel** observes that the Complaining Parties address the concern regarding potential allergic responses to GMOs in the context of Annex A(1)(b). It is our understanding from the evidence provided by the Parties that allergic responses are primarily associated with the ingestion of products consisting of or containing GMOs, rather than through contact with the GM plant *per se*. However, the European Communities has also argued that an allergic reaction could potentially result from exposure to an allergen produced by a GM plant other than through the ingestion of that plant as or in a food. We will address this concern in the context of our discussion of Annex A(1)(c).

7.333 Turning to allergenicity as a food safety concern, we note that Annex A(1)(b) is silent on whether risks arising from allergens produced in GM plants which are used as or in foods or feedstuffs are covered. Food allergenicity concerns were certainly widely known by Members at the time the *SPS Agreement* was drafted. While the absence of a reference to allergens in Annex A(1)(b) might conceivably reflect a deliberate choice to exempt food allergenicity risks from the scope of the *SPS Agreement*, equally, the absence of a reference to allergens could mean that allergens were considered to be covered by the text of Annex A(1)(b). The Complaining Parties in fact argue that allergens could be subsumed within the category of "toxins" or "disease-causing organisms". Below, we will examine whether allergens in foods or feedstuffs could be considered to fall within the category of "toxins".

7.334 The term "allergen" is commonly defined as "a substance that causes an allergic reaction".[480] The term "allergic" is defined as "of, caused by, or relating to an allergy"[481], and the term "allergy" is defined in turn as "a damaging immune response by the body to a substance to which it has become hypersensitive"[482]. It may be inferred from these definitions that an "allergen" is a substance which causes a damaging immune response by the body in humans or animals which have become hypersensitive to that substance. This is consistent with the definition of "allergen" provided in the

[477] *McGraw-Hill Dictionary of Scientific and Technical Terms*, 6th ed. (New York: McGraw-Hill), p. 2168. Canada notes that this definition of toxin applies only in the context of biochemistry. In other contexts, "toxin" might be interpreted differently, *e.g.*, mercury may be a considered a toxin although it is not produced by a living organism.

[478] *Ibid*, p. 2168.

[479] *Ibid*, p. 1626.

[480] *The Concise Oxford Dictionary*, 10th Edition, Judy Pearsall (ed.) (Oxford University Press, 1999), p. 35.

[481] *Ibid*.

[482] *Ibid*.

FAO Glossary of Biotechnology for Food and Agriculture, which describes an allergen as "an antigen that provokes an immune response".[483]

7.335 With specific reference to the products at issue in this dispute, we add that, in our understanding, allergens would be proteins generated through the expression of genes.[484] Thus, the concern about potential allergenicity of GMOs relates to the effect of modified genes on protein composition in GM plants and the subsequent exposure of humans or animals to these proteins through the consumption of food or feedstuffs produced using the GM plants.

7.336 As noted, the Complaining Parties argue that "allergens" would generally meet the definition of the term "toxins" as it is used in Annex A(1)(b). We have stated earlier that the term "toxin" in Annex A(1)(b) can be understood to refer to a poisonous substance produced by a micro-organism or other organism and acting as an antigen in the body. A "poison" is commonly defined as "a substance that causes death or harm when introduced into or absorbed by a living organism"[485], or as "a substance that through its chemical action is able to kill, injure, or impair an organism"[486].

7.337 We have said that allergens may be understood as substances which act as antigens and cause a damaging immune response by the body in humans or animals. From the information submitted to us, we understand that such immune responses can be very damaging to health, and in some cases may even be fatal, *e.g.*, in the event of an anaphylactic shock.[487] In the light of this, it seems to us to be correct to characterize food allergens as substances which can "cause death or harm" to health, or as substances which through their chemical action are able to "kill, injure or impair an organism". Thus understood, the kind of food allergens which might be produced by GMOs can be appropriately viewed as poisonous substances produced by an organism and acting as an antigen in the body. Consequently, we think that for the specific purposes of Annex A(1) the term "toxins" encompasses, *inter alia*, food allergens which might be produced by GMOs. We observe in this connection that we have seen no evidence establishing that the drafters of the *SPS Agreement* intended to exclude food allergens from the scope of the *SPS Agreement* in general, and the term "toxins" in particular.

7.338 We have pointed out earlier that in the specific context of this dispute, allergens would be proteins generated through the expression of genes in GMOs. It is useful to clarify, therefore, that we do not purport to suggest that "toxins" within the meaning of Annex A(1)(b) necessarily need to be proteins. Poisonous substances other than poisonous proteins may qualify as "toxins".

7.339 We have stated above that allergens are substances which cause a damaging immune response by the body in humans or animals which have become hypersensitive to that substance. The fact that

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[483] FAO Glossary of Biotechnology for Food and Agriculture, A. Zaid, H.G. Hughes, E. Porceddu and F. Nichols (eds.) (FAO, Rome, 2001),p. 8.

[484] In the context of GM foods, one of the experts advising the Panel, Dr. Nutti, indicated that "in this case [allergens] are a sub-category [of toxins] because they are proteins. The allergens are always protein." (Annex J, para. 1172) Dr. Nutti further noted that: "If you go to the Codex [Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants], when you go to the annex "Assessment of possible allergenicity", you see all newly expressed proteins produced by GMOs. As far as GMOs are concerned when you go to look for allergens you are looking for the proteins." (Annex J, para. 1188)

[485] *The Concise Oxford Dictionary*, 10th Edition, Judy Pearsall (ed.) (Oxford University Press, 1999), p. 1105.

[486] *Webster's New Encyclopedic Dictionary* (Könemann, 1993), p. 777.

[487] We note that the United States, with reference to H.A. Sampson, "Food allergy Part 1: Immunopathogenesis and Clinical Disorders", Journal of Allergy and Clinical Immunology, Vol. 103:00. 717-728, May 1999, has defined anaphylaxis as a sudden and severe reaction characterized by a sudden drop in blood pressure and breathing difficulties that may be fatal.

a food allergen does not present a risk to all human beings or animals does not, in our view, mean that it cannot qualify as a "toxin" in foods or feedstuff within the meaning of Annex A(1)(b). We see nothing in Annex A(1) or in the ordinary meaning of the term "toxin" which indicates that for a substance to qualify as a "toxin" in a food or in a feedstuff, the substance needs to be poisonous for each and every human being or animal which is exposed to it through the consumption of the food or feedstuff. Indeed, we find it difficult to believe that the term "toxins" was intended to have such a narrow meaning.[488] If that were the case, a measure applied by a Member to protect human health from risks arising from substances present in food which are poisonous for only a small fraction of its population would not be subject to the disciplines of the *SPS Agreement.* Conversely, a measure applied to protect from risks arising from substances present in food which are poisonous for the entire population would be subject to the *SPS Agreement*. In our view, it would be incongruous if Members were subject to stricter disciplines when it comes to controlling risks affecting the entire population than they would be when they seek to control risks affecting only a small segment of their population. Also, the measures taken in either case might have equivalent effects on trade.[489]

7.340 We note that Directive 2001/18 specifies that potential adverse effects of GMOs include "disease to humans including allergenic or toxic effects" and "disease to animals [...] including toxic, and where appropriate, allergenic, effects".[490] Furthermore, Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "[p]ossible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed".[491] In the light of this, to the extent that Directives 90/220 and 2001/18 seek to protect humans and animals from allergenic effects of GM plants used as or in foods, the Directives can, in our view, be considered as measures applied to protect human or animal life or health from risks arising from toxins produced in GM plants which are foods or feedstuffs.

"disease-causing organisms"

7.341 **Canada** and **Argentina** argue that the kind of food allergens which might be produced by GMOs could also be viewed as "disease-causing organisms" within the meaning of Annex A(1)(b). **Argentina** also argues that the risk arising from the mass consumption of products containing ARMG, which may lead to the development of bacteria resistant to antibiotics, falls within the definition given in Annex A(1)(b). According to Argentina, therefore, a measure based on such concerns is a measure aimed at protecting human and animal health from the risks arising from diseases and disease-causing organisms in foods, beverages and feedstuffs.

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[488] It is useful to point out in this context that food safety regulations establishing maximum residue levels for pesticides or veterinary drugs, or regarding the approval of the use of certain food additives, are frequently established to ensure the protection of the health of those segments of the population considered to be most vulnerable to the potential health risk, for example, infants, pregnant women or the elderly. The Codex Standard for Food Additives, for example, provides that: "Where the food additive is to be used in foods eaten by special groups of consumers, account shall be taken of the probable daily intake of the food additive by consumers in those groups." (Codex Stan 192-1995, Rev.5-2004.) Furthermore, specific standards have been developed with respect to special groups of consumers, such as the Codex Standard for Processed Cereal-based Foods for Infants and Children, Codex Stan. 74-1981 (amended 1985, 1987, 1989, 1991), FAO, Rome.

[489] Regarding effects on trade, we note that our view that protection of vulnerable sub-populations from food allergens falls within the scope of the *SPS Agreement* does not imply that products containing such allergens should be prohibited. Adequate protection might be achieved through a requirement that food products containing known allergens be labelled so that the susceptible population is informed of their content.

[490] Annex II.C.2.1 of Directive 2001/18.

[491] Annex II.D.2.7 of Directive 2001/18.

7.342 The **Panel** recalls that it has already found that the food allergens at issue in this dispute can be considered as "toxins" within the meaning of Annex A(1)(b), and therefore it is not necessary to address whether they could, in addition, be considered as "disease-causing organisms" within the meaning of Annex A(1)(b). Similarly, we have already found that ARMG could, in the case at hand, be considered to be "additives" within the meaning of Annex A(1)(b). Therefore, we do not find it necessary to address whether they could also be considered as "disease-causing organisms".

Preliminary conclusions concerning Annex A(1)(b)to the *SPS Agreement*

7.343 In light of the above considerations, we are of the view that, of the potential adverse effects of GMOs identified in Annex II of Directive 2001/18, the following fall within the scope of Annex A(1)(b) of the *SPS Agreement*:

– "disease to humans including allergenic or toxic effects"
– "altered susceptibility to pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors"
– "compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments, for example by transfer of genes conferring resistance to antibiotics used in human or veterinary medicine".

This does not exclude, however, that, depending on the circumstances, some of these potential adverse effects may also fall within the scope of other sub-paragraphs of Annex A(1).

7.344 Similarly, with respect to the concerns identified in Annex D.2 of Directive 2001/18 with respect to genetically modified higher plants (GMHP), we consider that the following falls within the scope of Annex A(1)(a), while recognizing that, depending on the circumstances, it may also fall within the scope of other sub-paragraphs of Annex A(1):

– possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed.

Annex A(1)(c) to the *SPS Agreement*: protection of human life or health from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread or pests

7.345 We now turn to analyse whether Directives 90/220 and 2001/18 fall within the scope of Annex A(1)(c) of the *SPS Agreement*. The Parties have addressed Annex A(1)(c) in connection with the issue of the potential allergenicity of GMOs and GMO-induced increased use of pesticides, hence we analyse these issues under corresponding headings.

allergenic effects of GMOs unrelated to consumption as food

7.346 We first turn to analyse the issue of the potential allergenic effects of GMOs which are not used as or in foods.

7.347 The **European Communities** notes that potential allergenic effects arising from GM plants may occur as a result of exposure other than through food. Consequently, the issue of allergenicity is not confined to food safety. Rather, the potential presence of allergens in the environment as a result of the release of GM plants may be considered a broader environmental issue, not included in the scope of Annex A(1) of the *SPS Agreement*.

7.348 The **United States** argues that measures taken to address risks from occupational or residential exposure to biotech plants, such as possible allergic reactions in farmers applying Bt microbial pesticides, would generally fall within paragraph 1(c), as measures "to protect human life or health [...] from risks arising from [...] the establishment or spread of pests."

7.349 The **Panel** recalls that it has addressed the issue of the risks arsing from the potential of GMOs to produce food allergens above in the context of its analysis under Annex A(1)(b). What is at issue here is the potential of GMOs to produce allergenic effects in persons working, or otherwise coming into contact, with GMOs.

7.350 We consider that if interaction with, and exposure to, GMOs other than as or in a food produced allergenic effects in persons, the GMOs in question could be viewed as "pests" within the meaning of Annex A(1). We recall our view that the term "pests" in Annex A(1) encompasses plants which are destructive, or which cause harm to the health of other animals, plants or humans. We also recall our view that allergens may be understood as substances which cause a damaging immune response by the body in humans, and that such immune responses can be very damaging to health, and in some cases may even be fatal, *e.g.*, in the event of an anaphylactic shock. In the light of this, we consider that to the extent a GM plant produces allergenic effects other than as a food, it would be a plant which causes harm to the health of humans and, as such, would qualify as a "pest". We recognize that a GM crop producing this type of allergenic effects would often be cultivated intentionally. From the perspective of the farmer cultivating the GM crop, the GM crop would not, therefore, constitute a "pest". However, from the perspective of the farm worker who is in contact with the crop in the field, or a person walking past the field, the GM crop may constitute a "pest" if the person is hypersensitive to the allergen.[492]

7.351 The European Communities has argued that a pest must be a living organism. We have previously noted that the term "pest" in Annex A(1) encompasses plants which are destructive, or which cause harm to the health of other animals, plants or humans. While it may be true that many organisms will lose their ability to act as pests if they are no longer alive, we are not persuaded that this is necessarily always the case. In particular, we are not convinced that all plants which are pests as living organisms cease to be destructive or harmful to health immediately after being harvested. As a result, we do not believe that GM plants which have been harvested could not be considered to be "pests" if they cause harm to the health of humans who may be handling them during harvesting, transport or processing.

7.352 We note that Directive 2001/18 specifies that potential adverse effects of GMOs include "disease to humans including allergenic or toxic effects".[493] Furthermore, Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "[p]ossible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the [GM plant] and persons working with, coming into contact with or in the vicinity of the [GM plant] release(s)".[494] We think that by controlling the release of GMOs into the environment to avoid effects of this kind, Directives 90/220 and 2001/18 serve to avoid the entry, spread or establishment of allergenic GMOs. In the light of this, we consider that Directives 90/220 and 2001/18 can be

[492] In our view, the ordinary meaning of the term "pest" as it is used in the context of Annex A(1)(c) does not suggest that for a plant to qualify as a "pest", it necessarily needs to cause harm to the health of each and every person coming in contact with it. This view is consistent with our interpretation of the term "toxin" in Annex A(1)(b).

[493] Annex II.C.2.1 of Directive 2001/18.

[494] Annex II.D.2.6 of Directive 2001/18.

appropriately viewed as measures applied to protect human life or health from risks arising from the entry, establishment or spread of GM plants *qua* "pests".[495]

possible health effects from increased herbicide use associated with GMOs

7.353 The **European Communities** argues that negative effects of the use of herbicides on human health do not fall within Annex A(1)(c) because the herbicide is not a "disease carried by animals, plants or products thereof" and because the risk arises even if the GM plant is not a pest. Negative effects on human health from the consumption of pesticide residues might, however, fall within the scope of Annex A(1)(b).

7.354 The **Panel** understands the European Communities to argue that the introduction of herbicide-resistant GM plants might entail use of herbicides in the field when no herbicides were previously used, increased use of herbicides or use of different herbicides, and that this might in turn cause harm to human health. We further understand the EC argument to be that the relevant harm would not be the result of herbicide residues in the GM plant, but of exposure to the herbicide other than through the consumption of the GM plant.[496] Thus, according to the European Communities, a change in weed control practices – specifically, changes in herbicide use – which may be associated with the introduction of herbicide tolerant GM crops might have adverse effects on human health, *e.g.*, for workers applying them in the field.

7.355 As an initial matter, we note that the European Communities has not explained why such potential health effects might arise. As noted by us earlier, it is our understanding that before a plant protection product can be used on any crop cultivated within the European Communities, the use of the product on the relevant crop is subjected to an assessment for safety. Therefore, it would seem that if herbicides used in conjunction with herbicide tolerant GM crops have been approved for use, and if they are applied in accordance with any conditions that may have been attached to their approval, such application should not normally be harmful to human health. Having said this, it may be that the European Communities' concern about possible negative health effects relates to improper use, or unanticipated effects, of approved herbicides. We therefore proceed with our analysis, assuming that there may be situations where the use of approved herbicides could cause harm to the health of persons applying the herbicide in the field or otherwise coming into contact with it.

7.356 We note that the scenario posited by the European Communities – that a change in weed control practices associated with the introduction of herbicide tolerant GM crops might have adverse effects on human health – is very similar to another scenario we have already considered, namely the scenario in which a change in weed control practices associated with the introduction of herbicide tolerant GM crops might have adverse effects on the environment. Accordingly, our analysis parallels that of the latter scenario.

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[495] We recall that Directive 2001/18 also specifies that potential adverse effects of GMOs include "disease to animals including allergenic or toxic effects". It would appear, therefore, that Directives 90/220 and 2001/18 could also be applied to prevent GMOs from producing allergenic effects resulting from exposure of animals to GMOs other than as or in a food. For completeness, we note that in this situation the GMOs could be viewed as "pests" in relation to susceptible animals. Accordingly, we think that if applied to prevent such effects, Directives 90/220 and 2001/18 may be appropriately viewed as measures applied to protect animal life or health from risks arising from the entry, establishment or spread of GM plants *qua* "pests". As such, they would be covered by Annex A(1)(a).

[496] We recall that in the context of our analysis under Annex A(1)(b) we have addressed a similar argument relating to the possibility of the increased use of herbicides leading to a higher level of contaminants, specifically herbicide residues, in GM plants used as or in foods or feedstuffs.

7.357 Thus, also in relation to the scenario involving adverse effects on human health, it is clear to us that the weeds against which a particular herbicide is used qualify as "pests" within the meaning of Annex A(1), and that the herbicide use constitutes a pest control measure. We likewise consider that risks to human health resulting from the use of a herbicide, or of a different herbicide, may be viewed as arising indirectly from the entry, establishment or spread of weeds *qua* relevant pests.

7.358 Regarding the link to GM plants, we note that Directives 90/220 and 2001/18 seek to avoid adverse effects of the release of GMOs into the environment, including indirect effects on human health, such as effects occurring through a change in management practices in the wake of the introduction of herbicide tolerant GM plants.[497] As we have observed earlier, herbicide tolerant GM plants are linked to the herbicide to which they are tolerant. Moreover, the herbicide to which GM plants are tolerant has been developed to help control and/or eradicate the relevant weeds. Thus, it is clear that, *via* the relevant herbicide, the GM plants in question are also linked to the weeds, and hence the pests, to be controlled.

7.359 The GM plants, the herbicide and the weeds being interlinked in this way, we consider that there is a rational relationship between controlling the release into the environment of herbicide tolerant GM plants and the purpose of protecting human health from risks arising indirectly from the entry, spread or establishment of weeds. We recall in this context that there is nothing in the text of Annex A(1) to suggest that the product subject to an SPS measure – in this case, a herbicide tolerant GM plant to be released into the environment – need itself be the pest which gives rise, directly or indirectly, to the risks from which the measure seeks to protect.

7.360 In the light of the foregoing, to the extent that Directives 90/220 and 2001/18 seek to avoid adverse effects on human health which arise from changes in management practices associated with the introduction into the environment of GMOs, we consider that the Directives can be viewed as measures applied to protect human life or health from risks arising indirectly from the entry, establishment or spread of weeds *qua* "pests".[498]

Preliminary conclusions concerning Annex A(1)(c) to the *SPS Agreement*

7.361 In light of the above considerations, we are of the view that, of the potential adverse effects of GMOs identified in Annex II of Directive 2001/18, the following falls within the scope of Annex A(1)(c) of the *SPS Agreement*:

– "disease to humans including allergenic or toxic effects".

This does not exclude, however, that, depending on the circumstances, this potential adverse effect may also fall within the scope of other sub-paragraphs of Annex A(1).

7.362 Similarly, with respect to the concerns identified in Annex D.2 of Directive 2001/18 with respect to genetically modified higher plants (GMHP), we consider that the following falls within the scope of Annex A(1)(c):

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[497] *See* the introductory paragraph of Annex II of Directive 2001/18, which defines "indirect effects" as "effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management".

[498] We made a similar point above in relation to the situation where target organisms, notably insects, develop resistance to a pesticide. We said there that risks to animal or plant life or health resulting from a change in pesticide use may be viewed as arising indirectly from the entry, establishment or spread of resistant target organisms.

– possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GMHP and persons working with, coming into contact with or in the vicinity of the GMHP release(s).

Annex A(1)(d) to the *SPS Agreement*: Prevent or limit other damage within the territory of a Member from the entry, establishment or spread of pests

7.363 We turn, finally, to analyse whether Directives 90/220 and 2001/18 fall within the scope of Annex A(1)(d) of the *SPS Agreement*. In order for us to determine whether Directives 90/220 and 2001/18 fall within the scope of Annex A(1)(d), we need to consider in particular the meaning and scope of the term "other damage" used in Annex A(1)(d) and address whether certain potential effects of GMOs could be said to give rise to "other damage".

"other damage"

7.364 The **United States** maintains that the term "other damage" means damage other than damage to animal or plant life or health, or to human life or health. This could include, for example, property damage by pests. However, nothing in the *SPS Agreement* excludes other non-life or non-health damage to plants, animals or humans caused by pests.

7.365 **Canada** observes that the ordinary meaning of the term "damage" is "harm done to a thing […]; *esp*. physical injury impairing value or usefulness."[499] The context of the term "damage" suggests that "damage" means the injurious or harmful potential biological and economic consequences that result from the occurrence of an event. The use of the term "other" suggests that the type of damage contemplated in Annex A(1)(d) is distinct from the damage to animal or plant life or health and human life or health arising from the entry, establishment and spread of pests that fall within the scope of Annex A(1)(a*)* and (c), respectively. Canada recalls its argument that the terms "animal" and "plant" are defined broadly in the *SPS Agreement*.[500] According to Canada, many of the risks to biodiversity or the environment cited by the European Communities fall within the risks to animal and plant life or health contemplated by Annex A(1)(a). Canada does not consider that plants, animals, or humans can be "damaged" unless there is damage to their "life or health"; it would be inconsistent with the object and purpose of the *SPS Agreement* to extend the definition of damage to plants, animals or humans to include so-called damage that is not based on injury or harm to their life or health. In this particular context, reduced yield of a crop, as a result of competition from a pest such as a weed, would be considered impairment to the health of the crop plant.

7.366 According to Canada, "other damage" is not limited to damage sustained by plants, animals or humans but includes damage from the entry, establishment or spread of pests to the functioning of the environment or the ecosystem taken as a whole, independent of damage to the life or health of specific plants or animals. This would include, for example, damage resulting from ecosystem destabilization and from control, eradication or management programs that would be needed if a pest were introduced, and impacts of such programs (*e.g.* pesticides…) on biological diversity. Other examples include environmental and other undesired effects of control measures; the capacity of a pest to act as a vector for other pests; significant effects on designated environmentally sensitive or protected areas; significant changes in ecological processes and the structure, stability or processes of an ecosystem (including further effects on plant species, erosion, water table changes, increased fire hazard, nutrient cycling etc.); effects on human use (water quality, recreational uses, tourism, animal

[499] *The New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. 1, p. 588.

[500] *See* paras. 7.205 and 7.215.

grazing, hunting, fishing); and costs of environmental restoration. Canada argues that this view is supported by the relevant international standard for analysing the risks associated with pests, including LMOs.[501]

7.367 **Argentina** maintains that the concept of "other damage" in Annex A(1)(d) refers to the prevention of situations not listed in paragraphs (a), (b) and (c) and related to pests. Examples of such "other damage" include concerns related to the fitness of plants, animals or humans. Argentina considers that the broader ecological consequences of a GM plant that grows where it is not wanted also constitute "other damage" caused by the "entry, establishment or spread of pests". Concerns regarding cross-contamination of other organisms by biotech products likewise fall under Annex A(1)(d). Measures to prevent or minimize adverse effects related to excessive population increase of a GM plant in the environment or to competitive advantage of the GMOs in relation to unmodified organisms also fall within the scope of Annex A(1)(d) of the *SPS Agreement*. While in Argentina's view, the most likely way in which biotech products could damage biodiversity or the ecological balance of an area is by negatively affecting wild flora and/or fauna, Argentina considers that the scope of Annex A(1)(d) is sufficiently broad to encompass any possible other damage to biodiversity or the ecological balance.

7.368 The **European Communities** considers that the term "other damage" covers damages arising from the entry, establishment or spread of a pest other than damage to the "life or health" of humans, animals and plants. The European Communities maintains that it is commonly accepted that the words "other damage" refer to economic damage. This includes, for example, a reduction in the value of a crop whose quality is reduced because of damage by a pest that does not threaten the life or health of the plant. However, the European Communities observes that "other damage" is expressly linked only to the risks arising from the entry, establishment or spread of a "pest". Since the European Communities argues that a GMO is not a pest unless it is growing in the wrong place and/or at the wrong time, this provision cannot be used to bring all measures applied to protect against damage to ecology or the environment arising from the introduction of a GMO under the scope of the *SPS Agreement*. In particular, according to the European Communities the effects of GMOs on non-living components in the environment, such as biogeochemistry, particularly carbon and nitrogen recycling through changes in soil decomposition of organic material, are among the concerns identified in the EC legislation which clearly fall outside the scope of the *SPS Agreement*.[502]

7.369 The **Panel** considers that it may be inferred from the reference in Annex A(1)(d) to "*other* damage" (emphasis added) that like Annex A(1)(d), sub-paragraphs (a) through (c) of Annex A(1) refer to measures which are applied to protect from a certain kind of potential "damage". The "damage" at issue in sub-paragraphs (a) through (c) of Annex A(1) is damage to plant, animal or human life or health. It follows, therefore, that the category of "other damage" covered by Annex A(1)(d) must comprise damage other than damage to the life or health of plants, animals or humans. This is indeed the view expressed by all of the Parties.

7.370 The residual category of "other damage" is potentially very broad.[503] In our view, "other damage" could include damage to property, including infrastructure (such as water intake systems,

[501] International Standard for Phytosanitary Measure No. 11, Pest Risk Analysis for Quarantine Pests, Including Analysis of Environmental Risks", FAO, Rome, 2004 (adopted April 2004), pp. 23-24.

[502] The European Communities notes, for example, Section C2.1, sixth indent in Annex II, and items II.A.11(f) and IV.B.15 in Annex IIIA, and D11 in Annex IIIB, of Directive 2001/18.

[503] We note that the text of Annex A(1)(d) refers to "other damage within the territory", and not to "other damage to humans, animals or plants". We therefore see no basis in the text of Annex A(1)(d) for construing the term "other damage" so as to encompass only other damage to humans, animals or plants. It is clear, however, that only damage from the entry, establishment or spread of "pests" can qualify as "other damage" within the meaning of Annex A(1)(d).

electrical power lines, etc.). In addition, we think "other damage" could include economic damage (such as damage in terms of sales lost by farmers). The dictionary defines the term "damage" as "physical harm impairing the value, usefulness, or normal function of something" and "unwelcome and detrimental effects"[504], or "a loss or harm resulting from injury to person, property, or reputation"[505]. These definitions cover harm resulting in a reduction of economic value, adverse economic effects, or economic loss. Also, interpreting "other damage" to include economic damage is consistent with the context of Annex A(1)(d). Article 5.3 of the *SPS Agreement* states that relevant "economic factors" to be taken into account in a risk assessment include "the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or a disease". Thus, Article 5.3 shows that the *SPS Agreement* elsewhere uses the term "damage" in an economic sense, and it does so in connection with damage from "pests". Thus, Article 5.3 contemplates a similar situation to that contemplated in Annex A(1)(d).

7.371 We note that damage to plant, animal or human life or health may entail consequential economic damage. Governmental measures protective of the life or health of plants and animals are sometimes taken precisely to avoid such adverse economic consequences. We therefore agree with Canada that measures taken, *e.g.*, to protect cultivated crops against weeds which might enter a field and out-compete and crowd out the cultivated crops, thus reducing crop yield, might be appropriately regarded as measures falling within the scope of Annex A(1)(a) rather than as measures falling within the scope of Annex A(1)(d). This view is consistent with the fact that Annex A(1)(d) omits reference to "diseases". Obviously, the entry, establishment or spread of diseases may, *inter alia*, lead to economic damage in the territory of a Member.[506] However, in the case of a disease, economic damage would be the result of the damage the disease causes to plant, animal or human life or health. The same is not necessarily true for a pest. We recall in this respect that the term "pest", as we interpret it, refers, not just to an animal or plant which is destructive of animals, plants or humans, or which causes harm to the health of other animals, plants or humans, but also to an animal or plant which causes other harm. It is therefore understandable that Annex A(1)(d) specifically and separately addresses measures applied to control damage other than damage to plant, animal or human life or health.[507]

7.372 In addition to physical damage to property or economic damage, we consider that the concept of "other damage" is also susceptible of encompassing damage to the environment other than damage to the life or health of living organisms (*i.e.*, animals or plants). We note in this regard Argentina's argument that the concept of "other damage" might encompass damage to "biodiversity". Dictionaries define "biodiversity" as "the variety of plant and animal life in the world or in a particular habitat"[508]

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[504] *The Concise Oxford Dictionary*, 10th Edition, Judy Pearsall (ed.) (Oxford University Press, 1999), p. 361.

[505] *Webster's New Encyclopedic Dictionary* (Könemann, 1993), p. 252.

[506] This is recognized in the aforementioned Article 5.3, which, to recall, refers to "the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or a disease".

[507] We note in passing that there may be situations where a pest gives rise to damage to the life or health of other animals or plants without this necessarily being considered a reason for applying a measure to protect the life or health of these other animals or plants. For instance, the affected other animals or plants might themselves be pests. However, the pest in question may, in addition and at the same time, give rise to economic damage which is different and separate from the damage it causes to the life or health of other animals or plants. That economic damage may be considered a reason for applying a measure to limit the pest. Thus, as this example shows, the mere fact that a pest gives rise, *inter alia*, to potential damage to the life or health of other animals or plants does not mean that any measure applied to combat that pest is automatically or exclusively covered by Annex A(1)(a).

[508] *The Concise Oxford Dictionary*, 10th edn., J. Pearsall (ed.) (Oxford University Press, 1999), p. 135.

or "biological diversity in an environment as indicated by number of different species of plants and animals"[509]. The *Glossary of Biotechnology for food and agriculture* defines "biodiversity" as "[t]he variability among living organisms from all sources, including, *inter alia*, terrestrial, marine and other ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems".[510] We deduce from the aforementioned definitions that damage to "biodiversity" implies damage to living organisms. Accordingly, we are not persuaded that the term "other damage" in Annex A(1)(d) includes damage to "biodiversity" as such. However, as we have noted earlier, a measure applied to prevent damage to "biodiversity" may qualify as a measure applied to protect animal or plant life or health from the kind of risks referred to in Annex A(1)(a) and (b).

7.373 Turning now to consider Directives 90/220 and 2001/18, we note that Directive 2001/18 specifies that potential adverse effects of GMOs include "effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition or organic material".[511] Furthermore, Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GMO plants, applicants should provide information on the "[p]ossible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s)".[512] We have already indicated that to the extent GMOs might affect the life or health of soil microfauna or -flora, the concern would be that GMOs might act as pests and, as such, give rise to risks to animal or plant life or health. In other words, this would be a concern falling within the scope of Annex A(1)(a). Likewise, if GMOs were to have effects on soil micro-organisms and this were to pose risks to the life or health of other animals or plants, we think this would be a concern that GMOs might act as pests which indirectly give rise to risks to animal or plant life or health.

7.374 The European Communities argues that concerns regarding effects of GMOs on biogeochemistry also include concerns about effects on non-living components in the environment, such as the recycling of carbon and nitrogen through changes in soil decomposition of organic material. In the European Communities' view, such concerns are outside the scope of the *SPS Agreement*. We are not persuaded by this argument. To the extent that GMOs might cause damage to (as opposed to mere changes in) geochemical cycles, such that there would be damage to the environment other than damage to living organisms, we think such environmental damage could be considered as "other damage" from the entry, establishment or spread of GMOs *qua* "pests" within the meaning of Annex A(1)(d). In the light of this, to the extent that Directives 90/220 and 2001/18 seek to avoid adverse effects of GMOs on "non-living components" in the environment, including those which are part of geochemical processes, the Directives can, in our view, be considered as measures applied to prevent or limit "other damage" from the entry, establishment or spread of GMOs *qua* "pests".

7.375 We note that Directive 2001/18 also specifies that potential adverse effects of GMOs include "effects on the dynamics of populations of species in the receiving environment"[513], which include the "potential for excessive population increase" and "competitive advantage of the GMOs"[514].

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[509] *Webster's New Encyclopedic Dictionary* (Könemann, 1993), p. 98.

[510] *FAO Glossary of Biotechnology for food and agriculture*, A. Zaid, H.G. Hughes, E. Porceddu and F. Nichols (eds.) Rome, 2001, p. 30.

[511] Annex II.C.2.1 of Directive 2001/18.

[512] Annex II.D.2.7 of Directive 2001/18.

[513] Annex II.C.2.1 of Directive 2001/18.

[514] Annex IIIA.iv.B.7 and 8 of Directive 2001/18.

Furthermore, Directive 2001/18 specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GMO plants, applicants should provide information on the "[l]ikelihood of the [GMO plant] becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats"; "[a]ny selective advantage or disadvantage conferred to the [GMO plant]"; "[p]otential for gene transfer to the same or other sexually compatible plant species under conditions of planting the [GMO plant] and any selective advantage or disadvantage conferred to those plant species"; "[p]otential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the [GMO plant] and target organisms, such as predators, parasitoids, and pathogens (if applicable)"; "[p]ossible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the [GMO plant] with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens".[515]

7.376 We have addressed these various adverse effects earlier. All of them relate to potential effects of "pests". In these situations, the GMOs themselves or cross-breeds might act as pests, or target organisms or non-target organisms might become pests, as a result of the release of GMOs into the environment. The Parties have not addressed whether any of the aforementioned types of "pests" could cause damage to the "non-living components" in the environment. We have no basis on which to determine whether this would or would not be possible. Therefore, we simply note that to the extent Directives 90/220 and 2001/18 seek to avoid adverse effects of GMOs on the environment other than adverse effects on animal or plant life or health or on geochemical processes, the Directives can, in our view, be considered as measures applied to prevent or limit "other damage" from the entry, establishment or spread of "pests".

7.377 We note, furthermore, that Directive 2001/18 also specifies that in order to allow competent authorities to draw conclusions on the potential environmental impact from the release of GM plants, applicants should provide information on the "[p]ossible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs".[516] The European Communities has argued that the use of GM crops as opposed to conventional crops may have adverse effects on the agro-ecological environment and on biodiversity. In this context, the European Communities has referred to research on the effect, if any, that the management practices associated with genetically modified herbicide tolerant crops might have on farmland wildlife, when compared with weed control used with non-GM crops.[517]

7.378 We have addressed the issue of the potential adverse effects on non-target organisms, including farmland wildlife, arising from changes in weed control practices (including changes in herbicide use) that may be associated with the introduction of GM crops in the context of our discussion of Annex A(1)(a). We determined that to the extent Directives 90/220 and 2001/18 are applied to avoid such effects, they can be viewed as measures applied to protect the life or health of animals or plants from risks arising indirectly from the entry, establishment or spread of weeds *qua* "pests". To the extent that changes in weed control practices might cause damage to the environment other than damage to the life or health of non-target organisms, we think such damage could be considered as "other damage" resulting indirectly (*i.e.,* via such changes), from the entry, establishment or spread of weeds *qua* "pests" within the meaning of Annex A(1)(d). In the light of

[515] Annex II.D.2.1-5 of Directive 2001/18.
[516] Paragraph 9 of Annex II.D.2. of Directive 2001/18.
[517] UK Department for Environment Food and Rural Affairs, "GM crops: Effects on farmland wildlife", October 2003. These studies are referred to as the "Farm Scale Evaluation".

this, to the extent that Directives 90/220 and 2001/18 seek to avoid adverse effects arising from management techniques associated with GMOs other than damage to the life or health of non-target organisms, the Directives can, in our view, be considered as measures applied to prevent or limit "other damage" resulting indirectly from the entry, establishment or spread of weeds *qua* "pests".

Preliminary conclusions concerning Annex A(1)(d) to the *SPS Agreement*

7.379 In light of these considerations, we are of the view that, of the potential adverse effects of GMOs identified in Annex II of Directive 2001/18, the following fall within the scope of Annex A(1)(d) of the *SPS Agreement*, *e.g.*, to the extent they relate to the protection of "non-living components" in the environment:

– effects on the dynamics of populations of species in the receiving environment;
– effects on biogeochemistry (biogeochemical cycles), particularly carbon and nitrogen recycling through changes in soil decomposition of organic material.

7.380 Similarly, with respect to the concerns identified in Annex D.2 of Directive 2001/18 with respect to genetically modified higher plants (GMHP), we consider that the following fall within the scope of Annex A(1)(d) of the *SPS Agreement*, *e.g.*, to the extent they relate to the protection of "non-living components" in the environment:

– likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats;
– any selective advantage or disadvantage conferred to the GMHP;
– potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GMHP and any selective advantage or disadvantage conferred to those plant species;
– potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GMHP and target organisms, such as predators, parasitoids, and pathogens (if applicable);
– possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GMHP with non-target organisms, (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), parasites and pathogens;
– possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GMO and target and non-target organisms in the vicinity of the GMO release(s);
– possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GMHP where these are different from those used for non-GMHPs.

Labelling to indicate presence of GMOs

7.381 Before concluding our examination of Directives 90/220 and 2001/18 under Annex A(1), it is necessary to address the labelling requirements imposed by Directive 2001/18. The Parties did not raise and discuss this issue as part of their arguments on whether Directive 2001/18 falls within the scope of Annex A(1). However, since the issue of labelling requirements is of some significance to our examination below of whether Regulation 258/97 falls within the scope of Annex A(1), consistency requires that we broach the issue as part of our examination of Directives 90/220 and 2001/18.

7.382 Directive 2001/18 provides that the applicant must submit a proposal for labelling. The proposal must include the commercial name of the relevant product containing a GMO, the name of the GMO, and a clear statement that a GMO is present, either on a label or in a document accompanying the product. The competent member State authorities must examine applications for compliance with the requirements of Directive 2001/18, including the labelling requirements. The applicant must not place a GMO on the market unless it has received the written consent of the competent authority and unless it has complied with any conditions required in the consent. The written consent must specify the labelling requirements. In all cases, the statement that a GMO is present must appear on a label or in an accompanying document.[518]

7.383 Furthermore, with regard to GMOs which have been approved for placing on the market, Directive 2001/18 requires member States to take all necessary measures to ensure that at all stages of the placing on the market, the labelling of the relevant GMOs comply with the requirements specified in the written consent.[519] The Directive does not specify the measures which need to be taken by member States in fulfilment of this requirement.

7.384 As we understand it, Directive 2001/18 requires labelling or documentation to indicate the presence of a GMO in cases where the competent authorities have determined, based on available scientific evidence, that the release of the relevant GMO into the environment is safe for both human health and the environment. A requirement to indicate the presence of a GMO in such cases may not at first glance appear to be a measure that would fall within the scope of the *SPS Agreement*. Therefore, we think we should examine whether the labelling requirement in Directive 2001/18 is linked to the purpose of protecting human health and the environment and hence is a measure applied for one of the purposes identified in Annex A(1).

7.385 We recall in this regard that the only stated purpose of Directive 2001/18, besides the approximation of member State laws, is to protect human health and the environment from risks arising from the deliberate release of GMOs into the environment.[520] This is in contrast to Regulation 258/97 (which we will consider below) that makes reference to other purposes, such as not misleading the consumer. In the light of this, we think that if the labelling requirement in Directive 2001/18 is rationally related to the stated purpose of Directive 2001/18, and in the absence of sufficient indications of a different or additional purpose, we may and should presume that the labelling requirement is intended to serve the purpose articulated in the Directive.[521]

7.386 In considering the issue whether the labelling requirement in Directive 2001/18 is rationally related to the stated purpose of Directive 2001/18, we find instructive, among other provisions, those of Article 20 of the Directive. Article 20 addresses situations where after the consent to the placing on the market of a product containing or consisting of a GMO has been given, new information becomes available to competent authorities, from the users of the product or other sources, which could have consequences for the risks of the GMO to human health or the environment. Article 20

[518] Articles 4(4), 13(2)(f) and 19(3)(e) as well as Annex IV of Directive 2001/18. While Directive 90/220 also imposed certain labelling requirements, it did not require a statement to the effect that a GMO is present. Article 11(1) and Annex III of Directive 90/220.

[519] Article 21(1) of Directive 2001/18.

[520] Article 1 of Directive 2001/18.

[521] We note that the 40th preambular paragraph of the Directive states that the presence of a GMO should be indicated on a label or in a document "[i]n order to ensure that the presence of GMOs in products containing, or consisting of, genetically modified organisms is appropriately identified". The phrase "appropriately identified" does not indicate that the labelling requirement is applied for the purpose of protecting human health and the environement. But this phrase likewise does not indicate that the labelling requirement is applied for a purpose other than, or additional to, the protection of human health or the environment.

provides that in such situations the consent to the placing on the market may be amended or terminated, depending on the results of a review procedure which is to be conducted when relevant new information becomes available.[522] While the Directive does not specify the precise consequences flowing from a decision to terminate the consent, it is reasonable to assume that the relevant product could no longer be lawfully made available by sellers to third parties, and that measures might be taken to inform the public of the newly discovered risks and to require or encourage users of the product to return it to the seller or to discontinue using it.

7.387 The requirement that the presence of a GMO in a product be explicitly identified on a label or in an accompanying document fits the situation contemplated in Article 20. As pointed out, Article 20 refers, *inter alia*, to situations where new information becomes available, from the users of a product, with regard to the risks of a GMO to human health or the environment after the consent to the placing on the market has been given. Explicit identification of the presence of a GMO alerts and sensitizes operators and users of a product containing or consisting of a GMO to the possibility that any observed adverse effects of the product on human health or the environment might be attributable to the presence of a GMO as opposed to other factors. Increased awareness of operators and users of the presence of GMOs may be presumed to lead to a situation where more observations which could be indicative of risks associated with a GMO are reported to consent holders and competent authorities, or where relevant observations are reported more promptly. Explicit identification of the presence in a product of a GMO may thus be presumed to result in consent holders and competent authorities being better informed, or informed more promptly, than they otherwise would be of unanticipated risks of a GMO to human health and the environment, allowing them to determine whether additional measures are necessary to protect human health and the environment.[523]

7.388 Additionally, we observe that explicit identification of the presence in a product of a GMO serves the purpose of health and/or environmental protection in situations of unexpected, accidental release of a GMO – *e.g.*, in connection with its storage or transport – into an environment in which the GMO is not be used or in which the potential for adverse effects has not specifically been considered in the risk assessment.[524] In such situations, it can, in our view, be presumed that explicit identification of the presence in a product of a GMO will result in consent holders and competent authorities being more promptly and more effectively informed of any relevant incidents than would be the case if the product being stored or transported did not explicitly identify the presence of a GMO. To use again the example of storage or transport, we note that persons storing or transporting GMOs (*e.g.*, the driver of a transportation vehicle) need not necessarily be persons under the supervision of the producer or user of GMOs or persons otherwise familiar with the specific characteristics of the product they are handling. For such persons in particular, explicit identification

[522] We also note that Article 23(1) of Directive 2001/18 requires member States to ensure that in the event of a severe risk, emergency measures, such as suspension or termination of the placing on the market, are applied, including information to the public.

[523] We are mindful of the fact that Directive 2001/18 contains monitoring requirements, *inter alia* to identify the occurrence of unanticipated adverse effects of GMOs on human health or the environment. However, information and data may in some cases be collected and reported through general surveillance practices already implemented for agricultural cultivars other than the GM crop in question. Therefore, users of GM crops may not necessarily associate monitoring with the presence of a GMO. Furthermore, monitoring plans may not always be implemented by those responsible for doing so. We consider that in such cases, by alerting users to the presence of GMOs, labelling to indicate their presence can be presumed to result in consent holders and competent authorities being better informed, or informed more promptly, than they otherwise would be of observations of unanticipated adverse effects of GMOs on human health or the environment.

[524] Accidental dissemination of GM seeds might occur, for instance, as a result of an accident involving a vehicle transporting GM seed bags from the seller to the farmer.

of the presence of a GMO renders more likely, and facilitates, an adequate and prompt response in situations of unexpected, accidental release of a GMO into the environment.[525]

7.389 In the light of the foregoing considerations, we are of the view that there is a rational relationship between, on the one hand, the purpose stated in Directive 2001/18 of protecting human health and the environment and, on the other hand, the particular labelling requirement contained in Directive 2001/18, which applies in cases where a product containing or consisting of a GMO has been found to be safe for human health and the environment. Furthermore, neither in Directive 2001/18 nor in any other piece of evidence before us do we see sufficient indications that the labelling requirement in Directive 2001/18 is intended to serve a purpose different from, or additional to, the purpose Directive 2001/18 says it seeks to achieve, *i.e.*, the protection of human health and the environment.[526]

7.390 We note that Annex A(1) to the *SPS Agreement* specifies that SPS measures include, "*inter alia*", "packaging and labelling requirements directly related to food safety". As is indicated by the term "*inter alia*" in Annex A(1), the requirements specifically mentioned are not necessarily intended to exclude similar requirements. Hence, while recognizing that labelling requirements imposed on food safety grounds may be more common, we consider that labelling requirements imposed for the purpose of protecting plant, animal or human health from the risks covered in Annex A(1)(a) and (c), or for the purpose of preventing or limiting other damage from the risk covered in Annex A(1)(d), would likewise be subject to the disciplines of the *SPS Agreement*.[527]

7.391 We have determined above that the labelling requirement in Directive 2001/18 is rationally related to the purpose of protecting human health and the environment. We have also observed that the Panel record does not contain sufficient indications of a purpose different from, or additional to, the protection of human health and the environment. In these circumstances, we think we may and should presume that the labelling requirement is applied to protect human health and the environment from possible unanticipated effects of GMOs. To the extent it is applied to protect the environment, it would fall within the scope of Annex A(1)(a), (b) or (d), depending on what the adverse effects would be. To the extent it is applied to protect human health, it would fall within the scope of Annex A(1)(b) or (c).[528] Thus, we consider that the labelling requirement in question does not remove Directive 2001/18 from the scope of the *SPS Agreement*.

7.392 We stress that our finding that the labelling requirement in Directive 2001/18 falls within the scope of the *SPS Agreement* does not necessarily imply that the requirement is consistent with the provisions of that Agreement. The consistency of the relevant requirement with the *SPS Agreement* is an issue that is not before us, and so we refrain from expressing a view on it.

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[525] We note that in the case of unexpected, accidental release there could be a need for a rapid response to prevent or limit adverse effects on human health or the environment.

[526] Further elaboration of this point is provided *supra*, at paras. 6.60 *et seq*., in response to a comment made by the European Communities at the interim review stage.

[527] The reference to "labelling requirements *directly related to food safety*" (emphasis added) in the second sub-paragraph of Annex A(1) is in our view intended to provide an example of a labelling requirement which clearly and unambiguously serves one of the purposes identified in Annex A(1). It may be inferred from this reference that some food-related labelling requirements would not be subject to the *SPS Agreement, e.g.*, food labelling required to provide quality assurance, volume of contents, or to reflect consumer preferences or moral considerations.

[528] We have addressed earlier how GMOs might give rise to risks falling within the scope of the various sub-paragraphs of Annex A(1), and so we refer to our earlier analysis in this regard.

Conclusions with respect to the purpose of Directives 90/220 and 2001/18

7.393 In our analysis above, we have identified and considered the risks or adverse effects Directives 90/220 and 2001/18 seek to avoid, either by their express terms or according to the European Communities. In relation to all of these risks, we have determined that, in terms of the origin of these risks and their possible consequences, they are risks covered by one or more of the sub-paragraphs of Annex A(1). In the light of this, and since the stated purpose of Directives 90/220 and 2001/18 is to avoid these risks, we are of the view that Directives 90/220 and 2001/18 can be considered as measures which are applied for the purposes identified in Annex A(1)(a) through (d). In other words, we consider that they meet the purpose element of the definition of the term "SPS measure". To that extent, Directives 90/220 and 2001/18 constitute SPS measures.[529]

(ii) Regulation 258/97

7.394 The Panel now turns to examine whether the specific risks or concerns identified in Regulation 258/97 are risks that fall within the scope of the definition of an SPS measure provided in Annex A(1) of the *SPS Agreement*. The Panel recalls that Regulation 258/97 concerns novel foods and food ingredients, including foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220, and foods and food ingredients produced from, but not containing, genetically modified organisms.

7.395 Regarding the purposes for which Regulation 258/97 is applied, we note Article 3(1) of the Regulation, which states that foods and food ingredients falling within the scope of the Regulation must not:

– present a danger for the consumer,
– mislead the consumer,
– differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer.

7.396 It is important to note that marketing approval is granted only if the novel food or food ingredient for which marketing approval is sought complies with the criteria of Article 3(1) of Regulation 258/97.[530]

7.397 We will determine below for each of the three purposes for which Regulation 258/97 is applied whether that purpose falls within the scope of Annex A(1). The Parties have addressed only some of the purposes of Regulation 258/97 and then only in relatively general terms. We therefore begin our task by setting out the Parties' main arguments on the purposes of Regulation 258/97.

7.398 The **United States** argues that European Communities' biotech approval regime for novel foods is unquestionably an SPS measure. Regulation 258/97 states that "[f]oods and food ingredients falling within the scope of the Regulation must not present a danger for the consumer" or be "nutritionally disadvantageous."[531] According to the United States, the specific risks articulated in the Regulation fall within the definition of an SPS measure under the *SPS Agreement*. For example, concerns that a biotech product might lead to an allergic or toxic reaction on the part of consumers,

[529] We note that we have yet to analyze whether Directives 90/220 and 2001/18 meet the other definitional elements of the term "SPS measure". We will do so once we have considered the purposes of Regulation 258/97.
[530] Articles 6(1) and 6(3) of Regulation 258/97.
[531] Article 3(1) of Regulation 258/97.

e.g., concerns regarding unacceptable levels of pesticide residue in pesticide-producing plant varieties, allergic reactions based on consumption of a biotech variety that incorporates a genetic trait that can lead to such reactions, or the presence of toxins or other contaminants in foods containing biotech products, fall within the definition of Annex A(1)(b), which covers measures applied to protect "human or animal life or health" from risks arising from "contaminants" or "toxins" in "foods, beverages or feedstuffs."

7.399 The United States further argues that concerns that widespread consumption of varieties containing ARMG might lead to the development of antibiotic resistant strains of bacteria also fall under the definition of Annex A(1)(b). Such concerns have been characterized as food safety issues. Thus, a measure based on these concerns is a measure designed to protect "human or animal life or health" from "disease-causing organisms" in "foods, beverages or feedstuffs."

7.400 **Canada** argues that the central purpose of Regulation 258/97 is to protect against risks identified in sub-paragraph (b) of Annex A(1) of the *SPS Agreement*, namely, to "protect human or animal life or health […] from risks arising from […] contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs". Regulation 258/97 identifies the "protect[ion] of public health" as a justification for adoption of a single safety assessment throughout the European Community.[532] The Regulation further states that "[f]oods and food ingredients falling with the scope of this Regulation must not: present a danger for the consumer" or be "nutritionally disadvantageous."[533]

7.401 Canada observes that Commission Recommendation 97/618 sets out the type of scientific information necessary to support applications for the placing on the market of novel foods and novel food ingredients under Regulation 258/97.[534] Safety assessments conducted under Regulation 258/97 should include an assessment of contaminants, toxins and disease-causing organisms resulting from the novel elements of the novel food or food ingredient in question. The safety assessment should address only "[c]hemical or microbiological contaminants of novel foods […] specifically related to the novelty […]" and "the presence of microbial toxins and microbial or viral infective agents […] [when] this is a consequence of the novelty."[535] Part XIII of the Commission Recommendation sets out the type of toxicological information that should be included in an assessment for novel foods under Regulation 258/97, including toxicity, mutagenicity and allergenicity studies.[536]

7.402 **Argentina** maintains that the EC approval procedures, including those for novel food under Regulation 258/97, are SPS measures. Argentina recalls that the definition of SPS measures in Annex A(1) explicitly includes "*inter alia* [...] approval procedures [..]". In particular, Argentina notes

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[532] 2nd preambular paragraph of Regulation 258/97.
[533] Article 3(1) of Regulation 258/97.
[534] Commission Recommendation 97/618.
[535] *Ibid.*, Article 5.
[536] *Ibid*, p. 14, Part XIII, which states:

"This scheme covers the set of toxicological information needed to assess the [novel foods]. The range of scenarios can extend from foods for which substantial equivalence can be established to foods for which substantial equivalence cannot be established and which, therefore, require an appropriate nutritional-toxicological testing program.

If substantial equivalence to a traditional counterpart cannot be established, the safety assessment based on a case-by-case evaluation must consider the following elements:- consideration of the possible toxicity of the analytically identified individual chemical components; toxicity studies in vitro and in vivo including mutagenicity studies, reproduction and teratogenicity studies as well as long term feeding studies, following a tiered approach on a case-by-case basis; studies on potential allergenicity."

that the purpose of the EC regulations for the approval of biotech products is to determine, by means of case-by-case assessment, the presence or absence of "additives", "contaminants" or "toxins" in foods, beverages or feedstuffs and the risks to human life and health resulting from their presence. Argentina considers that the risks to which the EC legislation refers, and which have been evaluated by the respective EC scientific committees, are covered by Annex A(1) because both the legislation and the scientific opinions refer to or deal with, *inter alia*, risks such as toxic or allergic effects in humans and animals, the growth of antibiotic-resistant bacteria and cross-contamination.

7.403 The **European Communities** argues that some of the matters addressed by Regulation 258/97 go beyond the risks envisaged and regulated by the *SPS Agreement*. The scope of the *SPS Agreement* depends on the objectives of a measure. Some aspects of Regulation 258/97 fall within the scope of the *SPS Agreement*, but other aspects do not. In particular, the European Communities argues that the GMOs with which this case is concerned are not additives according to the Codex definition for additives.[537] Furthermore, since both the GMOs and the proteins produced by the GMOs are *intentionally* present in food, they cannot be considered to be "contaminants" or "toxins" within the meaning of Annex A(1)(b).

"present a danger for the consumer"

7.404 The **Panel** begins its examination with the first purpose articulated in Regulation 258/97, which is to prevent GMOs used as or in foods from "present[ing] a danger for the consumer". Regulation 258/97 does not elaborate on how it is to be determined whether a product within the scope of the Regulation presents "a danger" for the consumer. Nonetheless, it is clear from the Regulation's preamble that a fundamental objective of the Regulation is to "protect public health"[538] and to ensure that GMOs present in foods are "safe for human health"[539]. We therefore think that the phrase "danger for the consumer" should be understood as referring to a danger for the life or health of the consumer.

7.405 This view is consistent with Commission Recommendation 97/618, which was referred to by Canada. Commission Recommendation 97/618 sets out the type of scientific information necessary to support applications for the placing on the market of novel foods and novel food ingredients under Regulation 258/97. This Recommendation indicates that, *inter alia*, the following must be assessed:

- critical nutrients, any critical toxicants and anti-nutritional factors;
- potential for toxigenicity and/or pathogenicity of any novel microorganisms;
- potential occurrence of allergic reactions to novel proteins or other constituents of novel foods; and
- potential toxicological effects related to the functions of marker genes (including antibiotic resistance marker genes).[540]

[537] According to the Codex Procedural Manual, a "[f]ood additive means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include "contaminants**Error! Bookmark not defined.**" or substances added to food for maintaining or improving nutritional qualities." Codex Procedural Manual, 14th Edition, Reference A, p. 43.

[538] 2nd and 6th preambular paragraph of Regulation 258/97.

[539] 8th preambular paragraph of Regulation 258/97.

[540] Commission Recommendation 97/618, p. 5 *et seq.*

7.406 We note that potential toxic, pathogenic and allergic effects of foods containing or consisting of GMOs all present dangers for the life or health of the consumer. We further note that Article 3(4) of Regulation 258/97 provides a derogation from the regular approval procedure for foods or food ingredients which have been found to be substantially equivalent to existing foods or food ingredients as regards their "composition, nutritional value, metabolism, intended use and the level of *undesirable substances contained therein*" (emphasis added). This makes clear that potential risks to the life or health of consumers could arise from "undesirable substances contained" in foods containing or consisting of GMOs.

7.407 We recall that Annex A(1)(b) brings within the scope of the *SPS Agreement* measures applied "to protect human or animal life or health [...] from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs". We have addressed the meaning and scope of Annex A(1)(b) when we analysed Directives 90/220 and 2001/18. Based on the above considerations, to the extent that Regulation 258/97 seeks to protect consumers from dangerous foods, it may, in our view, be considered as a measure applied to protect the life or health of consumers from risks arising from additives (including antibiotic resistance marker genes), contaminants (*e.g.*, pesticide residues in pesticide-producing or resistant GM plants) or toxins (including allergens) in foods. In other words, we are of the view that the first purpose of Regulation 258/97 is covered by Annex A(1)(b).

"mislead the consumer"

7.408 The second purpose identified in Regulation 258/97 is to avoid that foods containing or consisting of GMOs "mislead the consumer". We note in this regard that Article 8.1 of Regulation 258/97 requires the labelling of food to ensure that the final consumer is informed of:

- any characteristic or food property such as composition, nutritional value or nutritional effects, or the intended use of the food, which renders a novel food or food ingredient no longer equivalent to an existing food or food ingredient;
- the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population;
- the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which gives rise to ethical concerns; and
- the presence of an organism genetically modified by techniques of genetic modification.

7.409 We note that marketing approval is granted only if the relevant novel food or food ingredient complies with Article 3(1) of Regulation 258/97, which includes the requirement that the food or food ingredient not mislead the consumer, and if it is labelled in accordance with the above-mentioned requirements of Article 8(1) of the Regulation.[541]

7.410 The Panel recalls that pursuant to Annex A(1) of the *SPS Agreement*, SPS measures include, *inter alia*, "labelling requirements directly related to food safety". The term "food safety" as it is used in the *SPS Agreement* encompasses the safety of such substances as food additives, contaminants (including pesticide residues), etc.[542] Potential health risks arising from such substances are addressed in Annex A(1)(b). Therefore, we consider that labelling requirements related to food safety are labelling

[541] Articles 6(1) and 6(3) of Regulation 258/97.

[542] Annex A(3) specifies the relevant international standards for "food safety", which include Codex standards relating to food additives, pesticide residues and contaminants.

requirements which are applied to protect human health from risks arising from additives, contaminants, toxins or disease-causing organisms in foods.

7.411 Of the four above-mentioned issues on which Article 8(1) requires information to be provided, the second appears to be directly related to food safety (materials which may have implications for the health of certain sections of the population). The first and third issues seem unrelated to food safety (nutritional value or nutritional effects, or the intended use of the food, and on materials which give rise to ethical concerns). The fourth issue relates to information on the presence in a food of a GMO. This information parallels the above-noted labelling requirement in Directive 2001/18. The requirement in Regulation 258/97 is imposed irrespective of whether there is a food safety concern, that is to say, an actual or potential health risk associated with the presence of that GMO in the food in question. Since Regulation 258/97 seeks to ensure that novel foods not mislead the consumer in addition to ensuring that they not present a danger for the consumer, it is reasonable to assume that the requirement that the consumer be informed of the presence of a GMO irrespective of whether there is an associated health risk is at least in part imposed to prevent consumers from being misled. In other words, we consider that, at least in part, Regulation 258/97 requires the identification of the presence of a GMO in a food product in order to ensure that those consumers who have a preference for food not containing or consisting of GMOs are not misled into purchasing food containing or consisting of GMOs.[543]

7.412 We are of the view that to the extent Regulation 258/97 is applied to ensure that novel foods not mislead the consumer, it does not constitute a measure applied to protect the life or health of consumers from risks arising from, *e.g.*, additives or contaminants in foods. Accordingly, we consider that the second purpose of Regulation 258/97 falls outside the scope of Annex A(1).

"nutritionally disadvantageous"

7.413 The third purpose of Regulation 258/97 is to ensure that novel foods, including foods containing or consisting of GMOs, not differ from foods which they are intended to replace to such an extent that their normal consumption would be "nutritionally disadvantageous" for the consumer. We recall that the first purpose of Regulation 258/97 is to prevent novel foods from presenting a "danger" for the consumer. We have to assume, therefore, that the concept of "danger for the consumer", which we have said is linked to the protection of the life or health of the consumer, is distinct and separate from the concept of "nutritional disadvantage for the consumer". Indeed, conceptually, it makes sense to distinguish the two situations. The normal consumption of a novel food may be nutritionally disadvantageous for the consumer if it does not provide the body with nutrients in the right quantity or of the right quality. This fact alone would not mean, however, that the relevant novel food would present a danger for the consumer. To consider a hypothetical example, if oranges were to be genetically modified in such a way that they contained greatly reduced levels of Vitamin C, presumably juice produced from these oranges would likewise be a poor source of Vitamin C. Consumers who normally drank orange juice as an important source of Vitamin C in their diet might be nutritionally disadvantaged if they consumed juice from the genetically modified, low Vitamin C, oranges. However, this nutritional disadvantage could be rectified through the consumption of another source of Vitamin C. Based on these considerations, we are not convinced that the requirement that novel foods not be nutritionally disadvantageous for consumers is intended, as such, to protect the life or health of consumers.

[543] We do not mean to suggest that the absence of information about the presence of a GMO would necessarily lead to consumers being misled. Rather, our statement concerns the reasons for which we consider the European Communities is applying the identification requirement contained in Regulation 258/97.

7.414 The Panel recalls that, Annex A(1)(b) brings within the scope of the *SPS Agreement* measures applied "to protect human [...] life or health [...] from risks arising from additives, contaminants, toxins or disease-causing organisms in foods [...]". We have indicated that, in our view, the requirement in Regulation 258/97 that novel foods not be nutritionally disadvantageous for the consumer is not applied, as such, to protect "human life or health". Therefore, to the extent that Regulation 258/97 is applied to ensure that novel foods are not nutritionally disadvantageous for the consumer, we think it cannot be considered a measure applied to protect the life or health of consumers from risks arising from, *e.g.*, additives or contaminants. In other words, we consider that the third purpose of Regulation 258/97 is not covered by Annex A(1).

Conclusions with respect to the purpose of Regulation 258/97

7.415 In our analysis above, we have identified and considered each of the three separate and independent purposes for which Regulation 258/97 is applied. We have determined that to the extent the Regulation seeks to achieve the first of the three purposes – *i.e.*, ensuring that novel foods not present a danger for the consumer – it may be considered as a measure which is applied for the purpose identified in Annex A(1)(b). In other words, we consider that the first purpose of Regulation 258/97 meets the purpose element of the definition of the term "SPS measure".[544]

7.416 On the other hand, to the extent Regulation 258/97 is applied to achieve the second and third purposes – *i.e.*, ensuring that novel foods not mislead the consumer, and that they not be nutritionally disadvantageous for the consumer – it is not a measure applied for one of the purposes mentioned in Annex A(1). To that extent, the Regulation does not meet the purpose element of the definition of the term "SPS measure". Since the Regulation does not meet one of the constitutive elements of the definition of the term "SPS measure", it follows that Regulation 258/97 is not an SPS measure within the meaning of Annex A(1) to the extent it is applied to ensure either that novel foods not mislead the consumer or that they not be nutritionally disadvantageous for the consumer.

(c) Whether the EC approval procedures are SPS measures in terms of their form and by their nature

7.417 We now turn to analyse whether Directives 90/220 and 2001/18 as well as Regulation 258/97 are "SPS measures" in terms of their form and by their nature.

7.418 The **United States** argues that Directives 90/220 and 2001/18, as well as Regulation 258/97, are "approval procedures" under the *SPS Agreement*. Annex C to the *SPS Agreement* defines "approval procedures", as including, *inter alia*, "procedures for sampling, testing and certification". Because biotech products must be approved before they can be placed on the market,[545] the procedures are analogous to the types of procedures specifically articulated in Annex C, *e.g.*, procedures for certification. As such, the procedures fall within the definition of "approval procedures" provided for under the Annex. *Second*, these procedures are imposed to "ensure" that the requirements of the European Communities' approval legislation for biotech products are met. *Third*, the European Communities' approval legislation is a "sanitary or phytosanitary measure" as defined in Annex A(1) of the *SPS Agreement* because it is applied for the purpose of protecting human, animal, or plant life or health or preventing or limiting other damage within the territory of the Member from certain enumerated risks in Annex A.

[544] We note that we have yet to analyze whether Regulation 258/97 meets the other definitional elements of the term "SPS measure".

[545] *See* Articles 6(8) and 19(2) of Directive 2001/18; Articles 6(4) and 11(5) of Directive 90/220; Article 4(2) of Regulation 258/97.

7.419 **Canada** argues that the approval procedures contained in Directive 2001/18 (and its predecessor Directive 90/220) and Regulation 258/97 are clearly "approval procedures" for the purposes of Annex C of the *SPS Agreement*. It is clear that the approval legislation applicable to biotech products is a "law, regulation or requirement". Moreover, the approval procedures are imposed to "check and ensure" the fulfilment of the requirements of the European Communities' approval legislation, namely that food and food ingredients do not "present a danger for the consumer"[546] or that the release into the environment of biotech products "will be safe for human health and the environment".[547] The approval procedures check and ensure that all of the relevant information has been submitted and that the risks associated with placing biotech products on the market have been identified and assessed. Finally, the European Communities' approval legislation for biotech products is a "sanitary or phytosanitary" measure as defined in Annex A(1) of the *SPS Agreement*.

7.420 **Argentina** argues that the EC legislation which establishes the procedure for the prior approval of GMOs (Directive 90/220 and subsequently Directive 2001/18, and Regulation 258/97) defines the procedures for the approval of biotech agricultural products of both domestic and foreign origin. Argentina submits that this legislation contains provisions related to the system of control, inspection and approval.

7.421 The **European Communities** states that to the extent that its approval system set up under the relevant GMO legislation addresses risks coming under Annex A(1) of the *SPS Agreement*, it accepts that that system is a "procedure to check and ensure the fulfilment of sanitary or phytosanitary measures". The procedures sets forth in the relevant legislation are designed to ensure that adverse effects on human health and the environment are avoided. To the extent this is done by verifying and assessing the risks coming under the *SPS Agreement*, those procedures can be said to be applied in order "to check and ensure the fulfilment of sanitary or phytosanitary measures".

7.422 The **Panel** commences its analysis with the form element of the definition of the term "SPS measures". The second paragraph of Annex A(1) indicates that SPS measures "include" all "laws, decrees [and] regulations". In our view, the reference to "laws, decrees [and] regulations" should not be taken to prescribe a particular legal form. Rather, we consider that SPS measures may in principle take many different legal forms.

7.423 We note that Directives 90/220 and 2001/18, as well as Regulation 258/97, are legislative acts adopted by the European Council and the European Parliament.[548] As such, they are governmental measures attributable to the European Communities. We also note that they are legally binding. Directives 90/220 and 2001/18 are addressed to EC member States and are to be transposed by them through legislative or administrative action.[549] Regulation 258/97 states, *in fine*, that it is binding in its entirety and directly applicable in all EC member States. In the light of these elements, we consider that, for the purposes of Annex A(1), Directives 90/220 and 2001/18, as well as Regulation 258/97, may be assimilated to measures adopted in the form of "laws" and, therefore, meet the form element of the definition of the term "SPS measures".

7.424 Regarding the nature of SPS measures, we recall that the second paragraph of Annex A(1) refers to a variety of "requirements and procedures" which are quite different in nature. Among the "procedures" specified in Annex A(1) are "testing, inspecting, certification and approval procedures".

[546] Article 3 of Regulation 258/97.
[547] Preambular paragraph 47 of Directive 2001/18.
[548] Directive 90/220 was adopted by the Council only.
[549] Articles 23 and 24 of Directive 90/220; Articles 34 and 38 of Directive 2001/18.

In the present case, the Parties have consistently referred to Directives 90/220 and 2001/18, as well as Regulation 258/97, as setting out "EC approval procedures" for biotech products. Annex A(1) does not define the term "approval procedures". However, Annex C to the *SPS Agreement*, which is entitled "Control, Inspection and Approval Procedures", contains a footnote which clarifies that "[c]ontrol, inspection and approval procedures include, *inter alia*, procedures for sampling, testing and certification".[550] Furthermore, the lead-in to Annex C(1) makes clear that Annex C(1) establishes disciplines "with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures". On the basis of these elements, the term "approval procedures" can be understood as encompassing procedures applied to check and ensure the fulfilment of one or more substantive SPS requirements the satisfaction of which is a prerequisite for the approval to place a product on the market.

7.425 As is apparent from our earlier description of the procedures set out in Directives 90/220 and 2001/18, GMOs may not be released into the environment unless the consent of the competent authority has been obtained.[551] Similarly, in the case of Regulation 258/97, foods containing or consisting of GMOs may not be placed on the market unless an authorization decision has been obtained.[552] Thus, it is clear that Directives 90/220 and 2001/18 as well as Regulation 258/97 each impose a pre-marketing approval requirement.

7.426 In the case of Directives 90/220 and 2001/18 the granting of marketing approval is conditional on a demonstration to the satisfaction of the competent authorities that the GMO to be released into the environment does not pose a risk to human health or the environment.[553] We have already determined that Directives 90/220 and 2001/18, as measures which are applied to avoid adverse effects on human health and the environment which might arise from the deliberate release of GMOs, meet the purpose element of the definition of the term "SPS measure". Therefore, we consider that the requirement established by Directives 90/220 and 2001/18 that GMOs released into the environment not pose a risk to human health or the environment is a substantive requirement imposed for the purposes mentioned in Annex A(1).

7.427 Regarding Regulation 258/97, we note that the granting of marketing approval is conditional, *inter alia*, on a satisfactory demonstration that the novel food for which approval is sought not present a danger for the consumer.[554] We have determined above that to the extent the Regulation is applied for this purpose, it meets the purpose element of the definition of the term "SPS measure". Consistent with this, we consider that the requirement established by Regulation 258/97 that novel foods not present a danger is a requirement imposed for a purpose mentioned in Annex A(1).

7.428 If, as we suggest, Directives 90/220 and 2001/18, as well as Regulation 258/97, contain substantive SPS requirements the satisfaction of which is a prerequisite for the approval to place a product on the market, the next question to be considered is whether Directives 90/220 and 2001/18, as well as Regulation 258/97, contain procedures to check and ensure the fulfilment of these requirements. The answer is in the affirmative.[555] We have described in detail the procedures set out

[550] Footnote 7 of the *SPS Agreement*.

[551] Articles 6, 10, 11 and 13 and preambular paragraphs 17, 18 and 20 of Directive 90/220; Articles 4, 6, 13, 15 and 19, and preambular paragraphs 28 and 47 of Directive 2001/18.

[552] Articles 3, 4, 6 and 7 and preambular paragraph 2 of Regulation 258/97. We note that the exception of the simplified procedure provided for in Article 5 of Regulation 258/97.

[553] Articles 4, 11 and 13, as well as preambular paragraph 21 of Directive 90/220; Articles 4, 13 and 15, as well as preambular paragraph 47 of Directive 2001/18.

[554] Article 3(1) of Regulation 258/97.

[555] *See* Articles 11-13 and 21 of Directive 90/220; Articles 13-22 and 30 of Directive 2001/18; Articles 3, 4-7 and 11-13 of Regulation 258/97.

in Directives 90/220 and 2001/18, as well as Regulation 258/97. These procedures serve the purpose of checking and ensuring the fulfilment of the relevant substantive SPS requirements.

7.429 The foregoing considerations lead us to the view that the procedures set out in Directives 90/220 and 2001/18, as well as Regulation 258/97, are procedures applied to check and ensure the fulfilment of one or more substantive SPS requirements the satisfaction of which is a prerequisite for the approval to place a product on the market. We have said earlier that such procedures can be considered as "approval procedures" within the meaning of Annex A(1) and C(1).

7.430 Since we have found that Directives 90/220 and 2001/18, as well as Regulation 258/97 (to the extent it seeks to prevent novel foods from being a danger for the consumer), constitute "approval procedures" within the meaning of Annex A(1), it follows that they meet the nature element of the definition of the term "SPS measure".

7.431 In the light of the above, we conclude that Directives 90/220 and 2001/18, as well as Regulation 258/97 (to the extent it seeks to prevent novel foods from being a danger for the consumer), qualify as SPS measures within the meaning of Annex A(1) as far as their form and nature are concerned.

(i) Conclusion on whether the EC approval procedures are "SPS measures"

7.432 We have now considered Directives 90/220 and 2001/18, as well as Regulation 258/97, in terms of their purpose, their form and their nature. In relation to each of these issues, we have found that they satisfy the definition of the term "SPS measure" set out in Annex A(1). In the light of this, we come to the conclusion that Directives 90/220 and 2001/18, as well as Regulation 258/97 (to the extent it seeks to prevent novel foods from being a danger for the consumer), constitute "SPS measures" within the meaning of Annex A(1).

7.433 At this juncture, we could go on and address whether any of the three EC approval procedures at issue in this dispute embodies more than one SPS measure. However, neither the Complaining Parties nor the European Communities have argued that to the extent any of the EC approval procedures falls to be assessed under the *SPS Agreement*, it should be deemed to constitute more than one SPS measure. Indeed, in their submissions to the Panel, the Parties treated Directives 90/220 and 2001/18 as well as Regulation 258/97 as constituting one SPS measure each. Also, in this case, our disposition of the Complaining Parties' claims under the *SPS Agreement* (and, where appropriate, any implementing action to be taken in view of our disposition of particular claims) is not affected by whether we treat any of the EC approval procedures as constituting a single SPS measure or as embodying more than one SPS measure. Taking account of these elements, like the Parties, we will treat each of the EC approval procedures as constituting one single SPS measure.

(d) Whether the EC approval procedures may affect international trade

7.434 Article 1.1 of the *SPS Agreement* provides, *inter alia*, that the *SPS Agreement* "applies to all [SPS] measures which may, directly or indirectly, affect international trade". Thus, for an SPS measure to be subject to the disciplines of the *SPS Agreement*, it must be capable of affecting international trade. Accordingly, we now turn to consider, as an additional and separate matter, whether Directives 90/220 and 2001/18 as well as Regulation 258/97 may affect international trade.

7.435 In our view, it is not necessary to demonstrate that an SPS measure has an actual effect on trade. Article 1.1 merely requires that an SPS measure "may, directly or indirectly, affect international trade". Bearing this in mind, we first recall our earlier determination that

Directives 90/220 and 2001/18 as well as Regulation 258/97 set out procedures which are applied to check and ensure the fulfilment of a substantive SPS requirement the satisfaction of which is necessary to obtain approval to place a product on the market. It is uncontested that Directives 90/220 and 2001/18 as well as Regulation 258/97 apply to GMOs and foods containing or consisting of GMOs which are produced outside the European Communities and hence would be imported into the European Communities upon approval. Finally, we note that the procedures in question may themselves have a direct or indirect effect on international trade, *e.g.*, because their completion takes time, or because they impose information and documentation requirements on applicants.

7.436 For these reasons, we conclude that Directives 90/220 and 2001/18 as well as Regulation 258/97 (to the extent it seeks to prevent novel foods from being a danger for the consumer) are SPS measures which may, directly or indirectly, affect international trade within the meaning of Article 1.1 of the *SPS Agreement* and, as such, are subject to the provisions of the *SPS Agreement*.

7.437 With this conclusion in mind, we now proceed to examine the first measure challenged by the Complaining Parties, the alleged general EC moratorium on approvals.

D. GENERAL EC MORATORIUM

1. Measure at issue

7.438 The Panel begins its examination of the first measure at issue in this dispute – the alleged general EC moratorium – by setting out the Complaining Parties' descriptions of that measure as well as the European Communities' response thereto.

7.439 The **United States** asserts in its panel request that since October 1998, the European Communities has applied a moratorium on the approval of biotech products. Pursuant to the moratorium, the European Communities has suspended consideration of applications for, or granting of, approval of biotech products under the EC approval system. In particular, the European Communities has blocked in the approval process under the relevant EC legislation all applications for placing biotech products on the market, and has not considered any application for final approval. Thus, as described, the measure at issue is the suspension by the European Communities of consideration of applications for, or granting of, approval of biotech products.[556]

7.440 The United States subsequently added in its submissions that it is not claiming that each and every application stopped all progress beginning in 1998.[557] To the contrary, the moratorium was a decision by the European Communities not to move products to a *final* decision in the approval process. Thus, certain progress in the process, short of final decision, is not inconsistent with a moratorium on final approvals.

7.441 **Canada** asserts in its panel request that since October 1998, the European Communities has maintained a moratorium on the approval of biotech products. The European Communities effectively has suspended the consideration of applications for approval of biotech products, and the granting of approvals for those products, under the relevant EC approvals processes. Accordingly, as described, the measure at issue is the general suspension by the European Communities of its own

[556] *See* the US request for the establishment of a panel. WT/DS291/23, paras. 1 and 3.
[557] US first written submission, para. 2.

processes for the consideration of applications for, and of the granting of, approval of biotech products.[558]

7.442 Canada subsequently added in its submissions that the moratorium maintained by the European Communities did not involve the complete shutdown of the approval process, at every stage.[559] While the processing of certain applications was completely suspended, some progress was made in relation to other applications. Moreover, throughout the existence of the moratorium, the Commission continued to refer applications to the various scientific committees for their opinion. However, it is at the critical decision-making junctures, or key stages, of the approval procedure that applications were blocked.

7.443 **Argentina** asserts in its panel request that the European Communities has applied a *de facto* moratorium on the approval of agricultural biotechnology products since October 1998. This *de facto* moratorium has led to the suspension of consideration of, and failure to consider, various applications for approval of biotech products as well as to undue delays in finalizing the processing of applications for the approval of such products under the relevant EC legislation. Thus, the measure at issue is the suspension by the European Communities of consideration of, and failure to consider, various applications for approval of biotech products.[560]

7.444 Argentina subsequently added in its submissions that it is not arguing that there was a total lack of movement through the successive stages of the approval process.[561] Rather, Argentina argues that since 1998, any such movement has failed to lead to approval due to deliberate blockage or stalling at key stages of the approval process.

7.445 The **European Communities** suggests that the Complaining Parties' allegation that it suspended consideration of applications only at key stages in the approval process is at odds with the concept and definition of a moratorium.[562] The European Communities further suggests that the Complaining Parties are not challenging a measure, but an alleged practice – an alleged repeated pattern of suspending consideration of individual applications.

7.446 The European Communities argues that an examination of the applications identified by the Complaining Parties shows that there has never been a "general suspension" of approvals, and that the individual applications have not been stalled at any moment. The evaluation process has continued through the past years, with the EC and member States authorities taking into account the changing legislative and regulatory framework as well as the evolving scientific debate in the treating of the pending applications. The European Communities notes that many applications had to be re-submitted under Directive 2001/18 by January 2003, and that many applications have been withdrawn, usually for purely commercial reasons.

7.447 The European Communities observes that all pending applications have been subject to requests for additional information, often related to insufficient data having been provided in the dossier to allow for a proper risk assessment. Some requests, however, especially with regard to monitoring and traceability issues, were made in anticipation of the new legislation to be adopted, and were based on voluntary commitments from the applicants. The European Communities maintains

[558] *See* Canada's request for the establishment of a panel. WT/DS292/17, paras. 1 and 5.
[559] Canada's first written submission, para. 2.
[560] *See* Argentina's request for the establishment of a panel. WT/DS293/17, paras. 2 and 5.
[561] Argentina's first written submission, paras. 198 *et seq.*
[562] EC second written submission, para. 296.

that since the entry into force of Directive 2001/18 individual applications haves been moving smoothly through the different steps of the relevant EC approval procedures.

7.448 The **Panel** notes that the Complaining Parties use slightly different language to describe the measure at issue. Yet none of the Complaining Parties ever suggested that they were challenging different measures. Indeed, the Complaining Parties' submissions all refer to the measure in question as the "moratorium". The Panel therefore proceeds on the basis that the Complaining Parties are contesting one and the same measure – the alleged moratorium on the approval of biotech products.

7.449 According to the Complaining Parties, the alleged moratorium was in effect between October 1998 and 29 August 2003, which is the date this Panel and its terms of reference were established. It is important to point out in this respect that the Complaining Parties are not of the opinion that the alleged moratorium was lifted after August 2003. To the contrary, in the Complaining Parties' view, the alleged moratorium was still in effect in February 2005, when the Panel's second and last substantive meeting with the Parties was held.

7.450 The Complaining Parties sometimes refer to the measure at issue in this Section as the "general moratorium" or the "across-the-board moratorium". This reflects the fact that this particular measure is alleged to have been applied to all applications for approval of biotech products which were pending during the relevant time period (October 1998 to August 2003).[563] It is well to recall in this context that the Complaining Parties are also challenging certain product-specific measures, *i.e.*, measures which are alleged to apply only to individual biotech products.

7.451 The Complaining Parties did not identify a formal EC legislative or administrative act giving effect to the moratorium allegedly imposed by the European Communities. However, it is not the Complaining Parties' argument that the European Communities adopted a formal, *de jure* moratorium on approvals during the relevant time period. According to the Complaining Parties, the moratorium on approvals adopted and applied by the European Communities during the relevant time period was an effective, *de facto*, moratorium.[564]

7.452 In describing the measure at issue in their panel requests, all three Complaining Parties refer, *inter alia*, to a "suspension by the European Communities of the consideration of applications for approval of biotech products". This could be understood as meaning that the European Communities suspended the processing of all applications, and that all approval procedures were brought to a complete standstill. In their submissions to the Panel, the Complaining Parties point out, however, that they are not alleging that the European Communities suspended all consideration of applications, at all stages of the approval process. What they are alleging is that the European Communities effectively suspended consideration of applications at certain critical stages with a view to preventing the final approval of these applications. This allegation is not inconsistent with the reference in the panel requests to a "suspension by the European Communities of the consideration of applications for approval of biotech products". In the Panel's view, the Complaining Parties' submissions do not allege the existence of a measure which is different from that described in the panel requests. They rather provide further clarification of the descriptions contained in the panel requests.

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[563] US first written submission, para. 34; US second written submission, paras. 34-35 and 52; Canada's first oral statement, para. 38; Canada's second written submission, para. 1; Canada's third written submission, para. 203; Argentina's first written submission, para. 19; Argentina's second written submission, para. 137; Argentina's third written submission, paras. 53 and 59.

[564] US first written submission, para 3; Canada's first oral statement, para. 37; Argentina's first written submission, para. 52.

7.453 The European Communities suggests that the Complaining Parties' allegation that it suspended consideration of applications only at key stages in the approval process is at odds with the concept and definition of a moratorium.[565] The Panel is not convinced by this argument. In their panel requests, the Complaining Parties do not allege the existence of a moratorium on the processing of applications for approval. They allege the existence of a moratorium on the approval of applications. A moratorium on approvals does not necessarily imply a suspension of approval procedures at every stage in the approval process. As noted by the Complaining Parties, it is consistent with the notion of an approvals moratorium that individual applications are allowed to make some progress in the approval process, provided that no application is allowed to obtain final approval.

7.454 The European Communities further suggests that the Complaining Parties are not challenging a measure, but an alleged practice – an alleged repeated pattern of suspending consideration of individual applications. The United States responds that this is not the case. It points out that it is challenging the alleged moratorium, and not the pattern of non-decisions that resulted from the moratorium. The United States notes that it does not contend that the moratorium itself constitutes a mere practice. Rather, the United States argues that the moratorium is a measure. According to the United States, the absence of approvals is the result of a definitive, albeit unpublished, act – a conscious, political-level decision by the European Communities not to allow any application to reach the stage of final approval.[566]

7.455 The Panel does not understand Canada and Argentina to conceive of the alleged moratorium differently from the United States. Indeed, Canada contends that the European Communities decided to stop authorizing new biotech products, regardless of the actual risks involved for individual products.[567] In Canada's view, there was an effective "political" decision on the part of the European Communities not to approve applications. Canada considers that it is this effective "decision not to decide", or in other words, the effective decision not to complete any approval procedures, that is the source of the alleged moratorium.[568] Argentina also submits that the *de facto* moratorium is the result of a decision.[569] Argentina asserts that since 1998 there have been no approvals of biotech products because the European Communities decided that there should be no new approvals.[570] It is true that Argentina stated that the alleged moratorium has been applied and maintained as a practice in the European Communities.[571] However, Argentina also stated that the *de facto* moratorium is a measure. Moreover, Argentina used the word "practice" after noting that the alleged moratorium had been imposed *de facto* and was not set forth in any piece of legislation.[572] As the Panel understands it, Argentina's reference to a practice was intended to distinguish between, on the one hand, measures the existence of which is self-evident because they take the form of laws or regulations and, on the other hand, measures the existence of which is revealed by an observable pattern of conduct, *e.g.*, by repeated and systematic actions and omissions.

7.456 In conclusion, the Panel considers that the measure which is being challenged by the Complaining Parties is the alleged EC moratorium on the approval of biotech products. The essential

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[565] EC second written submission, para. 296.

[566] US first oral statement, para. 42; US second written submission, para. 45; US third written submission, paras. 5 and 17.

[567] Canada's third written submission, para. 124.

[568] *Ibid*., paras. 202, 203 and 214; Canada's replies to Panel question Nos. 172 and 179.

[569] Argentina's third written submission, para. 50; Argentina's second oral statement, p. 5.

[570] *Ibid*., paras. 17, 50 and 153; Argentina's second written submission, paras. 49 and 129.

[571] Argentina's first written submission, para. 34.

[572] *Ibid*.

elements characterizing the alleged EC moratorium, which the Complaining Parties say was in effect between October 1998 and the date of establishment of this Panel (*i.e.*, 29 August 2003), are the following:

(a) It was not adopted through a formal EC rule- or decision-making process, but it nonetheless constitutes a measure attributable to the European Communities.

(b) It was applicable to all applications for approval of biotech products which were pending or newly submitted during the relevant time period.

(c) It involved the effective suspension by the European Communities of final approval decisions with regard to the applications mentioned in the preceding sub-paragraph.

2. Existence of a general moratorium on approvals

7.457 The **European Communities** argues that there is no moratorium and no suspension that the Panel could rule on because there has been neither a moratorium nor a suspension of the approval process since October 1998. The European Communities acknowledges that no applications were approved between October 1998 and August 2003[573], and that some applications suffered important delays. But the European Communities submits that the absence of approvals and the delays were the result of prudent and responsible actions and not of a "decision not to decide".

7.458 The European Communities asserts that it has never adopted any formal or informal act of any kind to impose a moratorium on approvals. It also notes that the Complaining Parties were unable to identify a single decision attributable to the European Communities which imposed such a moratorium. It is therefore the contention of the European Communities that the measure described by the Complaining Parties did not and does not exist.

7.459 The **Panel** notes that the European Communities contests, not just certain aspects of the alleged general moratorium, but its very existence. It is therefore necessary to examine in detail whether the evidence supports the Complaining Parties' assertion that between October 1998 and August 2003 the European Communities applied a general *de facto* moratorium on the approval of biotech products.

7.460 The Panel will begin its examination by considering how, in the Complaining Parties' view, the European Communities allegedly suspended approvals and whether the European Communities could suspend approvals in this manner. Next, the Panel will determine whether there are any grounds for believing that the European Communities or one of its entities (the member States, the Commission, the Council, etc.) intended to suspend approvals. Then, the Panel will analyse whether the European Communities actually suspended approvals during the relevant time period. As part of this analysis, the Panel will in a first step determine whether any biotech products were approved during the relevant period. In a subsequent step, the Panel will review a substantial number of EC documents and statements by EC and member State officials which were submitted by the Complaining Parties and which they say acknowledge and confirm the existence of a general moratorium during the relevant time period. Finally, the Panel will review the facts and history of individual applications for the approval of biotech products. The Complaining Parties argue that these application histories support and confirm their other allegations, while the European Communities submits that the histories rebut the Complaining Parties' allegations.

[573] The European Communities notes, however, that a number of biotech food products were placed on the market during the period in question. *See infra*, para. 7.497.

(a) Alleged manner of suspending approvals

7.461 As noted above, the Complaining Parties allege that the European Communities suspended consideration of applications at certain critical stages of the EC approval process with a view to preventing the final approval of applications. This leaves open the question of which are relevant stages in the approval process and of which EC entities (member States, Commission, Regulatory Committee, Council, etc.) contributed to the suspension of approvals and how. Therefore, the Panel will now describe how, according to the Complaining Parties, the European Communities allegedly suspended approvals and examines whether it was possible for the European Communities to suspend approvals in this manner.

7.462 The **United States'** main contention in this respect is that at a certain point certain EC member States decided that they were not going to vote for new approvals of biotech products in the relevant Regulatory Committee or in the Council. The United States recalls that under the European Communities' rules of qualified majority voting in the Regulatory Committee or the Council, a minority of member States can block EC action. Blocking minorities in the Regulatory Committee or the Council may be overridden by a simple majority vote in the Commission. But, according to the United States, the record shows that the Commission decided not to do so. The Commission did not submit draft measures to the appropriate Regulatory Committee or to the Council. The United States further argues that if one of the member States that is unwilling to grant marketing approvals was the original recipient of an application, then that single member State could block an application all by itself. The same single member State could also block a product approval by refusing to complete the process, that is to say, by not allowing the product to be placed on the market once it has been approved at Community level by Commission decision.

7.463 **Canada** asserts that the European Communities has suspended the approval of applications through one or more of the following acts and omissions. *First*, at EC member State level, the competent authorities of certain EC member States have failed to ensure that the approval procedures are completed without undue delay. *Secondly*, at Community level, certain member States have routinely objected to favourable assessments by the competent authority of another member State. *Thirdly*, where an application is supported by favourable risk assessments, the Commission has in some cases failed to submit a draft measure to the relevant Regulatory Committee. *Fourthly*, certain member States have blocked the adoption of draft measures by the Regulatory Committee, regardless of the scientific merits of the application in question. *Fifthly*, where there has been an impasse at the Regulatory Committee, the Commission has failed to break the impasse by referring the matter to the Council. *Lastly*, when a product has been approved by Commission decision, the competent authority of the responsible member State has failed to allow that product to be marketed.

7.464 **Argentina** submits that the European Communities has prevented the approval of biotech products since 1998 through various actions and omissions. *First*, failure by the lead CA to complete the relevant approval procedures without undue delay. *Secondly*, failure by the Commission to present draft measures to the Regulatory Committee for approval of products that have received a favourable opinion from the scientific committees. *Thirdly*, systematic opposition by EC member States to approval when a draft is submitted, with no scientific grounds for opposing the Commission's draft measure. *Fourthly*, failure by the Commission to refer a proposal to the Council when the Regulatory Committee issues no opinion.

7.465 The **European Communities** notes that the kinds of "acts and omissions" referred to by the Complaining Parties are part of an internal EC decision-making process and do not have external legal effect. Only the definitive outcome of the decision-making procedure has legal effect. The European

Communities deduces from this that the "acts and omissions" referred to by the Complaining Parties are not reviewable as measures in their own right.

7.466 The **Panel** notes that, according to the Complaining Parties, there were two EC entities with responsibilities in the EC approval process which through their actions and/or omissions prevented the final approval of applications during the time period in question (October 1998 to August 2003). The two entities are EC member States and the Commission. The issue the Panel must consider, therefore, is whether it was possible for these two entities to prevent or delay approvals of biotech products in the manner alleged by the Complaining Parties.

7.467 The Panel first turns to consider the member States' ability to prevent or delay approvals through their actions and/or omissions. Based on its understanding of the relevant EC approval procedures, the Panel agrees with the Complaining Parties that during the relevant time period EC member States could prevent or delay approvals of biotech products in the following ways:[574]

(a) The member State acting as the lead CA could delay the completion and circulation of its initial assessment.

(b) Other member States could object to the placing on the market of a biotech product following a favourable assessment by the lead CA.

(c) A group of member States that constituted a blocking minority could prevent the relevant Regulatory Committee and the Council from reaching the qualified majority necessary to adopt draft measures proposing the approval of applications.

(d) The member State acting as the lead CA in the context of an approval procedure conducted under Directives 90/220 or 2001/18 could refuse to give its consent to the placement on the market of a biotech product after the Commission had approved an application.[575]

7.468 The Panel now turns to consider the Commission's ability to prevent or delay approvals. In this case as well, the Panel agrees with the Complaining Parties that during the relevant time period the Commission could prevent or delay approvals of biotech products in the following ways:[576]

(a) The Commission could delay the submission of a draft measure to the appropriate Regulatory Committee, or it could fail to convene the Regulatory Committee for a vote on a draft measure which has been submitted.

(b) The Commission could delay the submission of a draft measure to the Council where the Regulatory Committee was unable to reach the qualified majority necessary to deliver an opinion.

7.469 It is clear that in two of the above-mentioned scenarios involving member State action, such action would not be sufficient, in itself, to prevent the *final* approval of an application. One scenario

[574] We stress that we are focusing here on whether the member States had the ability to prevent or delay approvals of biotech products, and not whether it would have been legal under EC law for them to do so.

[575] As explained above, under Regulation 258/97 applications for which a decision has to be taken at Community level are approved by the Commission with direct and immediate effect. No subsequent consent at member State level is required.

[576] Here as well, we stress that we are focusing on whether the Commission had the ability to prevent or delay approvals of biotech products, and not whether it would have been legal under EC law for it to do so.

is that of one or more member States objecting to the placing on the market of a biotech product following a favourable assessment by the lead CA. Such member State objections alone could not prevent the final approval of an application because when such objections are raised, it is incumbent on the Commission to submit a draft measure to the Regulatory Committee for its opinion. The other scenario is that of a group of member States preventing the Regulatory Committee and/or the Council from adopting a draft measure proposing the approval of an application. The vote in the Regulatory Committee and/or the Council could not prevent the application from moving towards final approval because in such cases, it would be incumbent on the Commission to submit a draft measure to the Council and, if the Council were to fail to reach a qualified majority in favour or against the draft measure, to adopt the draft measure submitted to the Council. However, in both of these scenarios, the Commission could prevent the final approval of an application by not submitting draft measures to the Regulatory Committee or the Council.

7.470 The European Communities alleges that also in the scenario where the lead CA, in the context of an approval procedure conducted under Directives 90/220 or 2001/18, refuses to give its consent to the placement on the market of a biotech product, member State action would not be sufficient, in itself, to prevent the final approval of an application. The European Communities submits that in cases where a biotech product has been approved by Commission decision, the applicant would be entitled under EC law to place the product on the market even if the lead CA has not yet taken the necessary steps to allow that product to be marketed. According to the European Communities, the applicant could invoke before national courts the obligation imposed on the lead CA by the aforementioned Commission decision. This is an issue to which the Panel will revert later, when it discusses the approval procedures concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape. At this point, it is sufficient to note that even if the applicant could ultimately prevail before a national court, the lead CA could effectively prevent the product from being marketed until there was an enforceable court ruling.

7.471 Regarding the European Communities' argument that actions and/or omissions by member States or the Commission in the context of EC approval procedures are not reviewable measures in their own right, the Panel need only note its understanding that the Complaining Parties are not challenging these actions and/or omissions *per se*. The Complaining Parties are challenging the alleged moratorium on approvals. The actions or omissions of member States and the Commission are, however, directly relevant to the Complaining Parties' challenge as they are claimed to constitute the manner in which the European Communities gave effect to the alleged moratorium.

(b) Intention to suspend approvals

7.472 In the above analysis, it has been considered whether individual EC member States, a group of EC member States, and/or the Commission could prevent the final approval of applications during the time period in question (October 1998 to August 2003). The Panel was able to agree with the Complaining Parties' main contention in this regard.

7.473 The issue to which the Panel now turns is whether there are any grounds for believing that any member State and/or the Commission intended to prevent the final approval of applications during the time period in question.

(i) EC member States

7.474 With regard to the member States, the Complaining Parties provided to the Panel a formal declaration made by five member States (Denmark, Greece, France, Italy and Luxembourg) in June 1999. The declaration was made in the context of the meeting of the Council of 24/25 June 1999 at

which a political agreement – a common position – was reached on the proposal to amend Directive 90/220. The declaration reads as follows:[577]

> Declaration by the Danish, Greek, French, Italian and Luxembourg delegations concerning the suspension of new GMO authorizations
>
> The Governments of the following Member States (Denmark, Greece, France, Italy and Luxembourg), in exercising the powers vested in them regarding the growing and placing on the market of genetically modified organisms (GMOs),
>
> given the need to put in place a tighter, more transparent framework, in particular for risk assessment, having regard to the specifics of European ecosystems, monitoring and labelling,
>
> given the need to restore public and market confidence,
>
> point to the importance of the Commission submitting without delay full draft rules ensuring labelling and traceability of GMOs and GMO-derived products and state that, pending the adoption of such rules, in accordance with preventive and precautionary principles, they will take steps to have any new authorizations for growing and placing on the market suspended.

7.475 According to the **Complaining Parties**, the key element of the above-quoted declaration is the statement that:

> "[I]n exercising the powers vested in them regarding the growing and placing on the market of genetically modified organisms […] they [the five member States in question] will take steps to have any new authorizations for growing and placing on the market suspended."

7.476 In the Complaining Parties' view, this passage demonstrates that the five member States at issue decided that they would block the approval process. The Complaining Parties argue that the "steps" the five member States said they would take include using their votes in the relevant Regulatory Committee or the Council so as to block the adoption of draft measures approving applications. It has been pointed out in this regard that, taken as a group, the five member States in question have enough votes in the Regulatory Committee and the Council to form a blocking minority.

7.477 In response to a question from the Panel, the **European Communities** stated that declarations to Council minutes, such as the above-quoted June 1999 declaration by five member States, have no legal significance or effect in the European Communities, as confirmed by the jurisprudence of the European Court of Justice.[578] The European Communities submits that its member States are fully aware of this position, but have recourse to such declarations for political purposes – to send a message to other institutions, to the public or to satisfy a political need.

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[577] Declaration by the Danish, Greek, French, Italian and Luxembourg delegations concerning the suspension of new GMO authorizations, 2194th Council Meeting - Environment-, Luxembourg, 24/25 June 1999. Exhibits US-76 and 77; Exhibit CDA-3; Exhibit ARG-12.

[578] The European Communities refers to case C-375/98, *Ministério Público and Fazenda Pública v Epson Europe BV*, [2000] ECR I-4243, para. 26.

7.478 The **Panel** considers that the June 1999 declaration by Denmark, Greece, France, Italy and Luxembourg (hereafter the "Group of Five") clearly reveals an intention on the part of the Governments of the Group of Five countries to do what is within their power to prevent the approval of further applications, pending the adoption of EC rules ensuring "labelling and traceability of GMOs and GMO-derived products". The phrase "state that […] they will take steps" necessarily implies such an intention.

7.479 It is important to note, however, that the June 1999 declaration amounts to more than a statement of intent. It does more than tentatively pronounce how the Group of Five countries intend to exercise their powers. The declaration definitively announces how the Group of Five countries will exercise their powers. Indeed, the Group of Five countries in their declaration do not "state that [...] they [intend] to take steps" to prevent the approval of further applications. Rather, they "state that [...] they *will* take steps" (emphasis added) to do so. In the Panel's view, it may be inferred from this language that each of the Group of Five countries made a decision on how it would exercise its powers.

7.480 The European Communities pointed out that declarations like the June 1999 declaration have no legal effect under EC law. The text of the June 1999 declaration does not suggest otherwise. There is no indication that the declaration was intended to impose obligations on the Governments of the Group of Five countries *vis-à-vis* other member States or the Commission. The European Communities appears to infer from the circumstance that the 1999 declaration itself is not legally binding that it might not reflect the real intentions of the Governments of the Group of Five countries and that it may have been made merely for the sake of expediency, "to satisfy a political need". However, a panel must not lightly cast doubt on the good faith underlying governmental declarations and on the veracity of these declarations. In the instant case, the precise, legal-style drafting of the 1999 declaration demonstrates that it is not a casual statement, but a carefully considered one. What is more, the 1999 declaration is a formal, on-the-record declaration made on behalf of the Governments of the Group of Five countries and reflecting their official position. In these circumstances, and in the absence of evidence to the contrary, it may be presumed that the 1999 declaration by the Governments of the Group of Five countries accurately expresses their true intentions.[579]

[579] With respect to DS292 we note that Canada has introduced evidence which suggests that the Group of Five declaration was reiterated over time. *First*, evidence submitted by Canada suggests that the declaration was reiterated at the formal adoption of the Common Position on 9 December 1999. Exhibit CDA-32, p. 5. *Secondly*, Canada refers to a statement by the Group of Five countries plus Austria of 15 February 2001 which also reaffirmed the intention expressed in the June 1999 declaration. The statement accompanied the adoption by the Council of the definitive legislative act embodying the revised Directive 90/220, following the European Parliament's second reading under the co-decision procedure. The Council decided to make the statement public. It reads in full:

> "Statement by the Danish, Greek, French, Italian, Austrian and Luxembourg Delegations
>
> Having regard to the principle of prevention and precaution, the delegations of the following Member States: Denmark, Greece, France, Italy, Austria and Luxembourg
>
> - reaffirm the need to introduce a more rigorous, transparent and comprehensive framework concerning risk assessment and risk management (taking account of the specific characteristics of European eco-systems), monitoring, traceability and labelling of GMOs and to generally restore the confidence of the public and of operators;

7.481 Another element which needs to be noted in respect of the 1999 declaration is the fact that it is a joint declaration. More particularly, what is of interest is the composition of the Group of Five countries. During the time period in question (October 1998 to August 2003), the member States making up the Group of Five countries had enough votes in the appropriate Regulatory Committee or the Council to prevent these bodies from achieving the qualified majority that is necessary to adopt a draft measure proposing the approval of an application.[580] In other words, the Group of Five countries

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- note that the amended provisions of Directive 90/220/EEC significantly but only partially improve the existing arrangements and emphasise the essential improvements made concerning transparency, public access to information, regional biological monitoring of the countryside, gradual elimination of antibiotic resistance markers, legal certainty and ratification of the Carthagena Protocol;
- ask the Commission to follow up its commitment concerning the early submission of comprehensive legislative proposals on GMO traceability and labelling, environmental liability and ratification of the Carthagena Protocal.

Accordingly, the above delegations

- *reaffirm their intention, when exercising the powers conferred upon them, of ensuring that the new authorizations for cultivating and marketing GMOs are suspended pending the adoption of effective provisions concerning a complete traceability of GMOs that guarantees reliable labelling of all GMO products*;
- call on the Commission to make rapid progress towards the establishment of a system of environmental liability to supplement the regulatory framework necessary for development in the field of biotechnologies, as in other environmental fields." (Exhibit CDA-114; emphasis added).

We note that Argentina also refers to Exhibit CDA-114. Finally, evidence submitted by Canada suggests that the Group of Five countries plus Austria reaffirmed their previous declarations at the final adoption of the revised Directive 90/220 on 12 March 2001. Exhibit CDA-31, p. 1. Argentina also refers to Exhibit CDA-31, p.1.

[580] Article 21 of Directive 90/220 provides that Regulatory Committee opinions "shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission". It further provides that in those cases where a measure cannot be adopted after the Regulatory Committee stage and the matter goes before the Council, "[t]he Council shall act by a qualified majority". Article 148(2) of the *Treaty Establishing the European Community as Amended by Subsequent Treaties* provides in relevant part (emphasis added):

"Where the Council is required to act by a qualified majority, the votes of its members shall be weighted as follows:

Belgium	5
Denmark	*3*
Germany	10
Greece	*5*
Spain	8
France	*10*
Ireland	3
Italy	*10*
Luxembourg	*2*
Netherlands	5
Austria	4
Portugal	5
Finland	3
Sweden	4
United Kingdom	10

constituted a "blocking minority" at the level of decisions by the Regulatory Committee and the Council. It should be recalled in this context that the 1999 declaration states that the Governments of the Group of Five countries "will take steps to have any new authorizations for growing and placing on the market suspended". One of the steps open to the Governments of the Group of Five countries was to act as a "blocking minority" in the relevant Regulatory Committee or Council. Thus, to the extent that the 1999 joint declaration by the Group of Five countries was perceived as announcing or confirming the formation of a credible "blocking minority", it sent an important signal to other member States and the Commission. It would have signalled that if the Group of Five countries were to act in accordance with their declaration, applications could henceforth be approved only at Community level[581] and only if the Commission was willing (i) to submit draft measures to the Regulatory Committee and the Council and (ii) to override a "blocking minority" by adopting the proposed measures.

7.482 Before proceeding further, we also need to address the substance of the declaration by the Group of Five countries. To begin with, we recall that in their declaration, the Group of Five countries pointed to the importance of the Commission "submitting without delay full draft rules ensuring labelling and traceability of GMOs and GMO-derived products" and stated that "pending the adoption of such rules, they would take steps to have any new authorizations for growing and placing on the market suspended". This suggests that upon adoption of such rules, the Group of Five countries might no longer use the powers conferred upon them so as to prevent the approval of applications.[582] It is therefore important to be clear about the rules the Group of Five countries wanted to see adopted, all the more so as subsequent to the June 1999 declaration the European Communities adopted two legislative acts which specified labelling and traceability requirements.

7.483 In March 2001, the European Communities adopted the amended Directive 90/220 as Directive 2001/18. Directive 2001/18 laid down labelling requirements in Article 21 and certain traceability and monitoring requirements in Article 4(6) (and Annex IV) and in Article 20 (and Annex VII). In September 2003, *i.e.*, shortly after this Panel was established, the European Communities adopted Regulation 1830/2003 "concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC". For the reasons set out below, the Panel is of the view that the rules which the Group of Five countries wanted to see adopted are the rules adopted in September 2003 as Regulation 1830/2003, and not those adopted in March 2001 as Directive 2001/18.[583]

For their adoption, acts of the Council shall require at least:

62 votes in favour where this Treaty requires them to be adopted on a proposal from the commission."

Since the total number of votes is 86, the 30 votes of the Group of Five countries (Denmark, Greece, France, Italy and Luxembourg) are sufficient to prevent the required qualified majority of 62 votes from being achieved.

[581] It could be expected that in any case where a lead CA that was not part of the Group of Five countries made a favourable assessment at member State level, one or more of the Governments of the Group of Five countries would take the "step" of objecting to the product being placed on the market in order to force a decision at Community level where the Group of Five countries could take the further "step" of acting as a "blocking minority".

[582] It should be noted that in the context of the EC legislative process, the adoption of rules by the European Parliament and the Council is a stage that is different from the proposal for such rules by the Commission and the entry into force of such rules.

[583] As we explain further below, we think it is plausible that the new EC rules which the Group of Five countries wanted to see adopted also include the rules adopted in September 2003 as Regulation 1829/2003.

7.484 *First*, the June 1999 declaration by the Group of Five countries calls on the Commission to submit a proposal for rules ensuring labelling and traceability. By June 1999, the Commission had already submitted a proposal for an amendment of Directive 90/220.[584] In contrast, the Commission did not submit a proposal for what was to become Regulation 1830/2003 until 2001.[585] *Secondly*, the June 1999 declaration calls for rules "ensuring labelling and traceability of GMOs and *GMO-derived products*" (emphasis added). Neither Directive 90/220 nor Directive 2001/18 applied to GMO-derived products.[586] In contrast, Regulation 1830/2003 applies to such products.[587] *Lastly*, mention should be made of a June 1999 formal declaration by seven member States (Austria[588], Belgium[589], Finland, Germany, Netherlands, Spain and Sweden). Like the Group of Five declaration, the declaration in question was made in the context of the meeting of the Council of 24/25 June 1999 at which a political agreement was reached on the proposal to amend Directive 90/220. The declaration by the seven member States (hereafter the "Group of Seven") is reproduced in relevant part below:[590]

> "Declaration by the Austrian, Belgian, Finnish, German, Netherlands, Spanish and Swedish delegations
>
> Being aware of the increasing public concern about the potential risks to health and environment linked to the release and the placing on the market of GMOs, the above-mentioned delegations
>
> – stress the need to implement a more transparent and strict framework concerning critical issues such as risk assessment taking into account the specificity of European ecosystems, monitoring and labelling as well as the need to restore the trust of public opinion and of the market;
>
> – reaffirm their intention to work for a rapid finalisation of the legislative process concerning the proposal for an amendment of Directive 90/220/EEC and invite the European Parliament to join the Council and the Commission in their intention so that the legislative process can be rapidly finalised.
>
> Against this background the Governments of these Member States, having regard to the precautionary principle set out in Article 174(2) of the Treaty, intend:

That Regulation lays down additional labelling requirements for genetically modified food and feed. *See infra*, para. 7.1039.

[584] The proposal was published on 4 May 1998. Preamble to Directive 2001/18; Exhibit US-71.

[585] The proposal was published on 30 October 2001. Preamble to Regulation 1830/2003.

[586] Article 2(4) of Directive 90/220; Article 2(7) of Directive 2001/18.

[587] Article 2 in conjunction with Article 3(2) of Regulation 1830/2003.

[588] We recall that Canada submitted evidence which shows that Austria in February 2001 formally expressed its support for the June 1999 declaration by the Group of Five countries. Exhibit CDA-114. Argentina also refers to Exhibit CDA-114.

[589] We note that the United States submitted a document which suggests that Belgium as of December 2001 also supported the June 1999 declaration by the Group of Five countries. The document, which appears to be based on a press release, says that Belgium decided that new EC rules on traceability and labelling would need to be formally approved before other measures could be taken. The document also states that Belgium decided to discuss this issue again in October 2002. Exhibit US-79. Canada and Argentina also refer to Exhibit US-79.

[590] Declaration by the Austrian, Belgian, Finnish, German, Netherlands, Spanish and Swedish delegations, 2194th Council Meeting - Environment, Luxembourg, 24/25 June 1999. Exhibits US-76 and -77; CDA-3; ARG-12.

– to take a thoroughly precautionary approach in dealing with applications and authorizations for the placing on the market of GMOs,

– not to authorize the placing on the market of any GMOs until it is demonstrated that there is no adverse effect on the environment and human health, and

– to the extent legally possible to apply immediately the principles, especially regarding traceability and labelling, laid down in the political agreement for a revision of Directive 90/220/EEC reached by the Council on 24/25 June 1999.

Therefore, these delegations invite the Commission as a matter of urgency to make a proposal for effective implementation of the provisions regarding labelling and traceability of GMOs through the comitology procedure foreseen in Directive 90/220/EEC."

7.485 The declaration by the Group of Seven countries is of interest because it talks about "the principles […] regarding labelling and traceability of GMOs *laid down in the [June 1999] political agreement for a revision of Directive 90/220/EEC*" (emphasis added). The parallel declaration by the Group of Five countries, when referring to rules ensuring labelling and traceability, nowhere references the June 1999 political agreement. Had the Group of Five countries wanted to see the adoption of the provisions regarding labelling and traceability laid down in the June 1999 political agreement, one would have expected a reference to that agreement along the lines of the reference contained in the declaration by the Group of Seven countries.

7.486 We further find noteworthy that the declaration by the Group of Seven countries calls for a *de facto* implementation of the provisions regarding labelling and traceability of GMOs laid down in the June 1999 political agreement prior to the entry into force of the agreed amendment of Directive 90/220. Apparently, this was considered insufficient by the Group of Five countries. Reading the declaration by the Group of Five countries together with the declaration by the Group of Seven countries, it seems to us that the Group of Five countries considered it insufficient to adopt the provisions laid down in the June 1999 political agreement, even if those provisions were implemented before their adoption, as the Group of Seven countries requested. It appears that the Group of Five countries wanted to go further and adopt new rules which the Commission was invited to propose without delay.

7.487 Another issue which concerns the substance of the declaration by the Group of Five countries is whether the declaration also covers applications for the approval of biotech food products, *i.e.*, applications which fall within the scope of Regulation 258/97. At this point, it is sufficient to note that, in our view, the declaration can be interpreted to apply also to such applications. We will address this issue further at paragraphs 7.1038-7.1041 below.

(ii) Commission

7.488 Unlike in the case of the Group of Five countries, the Complaining Parties did not refer the Panel to a declaration by the Commission in which it stated an intention to delay or prevent the final approval of applications. Nor did the Complaining Parties argue that they had provided other direct evidence of such an intention on the part of the Commission. It is nevertheless clear that it is the contention of the Complaining Parties that the Commission intentionally delayed or prevented the final approval of applications during the relevant time period (October 1998 to August 2003). This

intention can be inferred, in the Complaining Parties' view, from the absence of approvals during the relevant time period and the Commission's conduct in the context of individual approval procedures. The Panel will address these two elements later in its analysis.

7.489 In the absence of evidence which directly establishes that the Commission intentionally delayed or prevented final approvals, it is pertinent to ask why in the Complaining Parties' view the Commission would have wanted to delay or prevent such approvals. As the Panel understands it, the Complaining Parties' answer is that the decision to do so was based on political considerations.[591] More particularly, the argument essentially appears to be that following the announcement by the Group of Five countries that they would act as a "blocking minority" in the Regulatory Committee and the Council, the Commission considered that it lacked the necessary political support for completing approval procedures by adopting its own draft measures.

7.490 It should be mentioned in this respect that the United States and Canada in their submissions both refer to, and quote from, the summary of a January 2001 meeting between the lead CA in the approval procedure concerning RR fodder beet and the applicant.[592] According to the summary, which was prepared by the applicant and sent to the lead CA (Denmark) by way of confirmation, the applicant was given to understand by the lead CA that – in the applicant's words – "[t]he re-start of the regulatory process will depend on the willingness of the Commission to do it. It is commonly analysed that the Commission will not promote an Art 21 [Regulatory Committee] vote meeting, if there are no indications that the member-states are supporting the process and/or expected to vote positively."[593] If the applicant's summary correctly reflects Denmark's statement, this statement suggests that the Commission at the time viewed the political support of member States as a necessary precondition for it convening Regulatory Committee meetings for votes on applications. It should be borne in mind, however, that Denmark is one of the Group of Five countries. Hence, even if Denmark made the statement in question, it might have overstated the importance of Group of Five countries' support.

7.491 Canada also submitted a Commission document entitled "GMOs Issues Paper – Strategy on Possible Ways Forward".[594] The document was prepared by the "services" for the "Commission orientation debate on GMOs" of 12 July 2000. Thus, it was written after the June 1999 declaration by the Group of Five countries, but before the adoption of Directive 2001/18. Against this background, the document states in a passage quoted by Canada that "[o]ur objective is to have, by the end of the conciliation process and the adoption of the revised Directive [90/220], the elements necessary to complete the authorization process and to convene a meeting of the regulatory committee under Directive 90/220/EC. *If the Member States are still not prepared to vote positively in the Committee, the Commission should be ready to make full use of the procedures set out in the Directive to complete the authorization process.*"[595] The last sentence implies that, at the time in question, the Commission could have considered member State opposition a reason for not making full use of the procedures envisaged in Directive 90/220 to complete the approval process. Otherwise there would have been no point in recommending that the Commission should be ready to complete the approval process. It must also be noted, however, that it cannot be assumed that the views expressed in a strategy paper prepared by the Commission services necessarily reflect those of the Commission.

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[591] US reply to Panel question No. 74; US second oral statement, paras. 36-38; Exhibit US-148; US third written submission, para. 21; Canada's second written submission, paras. 23 and 26; Canada's third written submission, paras. 202-203; Argentina's second written submission, para. 52.

[592] US third written submission, para. 92; Canada's second written submission, para. 34.

[593] Exhibit EC-64/At. 120.

[594] Exhibit CDA-113. The document was first submitted by Argentina as Exhibit ARG-50.

[595] Exhibit CDA-113, p. 3 (emphasis added).

7.492 In the Panel's view, it is clear even without the above-mentioned statements attributed to Denmark and the Commission services that member State support might in some circumstances be an issue for the Commission. To see why, it is useful to recall a fundamental aspect of the structure and design of the EC approval procedures. Canada described this aspect in the following terms:

> "Directives 90/220 and 2001/18 foresee an approval based on the lead member State's review as the primary route to a decision. Only in relatively limited cases should the Regulatory Committee need to become involved. And only as an exception to this exception is the Council required to act. And finally, only as an exception to the exception to the exception does the Commission have the final say."[596]

7.493 Canada may or may not be correct with regard to what should be the "primary route to a decision" and what should happen "only in relatively limited cases". But there can be little doubt that the Commission's "final say" was intended by the EC legislator as a last resort, to avoid deadlocks that might otherwise occur in the event that the member States in the Regulatory Committee and the Council fail to achieve the required qualified majority.[597] Notwithstanding this, exceptional circumstances might arise where the Commission routinely would have the final say and the "exception to the exception to the exception", as Canada put it, would become the rule, contrary to the design of the EC approval procedures. This could be the case, for instance, in circumstances where member State opposition to Commission proposals is not merely sporadic but systematic, and where the relevant member States at the same time have enough votes to act as a "blocking minority" in the Regulatory Committee and the Council.

7.494 As noted by the Panel in its preceding remarks, the Group of Five countries in June 1999 signalled precisely such systematic opposition to final approvals. In addition, the combined votes of the Group of Five countries enabled them to act as a "blocking minority". The Commission thus had reason to believe that it could no longer approve applications with the (qualified majority) support of the member States. In such highly exceptional circumstances, and considering the sensitivity of approvals of biotech products, it is plausible that the systematic lack of political support, and indeed opposition, by the Group of Five countries was an issue and concern for the Commission. This situation could, in our view, have dissuaded the Commission from making full use of the relevant procedures to complete the approval process, despite the applicable legal obligations[598].

(c) Absence of approvals during the relevant time period

7.495 The Complaining Parties assert not only that certain member States (notably the Group of Five countries) and the Commission had the ability and intention to prevent the final approval of applications during the time period in question. They also assert that these member States and the Commission actually prevented the final approval of applications during that time period. That there was an actual suspension on final approvals is evidenced, in the view of the Complaining Parties, by the following two elements: (i) the number of final approvals in the relevant time period, and (ii) official and internal EC documents as well as statements by EC and member State officials. In the

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[596] Canada's third written submission, para. 196. A statement along very similar lines could be made in respect of Regulation 258/97.

[597] It is useful to note in this context that the regulatory committee procedure, whereby the Commission is assisted by a regulatory committee, involves a delegation of implementing powers from the Council to the Commission. *See, e.g.*, Council Decision 1999/468 laying down the procedures for the exercise of implementing powers conferred on the Commission. The Decision is referred to in Article 30(2) of Directive 2001/18.

[598] Article 21 of Directive 90/220; Article 13(3) and (4) of Regulation 258/97.

present Subsection, the Panel addresses the first element – the issue whether there were any approvals in the relevant time period (October 1998 to August 2003).

7.496 The **Complaining Parties** argue that between October 1998 and August 2003, when the Panel's terms of reference were established, the European Communities failed to approve a single biotech product under either Directives 90/220 and 2001/18 or under Regulation 258/97. This is despite the fact that many applications were pending during that period and that many of these applications had been favourably assessed by the European Communities' own scientific committees. In contrast, up to October 1998 – the date of the last approval of a biotech product – the European Communities had approved at least ten biotech products.[599]

7.497 The **European Communities** responds that it does not contest that other than the biotech food products approved under the simplified procedure of Regulation 258/97[600], there have not been any approvals for a given period of time due to the fact that the EC regulatory regime was incomplete. Regarding the simplified procedure of Regulation 258/97, the European Communities states that between October 1998 and 2004 seven biotech food products were approved.

7.498 The **United States** submits that the simplified procedure set out in Regulation 258/95 does not require action by the Council or Regulatory Committee. The United States further states that the simplified procedure does not appear to be affected by the EC moratorium.

7.499 **Canada** notes that the simplified procedure is only available in limited circumstances and does not require the Commission to take a decision at Community level. Canada submits that each of the applications referred to by the European Communities were assessed by food assessment bodies from one member State. Other member States did not have an opportunity to block or stall this process. That the relevant member State food assessment bodies acted on the basis of sound science and in accordance with EC law does not, in Canada's view, disprove the existence of the moratorium.

7.500 **Argentina** argues that the simplified procedure of Regulation 258/97 only requires that one member State issue an opinion that the product is "substantially equivalent" to existing foods or food ingredients. Once that opinion is issued, the marketing of the product in question cannot be prevented by other member States or the Commission. Argentina submits on that basis that the simplified procedure is not an approval procedure, but a application procedure.

7.501 The **Panel** notes that it is not in dispute that during the relevant time period (October 1998 to August 2003) numerous applications for placing on the market were awaiting approval under either Directives 90/220 and 2001/18 or Regulation 258/97.[601]

7.502 Also uncontested are the following facts:

(a) Under Directive 90/220, no application was approved or rejected between October 1998 and October 2002, when Directive 90/220 was repealed.[602]

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[599] Canada contends that twelve biotech products were approved. Canada's first written submission, para. 65.

[600] For an explanation of the simplified procedure, *see* section VII.C.3(c): Novel foods and novel food ingredients: Regulation 258/97.

[601] *See* Subsection (e) below entitled "Facts and histories of individual approval procedures".

[602] It should be noted that, according to the European Communities, one application was withdrawn after it had received a negative assessment. EC reply to Panel question No. 14. As the European Communities

(b) Under Directive 2001/18, no application was approved or rejected between October 2002, when Directive 2001/18 entered into force, and August 2003.

(c) Under the ordinary procedure of Regulation 258/97[603], no application was approved or rejected between October 1998 and August 2003.

(d) Under the simplified procedure of Regulation 258/97[604], a number of biotech food products were placed on the market between October 1998 and August 2003.[605]

7.503 Accordingly, with the exception of biotech products subject to the simplified procedure of Regulation 258/97 to which the Panel will revert below, the European Communities did not approve or reject any biotech product between October 1998 and August 2003.[606]

7.504 It should also be noted, however, that both before October 1998 and after August 2003, the European Communities did approve applications for the placing on the market of biotech products. Up to and including October 1998, the European Communities approved the following ten agricultural biotech products:[607]

- BXN tobacco (in June 1994);
- MS1/RF1 oilseed rape (EC-161) (in February 1996; for breeding activities); MS1/RF1 oilseed rape (EC-89) (in June 1997; for import and processing)[608];
- MON soybeans (in April 1996);
- Transgenic red-hearted chicory (in May 1996);
- Bt-176 maize (in January 1997);
- MS1/RF2 oilseed rape (in June 1997)[609];
- Topas oilseed rape (in April 1998);
- T25 maize (in April 1998);

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provided no details, it is unclear whether this application had been submitted under Directives 90/220 or 2001/18 or under Regulation 258/97.

[603] The ordinary procedure is laid down in Articles 4, 6 and 7 of Regulation 258/97.

[604] The simplified procedure is laid down in Article 5 of Regulation 258/97.

[605] The European Communities asserts that between October 2003 and 2004 seven products were placed on the market. But the European Communities provides no documentary support which would allow the Panel to confirm this number. EC reply to Panel question No. 14. Evidence submitted by the United States (Exhibit US-107, Annex 5), Canada (Exhibit CDA-25) and Argentina (Exhibit ARG-6, Annex 4) supports the conclusion that between October 1998 and August 2003 a total of six biotech food products were placed on the market.

[606] The European Communities has pointed out that one application concerning a genetically modified potato was withdrawn after it had received a negative assessment, but no details were provided to the Panel.

[607] Exhibits US-97 and 107 (Annex 1); CDA-34 (Annex 1); ARG-6 (Annex 1). It is clear from these exhibits that in addition to the agricultural biotech products already mentioned, several more biotech products were approved (certain vaccines, a test kit to detect antibiotic residues in milk and certain carnation lines). Two of these additional products were approved in October 1998.

[608] MS1/RF1 oilseed rape (EC-161) and MS1/RF1 oilseed rape (EC-89) are the same products; but the scope of the underlying applications was different. Regarding MS1/RF1 oilseed rape (EC-89), the Complaining Parties assert that, despite the fact that the Commission took a favourable decision on the application concerning MS1/RF1 oilseed rape, the lead CA never granted written consent to the placing on the market of this product. The Panel will revert to this issue below at paras. 7.1018-7.1028.

[609] The Complaining Parties assert that, despite the fact that the Commission took a favourable decision on the application concerning MS1/RF2 oilseed rape, the lead CA never granted written consent to the placing on the market of this product. The Panel will revert to this issue below at paras. 7.1018-7.1028.

– Bt-11 maize (EC-163) (in April 1998); and
– MON810 maize (in April 1998).

7.505 After 29 August 2003, that is to say, after the Panel was established, and before the Panel's second substantive meeting with the Parties, a further three applications concerning two different biotech products were approved by the Commission:

– Bt-11 maize (food) was approved under Regulation 258/97 on 19 May 2004[610];
– NK603 maize was approved under Directive 2001/18 on 19 July 2004[611]; and
– NK603 maize (food) was approved under Regulation 258/97 on 26 October 2004[612].

7.506 Like the pre-October 1998 approvals, the aforementioned post-August 2003 approvals are relevant facts which the Panel may take into account in the context of its determination of whether the European Communities applied a general moratorium on approvals between October 1998 and August 2003. In respect of the post-August 2003 approvals, it is important to bear in mind, however, that they were all granted while the present panel proceedings were already under way.[613] The European Communities contends that these approvals are nevertheless evidence that there was no general moratorium during the relevant time period. Referring to the example of Bt-11 maize (food), which it describes as representative of other applications, the European Communities points out that the relevant application was submitted in 2000 and then steadily proceeded to the final approval in 2004.[614] Argentina considers that the approval of Bt-11 maize (food) may well be directly attributable to the present panel proceedings and should therefore not be regarded as representative of other applications.[615] The United States, for its part, asserts that the existence and timing of the approval of Bt-11 maize (food) is no coincidence and should be seen against the background of the panel proceedings and the entry into force of the new EC rules on labelling and traceability in April 2004.[616]

7.507 Significantly, all Complaining Parties also maintain that prior to being approved in 2004, the applications concerning Bt-11 maize (food), NK603 maize and NK603 maize (food) were affected by the alleged general moratorium. Thus, the fact that three applications were approved after August 2003 is not necessarily inconsistent with the Complaining Parties' assertion that between October 1998 and August 2003 certain member States and the Commission intentionally prevented the final approval of all applications.

7.508 It should be noted that after the Panel's second substantive meeting with the Parties, the European Communities sent two letters to the Panel and the other Parties, for information, stating that

[610] Exhibit EC-92/At. 81; Exhibits CDA-109 and 138; EC comments on Complaining Parties' replies to Panel questions, para. 63.

[611] Exhibit CDA-137; EC comments on Complaining Parties' replies to Panel questions, para. 62. This application was approved by the Commission pursuant to the provisions of Directive 2001/18. The record contains no information about whether the lead CA has since granted written consent to the placing on the market of the product in question.

[612] US third written submission, para. 101; EC comments on Complaining Parties' replies to Panel questions, para. 63. NK603 maize and NK603 maize (food) are the same products; but the scope of the underlying applications was different.

[613] The first of these approvals came a few weeks after the Complaining Parties filed their first written submissions. Prior to that, the Complaining Parties had already outlined their cases in their requests for the establishment of a panel. These requests are dated 7 August 2003.

[614] EC first oral statement, paras. 29-32.

[615] Argentina's second written submission, para. 23.

[616] US third written submission, para. 15; US second written submission, paras. 47-49.

the Commission approved two additional applications concerning two different biotech products. Specifically, the European Communities stated that:

- MON863 maize was approved under Directive 2001/18 on 8 August 2005[617];
- RR oilseed rape (EC-70) was approved under Directive 2001/18 on 31 August 2005[618].

7.509 As the European Communities sent its letters for information, no supporting evidence was provided and no arguments were exchanged in relation to the two Commission approvals. However, the Complaining Parties did not question the European Communities' contention that the two applications were in fact approved by the Commission under Directive 2001/18. The Panel further notes that, curiously, the approval procedure concerning MON863 maize was never examined by the Complaining Parties or the European Communities in their written or oral submissions.[619] As the Panel has been given no detailed information on this application and the Parties have offered no examination of this application, the Panel will not, and indeed cannot, address it for the purposes of its analysis of whether or not the European Communities applied a general *de facto* moratorium on the approval of biotech products between October 1998 and August 2003.

7.510 As indicated above, it is necessary to consider in more detail the simplified procedure of Regulation 258/97 under which a number of biotech food products were placed on the market during the relevant time period. At the request of the Panel, the European Communities provided an explanation of the simplified procedure, which is reproduced below in relevant part:[620]

> "Under the simplified procedure products cannot be placed on the market without having been notified. Application in turn is only possible if it has been demonstrated that the product in question is substantially equivalent to existing foods or food ingredients [...]
>
> Substantial equivalence, according to Article 3(4), in principle can be demonstrated in two ways: (1) by relying on scientific evidence available and generally recognized and (2) by relying on an opinion delivered by one of the competent food assessment

[617] The record contains no information about whether the lead CA has since granted written consent to the placing on the market of the product in question.

[618] The record contains no information about whether the lead CA has since granted written consent to the placing on the market of the product in question.

[619] In its first written submission, the European Communities stated that "in order to complete the picture", it would provide a brief overview of those applications which were not mentioned in the Complaining Parties' requests for the establishment of a panel. EC first written submission, paras. 196 and 334. While the European Communities listed a number of applications which had been submitted under Directive 2001/18 and were still pending, no mention was made of MON863 maize, even though that application was not mentioned in the Complaining Parties' panel requests. Subsequently, in its reply to Panel question No. 91, the European Communities made a passing reference to MON863 maize, stating nothing more than that the application would be discussed in the Regulatory Committee in the autumn of 2004. In relation to DS292, we note that Canada submitted two opinions by the GMO Scientific Panel of the European Food Safety Authority of April 2004 which concern MON863 maize. One was issued in respect of an application under Directive 2001/18 and the other was issued in respect of an application under Regulation 258/97. These opinions, which post-date the date of establishment of the Panel, were submitted, together with numerous other opinions, as attachments to a list provided in support of Canada's general assertion that there were applications pending under Directive 2001/18 and Regulation 258/97 which had received a favourable scientific opinion by an EC scientific committee. Canada's first written submission, paras. 50 and 54.

[620] EC reply to Panel question No. 15.

> bodies of the EU Member States (see Article 4(3)). Only the latter option, however, is *de facto* applicable to GM products as there exists no generally recognised scientific evidence on the substantial equivalence of these products. Accordingly, no applicant for GM products under the simplified procedure has ever even tried to demonstrate substantial equivalence under this first option.
>
> In order to obtain an opinion from a competent food assessment body in an EU Member State, an applicant has to submit a dossier on, and the competent body proceeds to a full assessment of, the product in question.
>
> Once the competent body has reached a positive opinion, the applicant may proceed to notifying the product on the basis of that opinion. The application is made to the Commission. Neither the Commission nor another Member State, at this stage, can prevent the application on the basis that it would not agree with the opinion. [...]"

7.511 In the European Communities' view, because biotech food products subject to the simplified procedure effectively require prior recognition of "substantial equivalence" through a member State food assessment body, they effectively require prior approval.[621] The issue therefore arises whether the simplified procedure is an approval procedure. If it is, the fact that a number of biotech food products were placed on the market during the relevant time period would present the further issue of whether the Complaining Parties are correct in claiming that no "applications" for the placing on the market of biotech products were "approved" in the relevant time-frame.[622]

7.512 Article 5 of Regulation 258/97, which lays down the simplified procedure, states that the applicant shall "notify the Commission of the placing on the market when he does so" and that "[s]uch applications shall be accompanied by the relevant details provided for in Article 3(4)". As pointed out by the European Communities, the relevant details commonly include an opinion delivered by a member State food assessment body confirming the "substantial equivalence" of the biotech food product in question. Thus, the text of Article 5 makes clear that the applicant may proceed to place the relevant product on the market without seeking prior approval or authorization. The applicant must merely "notify" the Commission when the product is placed on the market; the Commission is neither required nor authorized to take an authorization decision on the product.[623] Similarly, the relevant member State food assessment body is tasked with delivering a scientific "opinion" on "substantial equivalence"; it is not empowered to decide whether and on what conditions the relevant product may be placed on the market. As noted by the European Communities, once a member State food assessment body has delivered an opinion confirming "substantial equivalence", neither the relevant member State nor another member State can prevent the product from being placed on the market.[624]

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[621] *Ibid*.

[622] *See* the Complaining Parties' requests for the establishment of a panel as contained in documents WT/DS291/23, WT/DS292/17 and WT/DS293/17.

[623] In contrast, under the ordinary procedure of Regulation 258/97, the applicant may place the product on the market only if one of the following two conditions are met: (i) the lead CA has "decided", after an initial assessment, that no additional assessment is required and has informed the applicant that it "may" place the product on the market (*see* Articles 6(3) and 4(2) of Regulation 258/97), or (ii) the Commission has taken a favourable "authorization decision" in accordance with the regulatory committee procedure (*see* Article 7 of Regulation 258/97).

[624] In contrast, the record demonstrates that under the approval procedures set out in Directives 90/220 and 2001/18 as well as in Articles 4, 6 and 7 of Regulation 258/97, applicants did not and could not proceed to place their products on the market even though specialized bodies at member State or Community level had

7.513 In the light of the foregoing, the Panel considers that it would not be correct to say, in relation to the biotech food products which were placed on the market between October 1998 and August 2003, that the placing on the market of these products was "approved", or authorized, by the specialized member State food assessment bodies which confirmed their "substantial equivalence", and even less that there were "applications" for the placing on the market of these products which were "approved" by these specialized bodies. Accordingly, the Panel finds that the fact that a number of biotech food products were placed on the market during the relevant time period does not disprove the Complaining Parties' claim that no "applications" for the placing on the market of biotech products were "approved" by the European Communities in the relevant time-frame.

(d) Documents and statements referring to a "moratorium"

7.514 As previously noted, in support of their assertion that certain EC member States and the Commission actually prevented the final approval of applications during the relevant time period (October 1998 to August 2003), the Complaining Parties point to two elements of proof: (i) the absence of final approvals in the relevant time period, and (ii) official and internal EC documents as well as statements by EC and member State officials.[625] In this Subsection, the Panel addresses the second element.

7.515 The Complaining Parties have submitted numerous documents and statements which are identified further below[626] and which can be divided into five categories:

(i) Commission documents and statements by individual Commissioners;

(ii) Council documents;

(iii) European Parliament documents;

(iv) statements by member State officials; and

(v) EC statements at the WTO.

7.516 The **Complaining Parties** contend that these documents and statements acknowledge and demonstrate the existence of a general moratorium on approvals during the relevant time period.

7.517 The **European Communities** argues that none of the documents or statements referred to by the Complaining Parties represents the official position of the European Communities. The official position of the European Communities is that there was no moratorium between 1998 and 2003 and that there has been no moratorium since. Rather, every application is decided on its own merits, against the background of proposed and actual new legislation and changes in scientific knowledge and understanding.

7.518 The European Communities further argues that none of the documents and statements referred to by the Complaining Parties provide evidence of the existence of a *de facto* moratorium.

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delivered favourable scientific opinions on these products. This is because notwithstanding these favourable opinions, during the relevant time period no authorization decisions were taken in respect of these products.

[625] The Complaining Parties have all stated that they rely on the relevant documents and statements as evidence of the existence of the alleged general moratorium on approvals. US first oral statement, para. 25; Canada's first oral statement, para. 36; Argentina's first oral statement, paras. 18-19.

[626] *See infra*, para. 7.524 *et seq*.

They neither prove nor confirm the existence of a suspension of the approval process. Regarding the statements by EC officials or member State officials, the European Communities observes that they are expressions of opinion associated with specific persons or reflect views of individual member States. They simply describe a situation and do not assert the existence of a practice of suspending the approval process. The European Communities submits that the fact that there have been no authorizations for some time may be perceived from the outside as a situation of "standstill". But the absence of a decision is not the same thing as a decision not to decide. The European Communities states that the perceived "standstill" in reality is a reflection of the fact that in the relevant approval procedures there have been requests for additional information on complex risk assessment and risk management issues. Furthermore, in the great majority, the references in some of the documents and statements submitted to a "moratorium" or "*de facto* moratorium" were made in the context of legislative changes in the European Communities. While during that transition period approval procedures may in some cases have suffered important delays, that period has ended, and so the documents and statements referred to by the Complaining Parties do not establish a "moratorium" that is currently in existence.

7.519 The **United States** responds that the Complaining Parties are not relying on casual statements. The statements cited by the Complaining Parties are statements made by the European Communities' highest officials, by its official bodies and by its member States. In the United States' view, the numerous statements from every EC entity – member States, Commission, Council, and Parliament – are strong evidence of the existence of a general moratorium. The United States further argues that the relevant documents and statements do not refer simply to the fact that no biotech products reached final decision; they uniformly refer to the existence of a "moratorium". The United States submits that the term "moratorium" was used because it precisely fit the situation: namely, that the European Communities had decided not to allow any biotech application to move to final approval.

7.520 **Canada** argues that the relevant documents and statements are strong, consistent further confirmation by the most senior officials in the European Communities that it has maintained a moratorium. These statements are not casual, nor are they perceptions "from the outside".

7.521 **Argentina** considers that the statements in question demonstrate both the existence of the *de facto* moratorium and the period during which it has been applied. The statements show that the existence of the moratorium has been acknowledged by senior EC officials with direct competence on the matter considered in this dispute. Moreover, one document – a background note from the Council's press service of April 2004 – confirms that the moratorium was still in existence at that time.

7.522 The **Panel** begins by noting that there appears to be no disagreement among the parties that EC documents or statements by EC or member State officials may constitute evidence of the existence of a measure. The European Communities referred in this respect to the GATT panel report on *Japan – Semi-conductors*.[627] In that case, the panel considered a position paper of the responding party which described the measure at issue as well as the responding party's statements before the panel and found that they provided "further confirmation" of a certain fact.[628] In the Panel's view, it cannot be inferred from this that such documents or statements may be relied on to confirm facts that have already been found to exist based on other evidence, but that they may not be relied on, together with other evidence, to establish facts. At a minimum, such an inference would appear unwarranted in a case such as this one where the existence of a *de facto* measure is alleged. In such cases, it is often

[627] Panel Report, *Japan – Trade in Semi-Conductors*, BISD 35S/116.
[628] *Ibid*., para. 116; EC first written submission, para. 556.

inevitable that Complaining Parties base their complaints largely on circumstantial evidence. This said, it is clear that statements by individual government officials and similar evidence must be given proper weight, which weight can only be determined in the specific circumstances of each case.

7.523 The Panel now turns to review one by one the various documents and statements referred to by the Complaining Parties. The documents and statements have been divided into the above-mentioned five categories and are listed in chronological order. It should be noted that in no case did the European Communities question the authenticity of a document or statement or suggest that statements were incorrectly reported or wrongly attributed.

(i) Commission documents and statements by individual Commissioners

7.524 Following is a list of Commission documents referred to by one or more Complaining Parties:

(a) *November 2000 working document of the Commission services.* A working document of the Commission services states that "[a]gainst this background [of intense public and political debate about the impact of genetically modified organisms on the environment and food safety], it has become increasingly difficult to approve the placing on the market of new GMOs under Directive 90/220/EEC and a parallel situation has arisen for authorizations for products containing and derived from GMOs under product based legislation. As a result the current authorization procedure for commercial release of GMOs, including those that may end up in the food chain, has ground to a standstill. [...] The Commission [in July 2000] proposed a strategy to re-launch the authorization procedure".[629]

This document refers to a "standstill" in the "current authorization procedure". It does not support the EC argument that there was a standstill because of "requests [by member States or the Commission] for additional information on complex issues of risk assessment and management"[630]. Rather, it suggests that the standstill was the result of public concerns and political debate, which, according to the document, made it difficult to approve applications. The document also notes that the Commission proposed a strategy to "re-launch" the authorization procedure. It is not clear why the Commission would do so if the approval procedures were held up because the member States or the Commission were waiting for individual applicants to provide additional information. Thus, this document implies that there was a deliberate failure by relevant authorities to approve applications.

(b) *July 2001 Commission press release.* A Commission press release states that the adoption by the Commission of new legislative proposals for Regulations concerning traceability and labelling as well as genetically modified food and feed, together with the March 2001 adoption of Directive 2001/18, "will contribute towards the lifting of the de facto moratorium on the commercial release of GMOs".[631]

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[629] Advance Copy of Working Document of the Commission Services on Traceability and Labelling of GMOs and Products Derived from GMOs, ENV/620/2000, November 2000, p. 1 (footnote omitted) (Exhibits US-93; CDA-32).

[630] EC first written submission, para. 561.

[631] "Commission improves rules on labelling and tracing of GMOs in Europe to enable freedom of choice and ensure environmental safety", Commission Press Release IP/01/1095, 25 July 2001, p. 2 (Exhibit CDA-39; also referred to by the United States).

The quoted statement suggests that in July 2001 a moratorium was in effect. Also, the statement does not appear to "describe a factual situation"[632], but a measure that could be "lifted". The point that the legislative proposal for new EC rules concerning traceability and labelling would "contribute" to the lifting of the moratorium is consistent with the June 1999 declaration by the Group of Five countries. That declaration said that the Group of Five countries would use their powers to suspend approvals pending the adoption of such rules.

(c) *October 2001 working paper of the Commission services*. A working paper of the Commission services states that "[t]his reluctance to go forward with authorizations of GMOs has resulted in a *de facto* moratorium on the marketing of new GMOs and impacted on product approvals under the sector-based legislation".[633]

The quoted statement suggests that in October 2001 a moratorium was in effect. A review of the document shows that the "reluctance" referred to is the reluctance by the Group of Five countries as first expressed in the June 1999 declaration by the Group of Five countries. Thus, this document supports the view that the absence of final approvals was not the result of "requests for additional information" but of the declared intention of certain member States to prevent approvals.

(d) *July 2003 Commission fact sheet*. A Commission fact sheet on GMO regulation states that "[t]he revised Directive [90/220] and the two proposals for Regulations [concerning traceability and labelling and on genetically modified food and feed] are expected to pave the way for a resumption of GM authorizations in the European Union".[634]

The statement that Directive 2001/18 and the July 2001 Commission proposals for new Regulations are "expected to pave the way for a resumption of GM authorizations in the European Union" echoes the July 2001 Commission press release. It also suggests that after the entry into force of Directive 2001/18 there was no resumption of authorizations. This is consistent with the June 1999 declaration by the Group of Five countries.

(e) *January 2004 Communication to the Commission from the President*. A Communication to the Commission from the President of the Commission in association with a number of other Commissioners with responsibility for biotech products states in relevant part:[635]

> "[D]espite the 'interim approach' [agreed on by the Commission in July 2000 and entailing the anticipation of the key provisions (labelling, traceability, monitoring, etc.) of Directive 2001/18]:

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[632] *Ibid*., para. 561; EC second written submission, para. 295.

[633] Working Paper of DG Environment and DG Health and Consumer Protection: Resumption of the Authorization Procedure for GMOs, October 2001, p. 1 (Exhibits US-27; CDA-31).

[634] "Question and Answers on the regulation of GMOs in the EU", p. 12 (Exhibits US-107 and CDA-26).

[635] Communication to the Commission (from the President in association with Mrs Wallström, Mr Byrne, Mr Fischler, Mr Lamy, Mr Liikanen and Mr Busquin): For an orientation debate on Genetically Modified Organisms and related issues, January 2004, p. 3 (emphasis omitted) (Exhibit CDA-33; also referred to by the United States).

> – no authorizations have been granted since October 1998[636].
>
> […]
>
> To date,
>
> – authorization procedures under the Novel Foods Regulation are being finalised in line with the interim approach agreed on 12 July 2000 by anticipating the key forthcoming provisions agreed by the Council (i.e. labelling, traceability, monitoring, etc.) into individual authorizations of GMOs. […]
>
> - Applications under Directive 2001/18/EC are currently being processed in accordance with the authorization procedure. […]"
>
> The European Communities correctly notes that this communication does not confirm the existence of a suspension of the approval process. However, it is the Complaining Parties' assertion that there was a suspension of final approvals, and not that there was a suspension of the processing of applications. The Communication itself states that despite the fact that the so-called "interim approach" had allegedly been followed in respect of applications submitted under Directive 90/220 since July 2000[637], no such product had been approved before the entry into force of Directive 2001/18. Furthermore, the statement in the Commission Communication that "authorization procedures under the Novel Foods Regulation are being finalised" and that "[a]pplications under Directive 2001/18/EC are [...] being processed" does not necessarily imply that the relevant applications will be approved. Nonetheless, based on the quoted passage of the Communication alone, it cannot be determined whether a moratorium on approvals was in effect between October 1998 and August 2003 or whether the absence of approvals was the result of a series of delays due to "requests for additional information".

7.525 The following statements by the Commissioner for the Environment were referred to by all Complaining Parties:

(a) *July 2000 news report.* A news report notes that on 13 July 2000 the Commission at a news conference revealed its plan to propose the above-mentioned "interim approach" to member States. The report quotes then Commissioner Margot

[636] (*original footnote*) With the exception of applications under the simplified procedure of the Novel Foods Regulation (derogation from the full authorization procedure).

[637] In response to a question from the Panel, the European Communities described the "interim approach" as a practice by the Commission which "consisted in anticipating certain stricter requirements which were to be put in Directive 2001/18 as identified in the Council Common Position of June 1999 [...] in line with the precautionary principle. [...] [I]t was clear that the existing legislation, *i.e.*, Directive 90/220, did not provide a legal basis to impose these requirements on pending applications. The notifiers, therefore, were approached to see whether they would be willing to implement such requirements on a voluntary basis. [...] With the entry into force of Directive 2001/18 the 'interim approach' ended as applications could not be assessed under the new legal basis." EC reply to Panel question No. 13.

Wallström as stating in this context that "[w]e have already waited too long to act. The moratorium is illegal and not justified."[638]

The statement attributed to the Environment Commissioner explicitly refers to the existence of a moratorium in July 2000. Together with the Commissioner for Health and Consumer Protection, the Environment Commissioner is responsible within the Commission for the approval of applications for the placing on the market of biotech products. Clearly, therefore, the statement does not reflect a "perception from the outside"[639].

(b) *October 2001 news report.* A report on a news conference states that following a meeting of the Environment Council, Commissioner Wallström "admitt[ed] that no end was in sight for the moratorium, which she said was an illegal, illogical, and otherwise arbitrary line in sand."[640] She is quoted as saying that "[t]here is no other EU legislation in the same situation where we just simply decline to take a decision" and that "[w]e have 11 GMO seed applications approved. [...] But then there was an arbitrary line drawn before I came into office [in 2000] to stop all approval for the 13 other pending applications. But many of these 13 are simply varieties of the first 11 approved. They are essentially the same products. There is no science that says these are more or less dangerous than others".[641]

The statement attributed to the Environment Commissioner suggests that in October 2001 a moratorium was still in effect. It also suggests that the absence of approvals was the result of a "decision not to decide"[642] and not, as the European Communities contends, of delays due to requests for additional information.

7.526 The following statements by the Commissioner for Health and Consumer Protection and his spokesperson were referred to by one or more Complaining Parties:

(a) *June 2000 speech*. A speech by then Commissioner David Byrne at the European Business Summit in Brussels states that "[t]he horizontal directive 90/220 [...] was adopted in 1990, at a time when concern about GMOs was less obvious. The authorization procedure became obsolete as consumer concerns grew and consequently, Member States have become more and more reluctant to approve the placing on the market of new GMOs under Directive 90/220. This has resulted in a complete standstill in the current authorizations and a de facto moratorium on the commercial release of GMOs".[643]

It should first of all be recalled that the Commissioner for Health and Consumer Protection and the Environment Commissioner are responsible within the

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[638] "EU Moves to Break Gene Crop Deadlock", Reuters, 13 July 2000 (Exhibits US-33, CDA-42 and ARG-29).

[639] EC first written submission, para. 561.

[640] "EU Moratorium on GMOs Could Last Until Traceability, Labeling Regime in Place," BNA Daily Report for Executives, Regulation, Law & Economics, 30 October 2001, p. A-8 (Exhibits US-2, CDA-43, ARG-14).

[641] *Ibid*.

[642] *See* EC second written submission, para. 294.

[643] "Biotechnology: Building Consumer Acceptance," Speech by David Byrne, European Commissioner for Health and Consumer Protection, European Business Summit, Brussels, 10 June 2000, p. 3 (Exhibits US-1 and CDA-44).

Commission for the approval of applications for the placing on the market of biotech products. Hence, the remarks of the Commissioner for Health and Consumer Protection on the functioning of the EC approval process cannot be considered "perceptions from the outside"[644]. The speech suggests that in June 2000 a moratorium was in effect. It should also be pointed out that the quoted portion of this speech is closely similar in content to the above-noted November 2000 and October 2001 working documents of the Commission services.

(b) *November 2000 speech*. A speech by Commissioner Byrne at the conference on "Genetics and the future of Europe" in Brussels states that "[i]n the EU public concerns about the application of biotechnology in the agri-food sector have resulted in a de-facto moratorium on authorizations of new GMOs. In fact no GMOs have been approved over the last two years".[645]

This speech echoes the June 2000 speech.

(c) *July 2001 public statement*. A statement by Commissioner Byrne, made on the day the Environment Commissioner and himself presented to the Commission two proposals for new Regulations concerning traceability and labelling as well as genetically modified food and feed, reads in relevant part: "The adoption of today's proposals together with the recent adoption of the revised legislation on the deliberate release of GMOs into the environment will build up public confidence by responding to questions and concerns raised by the general public and providing a high level of protection for human health and the environment. This will contribute towards the lifting of the de facto moratorium on the commercial release of GMOs and the standstill on the authorizations of GMOs and GM-products in Europe".[646]

This statement is closely similar in content to the above-noted July 2001 Commission press release. It suggests that in July 2001 a moratorium was in effect.

(d) *September 2001 speech*. A speech by Commissioner Byrne at an informal Agriculture Council on new technologies in agriculture in Alden Biesen states that "[i]n the EU, the Scientific Committees have already assessed a number of GMOs and concluded that they do not pose a danger to the environment or to human health. However, these GMOs are still pending final approval and some of them have now been awaiting approval for quite some time."[647]

The quoted passage of this speech does not explicitly state that the absence of final approvals was the result of a moratorium or of reluctance by member States to approve applications in the face of public concerns. The passage could, however, be interpreted to imply such a statement. Such an interpretation does not seem

[644] EC first written submission, para. 561.

[645] Speech by David Byrne, European Commissioner for Health and Consumer Protection, Conference on "Genetics and the future of Europe", Brussels, 7 November 2000, p. 3 (Exhibit ARG-17).

[646] "The Right to Know about GM Food", Statement by David Byrne, European Commissioner for Health and Consumer Protection, 25 July 2001, p. 3 (Exhibits US-34, CDA-45 and ARG-18).

[647] "New Technologies in Agriculture – Biotechnology", Speech by David Byrne, European Commissioner for Health and Consumer Protection, Informal Agriculture Council, Alden Biesen, 18 September 2001, p. 7 (Exhibit ARG-8). The same statement is made in "Proposal for a regulation on GMO Food and Feed", Speech by David Byrne, European Commissioner for Health and Consumer Protection, European Parliament, Brussels, 11 September 2001, p. 4 (Exhibit ARG-20).

unreasonable in the light of, *e.g.*, Commissioner Byrne's November 2000 speech, his July 2001 statement and his subsequent October 2001 speech.

(e) *October 2001 speech*. A speech by Commissioner Byrne to the National Press Club in Washington, D.C., states that "[t]he final point I wish to make on biotechnology relates to the effective moratorium on new approvals in the EU. This is an unfortunate situation and has helped nobody in my view. It is my firm hope and intention that we can get the approvals process working again. I have mandated my officials to start a dialogue with the Member States of the European Union with a view to re-starting approvals".[648]

The quoted passage suggests that there was a moratorium on new approvals in October 2001. This is consistent with the above-mentioned October 2001 news report quoting a similar statement by the then Environment Commissioner.

(f) *October 2001 news report*. A news report quotes the spokeswoman of Commissioner Byrne as saying that "[t]he moratorium has no legal basis".[649]

The statement attributed to the spokesperson of Commissioner Byrne suggests that there was a moratorium on new approvals in October 2001. Again, this is consistent with the October 2001 news report quoting a similar statement by the then Environment Commissioner.

(g) *November 2001 speech*. A speech by Commissioner Byrne at the European Voice Conference "Farm to Fork" in Brussels states that "[d]espite our scientific advisors having given the green light for growing and marketing GMO plants and foods, our Member States have blocked new authorizations since 1998. This is, I believe, an untenable situation".[650] Three paragraphs later, the text continues: "The effective moratorium on new approvals in the EU is an unfortunate situation and its continuation, in my personal view, helps nobody."[651] And another three paragraphs later, the text says: "As a result [of the June 1999 declaration by the Group of Five countries], the authorization of both pending and new products has come to a grinding halt".[652]

The quoted passages of this speech suggest that in November 2001 a moratorium on new approvals was in effect. The speech further suggests that the absence of approvals was the result of the June 1999 declaration by the Group of Five countries, and not of a series of delays due to requests for additional information.

(h) *February 2003 news report*. A news report quotes Commissioner Byrne as stating at a press conference that "[w]e have taken account of the opinions of the scientists and

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[648] "A European approach to food safety and GMOs", Speech by David Byrne, European Commissioner for Health and Consumer Protection, National Press Club, Washington D.C., 9 October 2001, p. 3 (Exhibit ARG-9).

[649] "EU States Seek Stricter GM Labelling", Reuters, 16 October 2001 (Exhibits US-35 and CDA-46).

[650] "Risk versus benefit", Speech by David Byrne, European Commissioner for Health and Consumer Protection, European Voice Conference "Farm to Fork", 22 November 2001, p. 2 (Exhibit ARG-10; also referred to by Canada).

[651] *Ibid*.

[652] *Ibid*.

put legislation in place ... now let's turn over the page! The conclusion of all this is that we must lift the moratorium".[653]

The statement attributed to Commissioner Byrne suggests that in February 2003 a moratorium was in effect. It also suggests that the term "moratorium" is used to describe a measure that should be "lifted" rather than a mere "factual situation"[654] characterised by the absence of any approvals.

7.527 The following statement by the Commissioner for Trade was referred to by two Complaining Parties:

(a) *January 2002 speech*. A speech by then Commissioner Pascal Lamy at the Woodrow Wilson International Center for Scholars in Washington, D.C., states that "the current moratorium is not plucked out of thin air by the Member States for protectionist reasons: it reflects the fact that food safety is a highly sensitive and political issue for European citizens".[655]

The quoted passage of this speech suggests that in January 2002 a moratorium was in effect. The Trade Commissioner is not responsible within the Commission for approvals of biotech products. However, as is evidenced by the present panel proceedings, the absence of approvals is also a trade issue. As a result, and in view of the similar statements made by the Commissioners with direct responsibility for approvals, the view expressed by the Trade Commissioner cannot be dismissed as a "perception from the outside".

(ii) Council documents

7.528 Following is a list of Council documents referred to by one or more Complaining Parties:

(a) *July 2003 note by the General Secretariat of the Council*. A note issued by the General Secretariat of the Council to the Committee of Permanent Representatives on the outcome of the European Parliament's second reading of the proposed new EC rules on traceability and labelling of biotech products attributes to the rapporteur of the relevant committee of the European Parliament the statement that the proposed rules would "possibly lead to the lifting of the current *moratorium*."[656]

The statement attributed to the rapporteur of one of the committees of the European Parliament dealing with biotech products suggests that in July 2003 a moratorium was in effect. While the rapporteur was not involved in the day-to-day operation of the EC approval process, it is nevertheless reasonable to assume that he and his committee were aware of the possible implications of the adoption of the new rules in question, including the possible implications on the operation of the approval process. The view apparently expressed by the rapporteur – that new EC rules on labelling and

[653] "Sine die postponement of inter-ministerial meeting planned on GMOs in Washington", Agence Europe, 6 February 2003, p. 2 (Exhibit US-37).
[654] *Ibid*.; EC second written submission, para. 295.
[655] "Steeling the EU-US Relationship for the challenges ahead", Speech by Pascal Lamy, European Commissioner for Trade, Washington, D.C., 25 January 2002, p. 4 (Exhibits US-89 and ARG-15).
[656] Note from the General Secretariat, 3 July 2003, p. 1 (Exhibits US-38 and CDA-41).

traceability might lead to the lifting of the moratorium – is consistent with the June 1999 declaration by the Group of Five countries.

(b) *April 2004 background note by the General Secretariat of the Council*. A background note from the press office of the Council's General Secretariat concerning the Agriculture and Fisheries Council of April 2004 at which the Council was to decide on the application concerning Bt-11 maize (food) states that "[t]he adoption of a decision to authorize Bt11 would bring an end to the current *moratorium* on genetically modified food and feed in Europe".[657]

This background note, which expresses the view of the General Secretariat of the Council, suggests that in April 2004 a general moratorium was in effect. The note was issued shortly before the Council voted on the application concerning Bt-11 maize (food). It can therefore be assumed that the Council's own General Secretariat was in a position to assess correctly the significance of the Council vote and the context within which it took place.

(iii) European Parliament documents

7.529 Following is a list of European Parliament ("EP") documents referred to by one or more Complaining Parties:

(a) *February 2001 motion for an EP resolution*. A European Parliament resolution proposed for adoption by the Committee on Industry, External Trade, Research and Energy "[o]bserves that the existing de facto moratorium particularly harms small and medium sized enterprises which, unlike multinational corporations, are often unable to perform their research work in countries outside the EU", and in the following paragraph "[w]elcomes the agreement reached between Council and Parliament in the conciliation committee on the amendment of the directive on the release of genetically modified organisms and the assurances given by the Commission in that connection with regard to labelling and traceability, and considers that a clear framework now exists for the release of genetically modified organisms in Europe which will ensure maximum consumer protection and environmental protection, and that it would therefore not be justified to continue the de facto moratorium on the release of GMOs".[658] The accompanying explanatory statement notes that "no authorizations have been approved under this directive [90/220] since October 1998. This demonstrates a lack of mutual recognition between Member States and a de facto moratorium on all development".[659]

This motion for a resolution suggests that in February 2001 a general moratorium was in effect.[660] The motion was sponsored by the Committee on Industry, External Trade, Research and Energy. It is reasonable to assume that the members of that Committee were familiar with the situation and concerns of researchers and the

[657] General Secretariat of the Council, Press Office, Background for Agriculture and Fisheries Council of 26 (and possibly 27) April 2004, 23 April 2004, p. 2 (Exhibits US-109; CDA-108; also referred to by Argentina).

[658] European Parliament, Committee on Industry, External Trade, Research and Energy, Report on the Future of the Biotechnology Industry, Motion for a European Parliament resolution, FINAL A5-0080/2001, 28 February 2001, p. 12 (Exhibit US-119).

[659] *Ibid*., p. 20.

[660] The record does not indicate whether the resolution was ever adopted by the European Parliament.

industry in the biotechnology sector and otherwise sufficiently well informed to express a view on whether or not a general moratorium was in effect at the time.

(b) *June 2002 EP committee report*. The European Parliament Committee on the Environment, Public Health and Consumer Policy, in its report on the proposal for new Regulations concerning traceability and labelling as well as food and feed, states that the fragmentation of then-existing EC legislation concerning biotech products "led to reservations and a moratorium over the last three years on the marketing authorization procedures at EU level, pending the adoption of an integrated traceability and labelling system".[661]

The quoted passage from the report by the Committee on the Environment, Public Health and Consumer Policy suggests that in June 2002 a moratorium was in effect, and that it might remain in place until the new Regulation concerning traceability and labelling of biotech products was adopted. The latter suggestion is consistent with the June 1999 declaration by the Group of Five countries. The Committee on the Environment, Public Health and Consumer Policy was not directly involved in the operation of the EC approval procedures. However, it seems clear that in order to report to the European Parliament on the merits of the legislative proposals, the Committee needed to have an understanding of the political context within which the proposals for the two new Regulations were made. The moratorium referred to in the report forms part of that context.

(c) *November 2002 EU bulletin*. The EU Bulletin, in a summary of the content of a resolution by the European Parliament on the Communication from the Commission on "Life Sciences and Biotechnology – A Strategy for Europe"[662], contains the following sentence: "With regard to food supply, the Parliament fully shares the opinion that an end must be called to the current 'de facto' moratorium that has been imposed on genetically modified foods since 1998, which should be lifted in 2003, to provide greater choice and increased benefits to the consumer as well as to promote innovation".[663]

The statement attributed to the European Parliament suggests that a moratorium on biotech food products was in effect in November 2002. The reference to the year 2003 is probably a reference to the presumed date of adoption of the two proposed Regulations on labelling and traceability as well as food and feed. As is confirmed by the above-mentioned June 2002 committee report, the European Parliament was considering these proposals at the time. While the European Parliament does not have a role in the day-to-day operation of the EC approval procedures, it is reasonable to assume that it would not call for the lifting of a moratorium in a resolution if there was uncertainty as to whether such a moratorium on approvals of biotech food products existed.

[661] European Parliament, Committee on the Environment, Public Health and Consumer Policy, Report on the proposal for a European Parliament and Council regulation concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, FINAL A5-0229/2002, 12 June 2002, p. 27 (Exhibits US-36 and CDA-40).

[662] The Communication was not submitted to the Panel.

[663] "Resolution of the European Parliament on the Communication of the Commission on 'Life Sciences and biotechnology – A strategy for Europe", EU Bulletin, November 2002, section 1.3.64 (translated from Spanish) (Exhibit ARG-7).

(d) *March 2003 motion for an EP resolution*. A motion by two Members of the European Parliament for an EP resolution states in a preambular paragraph that "in view of the risks which GMOs represent, there are no grounds for lifting the *de facto* moratorium on GMO authorization, especially since no labelling and tracing system has been introduced and no assessment has been carried out of the impact which GMOs may have on organic/conventional farming" and "[u]rges the Council and the Commission to continue the moratorium and to launch a broad public debate on the impact of GMOs on organic/conventional farming".[664]

This motion for a resolution suggests that in March 2003 a moratorium was in effect, and that it was within the power of the Council and the Commission to continue or end it. The motion represents the view of two Members of the European Parliament[665], but the statement that a moratorium existed in March 2003 is consistent with the above-mentioned February 2003 news report quoting Commissioner Byrne and the July 2003 Commission fact sheet.

(e) *June 2003 statement by an EP committee rapporteur*. The rapporteur of the European Parliament Committee on the Environment, Public Health, and Consumer Policy in an explanatory statement on the recommendation for the second reading of the Parliament on the common position of the Council with a view to adopting a new Regulation concerning traceability and labelling of biotech products states that he is of the view that the prompt adoption of the new Regulation, as well as of the new Regulation concerning genetically modified food and feed, "will lead to the removal of the 'de facto' moratorium on the approval of new GMOs [...]".[666]

This statement suggests that in June 2003 a general moratorium was in effect. The statement appears to be the same as that which is referred to in the previously addressed July 2003 note from the General Secretariat of the Council.

(iv) Statements by member State officials

7.530 Following is a list of statements by high-ranking member State officials which were referred to by one or more Complaining Parties:

(a) *July 2003 news report*. A press article reporting on the meeting of 22 July 2003 of the Agriculture and Fisheries Council attributes to the then French Agriculture Minister the statement that "public information campaigns would be necessary in advance of lifting the moratorium" and to Italy's Agriculture Minister the statement that "no decision on lifting the moratorium on the authorization of GMO crops could

[664] European Parliament, Motion for a European Parliament resolution on the impact of genetically modified organisms (GMOs) on organic/conventional farming by Ilda Figueiredo and Jonas Sjöstedt, B5-0190/2003, 18 March 2003, p. 2 (Exhibit US-120).

[665] The record does not indicate whether the resolution was ever adopted by the European Parliament.

[666] European Parliament, Committee on the Environment, Public Health and Consumer Policy, Recommendation for the second reading on the common position of the Council with a view to adopting a European Parliament and Council regulation on traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, FINAL A5-0204/2003, 4 June 2003, p. 22 (Exhibit ARG-11).

be made until there is agreement on the European Commission proposals on guidelines for the coexistence of GMO crops and non-GMO crops".[667]

The statements attributed to the then French and Italian Agriculture Ministers suggest that in July 2003 a moratorium was in effect. As noted above, it was the Council of Agriculture and Fisheries Ministers that voted on the Bt-11 maize (food) application. Thus, the Agriculture Ministers have direct responsibility, perhaps jointly with other Ministers, for approvals of biotech products. Moreover, both France and Italy are part of the Group of Five countries which had declared in June 1999 that they would exercise their powers so as to suspend approvals. Finally, it should be noted that the reported statements clearly use the term "moratorium" to refer to a measure that could be lifted and not to describe a "factual situation"[668] where no approvals had been granted.

(b) *June 2004 parliamentary response*. A response provided by the French Minister for Research to a question from a Member of the French Parliament states that "[i]n 1999, in order to take account of the legitimate concerns of public opinion, France and four other member States of the European Union – Denmark, Italy, Greece, and Luxembourg – obtained a moratorium from the European Commission suspending any new authorizations for growing and placing on the market of genetically modified plants pending both effective rules concerning the traceability and informative labelling of all GMO-derived products, and the necessary clarifications concerning different aspects of the law relating to the use of these new technologies. [...] This moratorium period made it possible [...] to progressively reconcile the positions of the member States and harmonize the assessment and authorization periods. Thus [...] Directive 2001/18/EC was adopted [...]. The new Directive, coupled with the two community regulations, 1829/2003 and 1830/2003, provides a tight, general and very complete framework in which the Government has expressed its full confidence when it comes to proceeding, at the European level, with new GMO commercial authorizations, which will be granted on a case by case basis".[669]

The response by the French Minister for Research suggests that a moratorium had been in effect since 1999 when the Group of Five countries made their declaration at the June 1999 Environment Council. The response also suggests that in June 2004 France no longer saw a need to use its powers to suspend approvals, although it is unclear when the French Government made that decision, i.e., whether the decision was made after the adoption in September 2003 of the new Regulations concerning labelling and traceability as well as food and feed (as France had indicated in the June 1999 declaration by the Group of Five countries), or after their entry into force in April 2004.

[667] "EU Ag Ministers Approve GMO Traceability Plan Opposed by White House, U.S. Farmers" International Trade Reporter, 24 July 2003, p. 1 (Exhibits US-39 and CDA-47) .

[668] *Ibid*., para. 561; EC second written submission, para. 295.

[669] Reply to question No. 27131 of Mr Martin Philippe-Armand (Union for a Popular Movement (UMP) – Marne), 12th legislature, 1 June 2004 (translation from French) (Exhibit ARG-48).

(v) EC statements at the WTO

7.531 The following WTO document was referred to by one Complaining Party:

(a) *November 2001 minutes of meeting*. The minutes of a meeting of the WTO Committee on Sanitary and Phytosanitary Measures state under the heading "US concerns on EC agricultural biotechnology approval processes" that "[t]he representative of the European Communities reaffirmed the European Commission's interest and positive actions aimed at allowing the authorization procedures to continue. The recent meeting of the European Environment Council had started a very important discussion on proposals presented by the Commission to restart the authorization procedure".[670]

This statement, which was made on behalf of the European Communities, suggests that in November 2001 a moratorium was in effect, as it refers to the need to "restart the authorization procedure". The statement is consistent with the above-mentioned July 2001 statement by Commissioner Byrne and uses language similar to that used in the November 2000 Commission working document.

(vi) General assessment

7.532 The Panel considers that all of the above-listed documents and statements are relevant to the issue of whether certain member States and the Commission intentionally prevented the final approval of applications. With few exceptions, the statements referred to were made by the highest-ranking officials of the Commission or member States, or by or on behalf of key parliamentary committees. Also, each of the Complaining Parties submitted documents or statements not just from a single source, but from multiple EC institutions or representatives thereof. Many of the documents provided were prepared directly by the competent administrative services or parliamentary committees, and the statements by Commissioners and Ministers were made by Commissioners and Ministers with responsibility for biotech products. Accordingly, the documents and statements cannot be said to represent outsiders' perspectives. For the most part, the statements referred to consist of prepared statements, such as speeches. Such statements cannot properly be considered casual statements. While a small number of the statements submitted were made in the context of news conferences, the content of these statements is very similar to that of the other statements or documents submitted. Finally, it is important to note that notwithstanding the fact that the documents and statements stem from different EC institutions or representatives thereof, they all consistently, albeit not identically, refer to the existence of a "moratorium" or of a "standstill", or to a possible "resumption" of approvals. For all these reasons, the Panel is unable to agree with the European Communities that the documents and statements referred to by each Complaining Party provide no evidence of the existence of a *de facto* moratorium.[671]

7.533 The documents and statements relied on by each Complaining Party add an important element to the evidence discussed in the previous Subsection: they point to a reason for the absence of approvals during the relevant time period. The relevant documents and statements suggest that there were no approvals because a moratorium on approvals was in effect. Of the twenty-six documents or

[670] Document G/SPS/R/25, para. 105.
[671] EC first written submission, para. 553.

statements listed above, twenty-one explicitly use the term "moratorium". The other five documents are all consistent with the view that there were no approvals because a moratorium was in effect.[672]

7.534 Conceptually, a moratorium on approvals implies a temporary absence of approvals. But in addition the concept of a moratorium on approvals implies that the absence of approvals must be the consequence of a deliberate temporary suspension of approvals. This is confirmed by the dictionary definition of the term "moratorium". As noted by the European Communities, the dictionary defines the term "moratorium" as "a postponement or deliberate temporary suspension of some activity".[673] In the light of this, the Panel considers that the references in the various documents and statements to an EC "moratorium" on approvals support what the Complaining Parties are asserting: that action was taken by relevant authorities, or deliberately not taken, so as to prevent approvals for a certain period of time. The Panel is not convinced that the relevant documents and statements use the term "moratorium" merely to describe a "factual situation"[674] – a temporary absence of approvals. The documents and statements do not support such a conclusion. For example, the November 2000 speech by Commissioner Byrne states that "public concerns […] have resulted in a de-facto moratorium on authorizations of new GMOs. In fact no GMOs have been approved over the last two years".[675] If the term "moratorium" in the first part of this statement were understood as merely referring to a temporary absence of approvals, it would be unclear why the term "*de facto*" was used. It makes little sense to say that there was a *de facto* absence of approvals. Conversely, it makes sense to say that there was a *de facto* suspension of approvals.

7.535 The European Communities appears to argue in the alternative that the references to a "moratorium" were made, for the most part, during what it refers to as the "transition period" from 1998 to 2001.[676] During that period, Directive 90/220 was being revised and the new Directive 2001/18 – the Directive amending Directive 90/220 – entered into force. The European Communities submits that the documents and statements which were made during that period and which refer to a "moratorium" all imply that the "moratorium" would end when the transition period ends. It is correct that a number of documents and statements indicate that the adoption of Directive 2001/18 would contribute to the lifting of the "moratorium". However, there is no document or statement which suggests that this would be a sufficient condition for the lifting of the "moratorium". Rather, the documents or statements mention the new Regulation concerning labelling and traceability as an additional condition, which is consistent with the June 1999 declaration by the

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[672] It should nonetheless be recalled that the January 2004 Communication to the Commission and the September 2001 speech by Commissioner Byrne, when considered in isolation from the other documents and statements, could also be interpreted so as to be consistent with the European Communities' view that the absence of approvals was due to "requests for additional information".

[673] *The New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. I, p. 1828.

[674] EC first written submission, para. 561.

[675] Similar language was used in Commissioner Byrne's June 2000 speech and in the October 2001 Commission working paper.

[676] The European Communities' submissions are less than clear regarding when the so-called "transition period" ended. The Panel is assuming that the European Communities meant to argue that the period ended in 2001, when Directive 2001/18 was adopted. EC first written submission, para. 4; EC second written submission, paras. 292. Other EC statements appear to suggest, however, that the period ended in 2003. EC second written submission, para. 293. But the relevance of 2003 is nowhere explained. Directive 2001/18, which is referred to in the aforementioned paragraphs of the EC written submissions, came into force in 2002. In contrast, in none of the aforementioned paragraphs of the EC submissions is there a reference to the adoption in 2003 of the new EC regulations on labelling and traceability as well as food and feed. In any event, the Panel's analysis of the EC argument about the transition period is unaffected by the issue of whether that period ended in 2001 or 2003.

Group of Five countries.[677] Moreover, all three Complaining Parties have referred to documents or statements which suggest that a moratorium was still in effect after the adoption of Directive 2001/18 in March 2001, and even after the entry into force of that Directive in October 2002.[678] In fact, the April 2004 background note by the Council's General Secretariat, which was relied on by all Complaining Parties, suggests that a moratorium continued to be in effect even after the adoption in September 2003 of the new Regulation concerning labelling and traceability. The note also implies that a moratorium was in effect in August 2003, the date of establishment of this Panel.[679]

7.536 It should be mentioned as well that all Complaining Parties have submitted a document or statement which refers to the fact that no applications have been approved under Directive 90/220 since October 1998.[680] However, the fact that no applications have been approved since October 1998 does not necessarily mean that a moratorium was in effect as from October 1998. None of the documents or statements submitted by the United States and Canada suggests that a moratorium was in effect as of October 1998. The June 2002 EP committee report refers to "a moratorium over the last three years", implying that a moratorium was in effect since June 1999, which is when the Group of Five countries issued their joint declaration. Argentina submitted one document, the November 2002 EU Bulletin, which refers to an EP resolution according to which "the current 'de facto' moratorium that has been imposed on genetically modified foods since 1998 […] should be lifted in 2003". This suggests that a *de facto* moratorium was in effect since 1998. It is possible, though, that the year 1998 was referred to simply because after 1998 no applications were approved until 2004. In any event, other statements and documents submitted by Argentina – the November 2001 speech by Commissioner Byrne[681] and the June 2004 parliamentary response by the French Minister for Research[682] – support the view that a moratorium was in effect only as from June 1999.[683] In the light

[677] *See, e.g.*, the July 2001 Commission press release; the July 2003 Commission fact sheet; the July 2001 statement by Commissioner Byrne; and the June 2004 parliamentary response by the French Minister for Research.

[678] *See, e.g.*, the July 2003 Commission fact sheet; the February 2003 news report quoting Commissioner Byrne; the July 2003 note by the Council's General Secretariat; the April 2004 background note by the Council's General Secretariat; the March 2003 motion for an EP resolution; the June 2003 statement by an EP committee rapporteur; and the July 2003 news report quoting Ministers of France and Italy.

[679] The July 2003 Commission fact sheet, the July 2003 note by the Council's General Secretariat, the June 2003 statement by an EP committee rapporteur and the July 2003 news report quoting Ministers of France and Italy all indicate that a moratorium was in effect in June and July of 2003.

[680] *See* the January 2004 Communication to the Commission; the November 2000 speech by Commissioner Byrne; and the February 2001 motion for an EP resolution.

[681] Commissioner Byrne's speech suggests that it was as a result of the positions expressed by the Group of Five countries in 1999, specifically their positions expressed in the June 1999 joint declaration, that "the authorization of both pending and new products has come to a grinding halt". The speech in question also contains the statement that "[d]espite our scientific advisors having given the green light for growing and marketing GMO plants and foods, our Member States have blocked new authorizations since 1998". The Panel understands this statement to refer to the fact that in four successive votes held in the Regulatory Committee from October 1998 onwards, the Regulatory Committee failed to achieve a qualified majority, even though the relevant applications had all received favourable opinions from an EC scientific committee. After these four votes, no further votes were held in the Regulatory Committee prior to the date of establishment of this Panel. EC reply to Panel question No. 96(c). As is explained in more detail below, in the Panel's view, the votes in question do not support the view that a moratorium was in effect as from October 1998. *See, infra*, para. 7.1248.

[682] The Minister's response, in what seems to be a reference to the fact that the Group of Five countries issued a joint declaration in June 1999, states that it was in 1999 that the Group of Five countries gained the Commission's support for a moratorium.

of this, the Panel does not consider that the documents and statements submitted by each Complaining Party permit the inference that a general *de facto* moratorium was in effect before June 1999.

7.537 The documents and statements are important also because they lend support to the Complaining Parties' assertion that the European Communities applied an across-the-board moratorium, *i.e.*, a moratorium applicable to all pending and new applications for the approval of biotech products. Many of the documents and statements relied on by each Complaining Party explicitly refer to a generally applicable moratorium.[684] Others refer more broadly to a "moratorium".[685] However, given the absence of a textual qualifier, and reading the statements and documents concerned together with others, there is no reason to assume that the broad references to a "moratorium" should be understood as meaning that the "moratorium" in question was selective, that is to say, that it applied to only some applications. Separately, it should be pointed out that the documents and statements relied on by each Complaining Party suggest that an across-the-board moratorium was in effect between June 1999 and August 2003.[686]

7.538 It has been observed above that almost all of the relevant documents and statements refer to a "moratorium" on approvals and that this implies that actions were taken by relevant authorities, or deliberately not taken, so as to prevent approvals for a certain period of time. The Complaining Parties assert that the relevant authorities are certain member States – notably the Group of Five countries – and the Commission, and that they intentionally prevented applications from reaching the stage of final approval. The documents and statements provide some, albeit limited, confirmation of this assertion. To begin with, according to the October 2001 news report, Commissioner Wallström characterized the "moratorium" as a "situation where we just simply decline to take a decision". While this statement does not make clear who is meant by "we", it tends to confirm that there was a "decision not to make final decisions" and not to allow final approvals. Furthermore, all Complaining Parties have relied on documents or statements which suggest that the "moratorium" is the result of

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[683] *See also* para. 7.1254 *et seq*. for our discussion of Argentina's argument that the Commission's conduct prior to the June 1999 declaration by the Group of Five countries confirms the existence of a general moratorium on approvals as from October 1998.

[684] *See, e.g.*, the October 2001 Commission working paper ("a *de facto* moratorium on the marketing of new GMOs"); the July 2001 statement by Commissioner Byrne ("the *de facto* moratorium on the commercial release of GMOs and GM-products"); the April 2004 background note by the Council's General Secretariat ("the current *moratorium* on genetically modified food and feed"); the February 2001 motion for an EP resolution ("the de facto moratorium on the release of GMOs"); the June 2002 EP committee report ("a moratorium […] on the marketing authorization procedures at EU level"); the November 2002 EU Bulletin summarizing an EP resolution ("the current 'de facto' moratorium that has been imposed on genetically modified foods since 1998"); the June 2003 statement by an EP committee rapporteur ("the 'de facto' moratorium on the approval of new GMOs"); the July 2003 news report quoting the Agriculture Minister of Italy ("the moratorium on the authorization of GMO crops"); and the June 2004 parliamentary response by the French Minister for Research ("a moratorium [...] suspending any new authorizations for growing and placing on the market of genetically modified plants ").

[685] *See, e.g.*, the July 2000 news report quoting Commissioner Wallström; the October 2001 news report quoting Commissioner Wallström; the October 2001 news report quoting the spokeswoman for Commissioner Byrne; the January 2002 speech by Commissioner Lamy; and the July 2003 note by the General Secretariat of the Council.

[686] *See, e.g.*, the November 2000 Commission working document; the November 2000 speech by Commissioner Byrne; the June 2002 EP committee report; the November 2002 EU Bulletin summarizing an EP resolution; the July 2003 Commission fact sheet; the June 2003 statement by an EP committee rapporteur; the July 2003 news report quoting the Agriculture Minister of Italy; the April 2004 background note by the Council's General Secretariat; and the June 2004 parliamentary response by the French Minister for Research.

member State opposition to approvals.[687] In addition, the March 2003 motion for a European Parliament resolution, which was referred to only by the United States, implies that the "continuation" of the "moratorium" depends not only on the member States but also the Commission.[688] Similarly, the June 2004 parliamentary response by the French Minister for Research, which was referred to only by Argentina, implies that a "moratorium" could not have been imposed without Commission involvement.[689]

(vii) Official EC position

7.539 The final point to be addressed is the EC argument that whatever the documents or statements submitted by the Complaining Parties may say, none of them represents the official position of the European Communities. For its official position, the European Communities refers the Panel to the following two documents:[690]

(a) *Commission press release of May 2003*. This press release was issued on the day the United States announced its intention to file a WTO complaint. It quotes then Trade Commissioner Pascal Lamy as saying that "[t]he US claim that there is a so-called 'moratorium', but the fact is that the EU has authorized GM varieties in the past and is currently processing applications".[691]

(b) *EC opening statement during the consultations of June 2003*. This statement was delivered by the European Communities during the consultations preceding the present panel proceedings. It states that "[u]nder the old regime, 18 GMOs were approved. With the new rules [contained in Directive 2001/18], pending applications have been revised and they are being examined with a view to making decisions on the authorization of new products. Currently 20 applications are being examined under Directive 2001/18. That is a fact: not an allegation, not an opinion, not a press statement."[692]

7.540 The Panel notes that neither of these statements contradicts the Complaining Parties' basic assertions. As already discussed in the previous Subsection, the Complaining Parties do not dispute the fact that biotech products were approved prior to October 1998. Nor do they contest that applications were being processed, or examined, between October 1998 and August 2003. The Complaining Parties' assertion is that the European Communities imposed a *de facto* moratorium on final approvals. According to the Complaining Parties, under this type of moratorium, applications were in most cases allowed to complete some stages of the EC approval process, but in no case were they allowed to proceed to the stage of final approval. The documents and statements submitted by

[687] *See, e.g.*, the October 2001 Commission working paper; the June 2000 speech by Commissioner Byrne; the November 2001 speech by the same Commissioner (referring specifically to the Group of Five countries); and the January 2002 speech by Commissioner Lamy.

[688] The motion urges "the Council and the Commission to continue the moratorium".

[689] The response states that the Group of Five countries "obtained a moratorium from the European Commission suspending any new authorizations".

[690] EC first written submission, para. 557.

[691] "European Commission regrets US decision to file WTO case on GMOs as misguided and unnecessary", Commission Press Release IP/03/681, 13 May 2003, p. 1 (Exhibit EC-113).

[692] Exhibit EC-112, p. 2.

each Complaining Party support the assertion that the "moratorium" affected the final approval of applications, but not necessarily their processing at every step in the process.[693]

(e) Facts and histories of individual approval procedures

7.541 In their submissions to the Panel, the Complaining Parties have also addressed individual applications for the placing on the market of biotech products. According to the **Complaining Parties**, the approval procedures for these applications confirm that certain member States and/or the Commission did in fact prevent the final approval of applications in the manner asserted by the Complaining Parties. In other words, in the Complaining Parties' view, the relevant approval procedures confirm that member States and/or the Commission suspended the approval of applications through one or more of the acts and/or omissions identified in Subsection (a) above.

7.542 In discussing individual approval procedures, the Complaining Parties in their first written submissions relied largely on publicly available information.[694] Subsequently, they mainly used the information submitted by the European Communities at its own initiative or at the request of the Panel. It should be noted in this respect that most of the information relating to individual applications is in the sole possession of member States, the Commission and the applicants. However, some information – *e.g.*, the minutes of Regulatory Committee meetings or communications between member States and the Commission – is in the exclusive possession of the European Communities. Also, while some of the applicants are US companies, others are European companies. There do not appear to be any applicants which are Canadian or Argentinean companies.[695] The Panel notes nonetheless that all of the Complaining Parties produce for export products subject to this complaint.

7.543 The **European Communities** argues that the claims relating to the general moratorium collapse when the specific facts and history of each approval procedure are considered. The European Communities submits that an analysis of the facts shows that during the relevant time period (October 1998 to August 2003) there were no acts and omissions that stalled applications at key decision-making stages in the approval process. The processing of individual applications continued without interruption, and applications were not systematically stalled.

7.544 According to the European Communities, in assessing applications, the competent authorities tried to take account of the changing EC legislative and regulatory framework as well as the evolving scientific debate. In some cases, this necessitated long discussions between the lead CA and the applicant on a number of scientific or regulatory issues that were not appropriately addressed in the original application, which delayed the forwarding of applications to the Community level. In other cases, discussions took place at Community level, before and/or after the opinion of the EC scientific

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[693] *See, e.g.*, the July 2001 Commission press release; the October 2001 Commission working paper; the July 2003 Commission fact sheet; the October 2001 news report quoting Commissioner Wallström; the June 2000 speech by Commissioner Byrne; the November 2000 speech by Commissioner Byrne; the July 2001 statement by Commissioner Byrne; the October 2001 speech by Commissioner Byrne; the November 2001 speech by Commissioner Byrne; the March 2003 motion for an EP resolution; the June 2003 statement by an EP committee rapporteur; the July 2003 news report quoting the Italian Agriculture Minister; and the June 2004 parliamentary response of the French Minister for Research.

[694] *See, e.g.*, Exhibits US-30 and -31; CDA-26 and -34; ARG-6.

[695] The European Communities argues that the relevant information should have been known to the Complaining Parties before the initiation of these proceedings, through their contacts with applicants. EC second written submission, para. 254. Canada indicated that it consulted with applicants in preparing its case, but nevertheless suggests that it did not have full access to the information in question, despite a request to the European Communities for disclosure during the consultations. Canada's third written submission, para. 8.

committees, among various member States. Furthermore, an important number of applications were withdrawn by the applicants because of various commercial reasons and changes in strategies. There is, however, no consistent pattern in respect of the applications pending during the relevant time period. Each application was dealt with on its own merits. In the light of this, the Panel cannot determine whether there was a general "moratorium" without looking at the decisions and actions taken in relation to each individual application. The Panel must consider each of the relevant approval procedures for the applications.

7.545 Finally, the European Communities submits that even if the delays that affected certain approval procedures before, and because of, the adoption of new legislation were to be seen as the result of a measure (the alleged "moratorium"), that measure would have ended with the entry into force of that legislation, namely with the entry into force in January 2003 of Directive 2001/18.

7.546 The **Panel** notes the contention of all Parties that the facts and history of individual approval procedures confirm their respective positions. The European Communities in particular insists on the importance of individual application histories, arguing that no conclusion can be drawn with regard to whether a general moratorium on approvals was in effect between October 1998 and August 2003 until and unless each application has been considered individually. Further below, the Panel undertakes a separate analysis of each relevant application.

7.547 The applications covered by the Panel's analysis are those mentioned by the Complaining Parties in their requests for the establishment of a panel, with one exception.[696]. We are mindful of the fact that the Complaining Parties' panel requests mention specific applications in connection with their product-specific claims, and not in connection with their general moratorium claim. However, we are referring to the panel requests here merely to identify the applications covered by our analysis. Since the Complaining Parties' claim in respect of the alleged general moratorium is that the moratorium was applicable to any and all applications pending between October 1998 and August 2003, it is clear that, for the purposes of establishing the general moratorium claim, each of the Complaining Parties may put forward evidence and arguments in respect of any and all pending applications.

7.548 The applications mentioned by the Complaining Parties in their panel requests include those which were withdrawn between October 1998 and August 2003. We think that they are pertinent to the Panel's assessment of whether the alleged general *de facto* moratorium on final approvals existed. Up until the date of their withdrawal, these applications, and the relevant approval procedures, constitute factual evidence which the Panel is not only entitled to take into account, but is required to take into account in view of its obligation to make an objective assessment of the facts of the case. We also note that the findings we make with regard to the relevant approval procedures relate to the Complaining Parties' claim that the European Communities applied a general moratorium on final approvals. They do not relate to the issue of the WTO-consistency of actions or omissions by relevant EC entities in the context of the approval procedures in question.

7.549 The Panel's analysis also covers one additional application referred to by the European Communities.[697] It does not cover eight other applications which were mentioned by the European

[696] The application concerning T14 maize was mentioned by Argentina. However, according to information provided by the European Communities, that application, which was submitted to France in June 1996, was withdrawn by the applicant on 15 July 1998. Exhibit EC-156/At. 57. In other words, the approval procedure concerning T14 maize was terminated prior to the alleged moratorium period (October 1998 to August 2003).

[697] Application concerning Transgenic green-hearted chicory.

Communities "in order to complete the picture".[698] Regarding the eight applications mentioned by the European Communities for completeness' sake, we note that seven of these were submitted under Directive 2001/18. Of those seven, three were submitted after the date of establishment of this Panel (29 August 2003)[699]. They are not relevant to a determination of whether a general moratorium was in effect until 29 August 2003. One application was submitted in July 2003[700], which means it had been assessed by the relevant member State for only one month when this Panel was established.[701] For the remaining three applications, unlike for all applications referred to by the Complaining Parties, the European Communities submitted no detailed chronologies with supporting documents. Instead, it provided status reports which indicate the state of play of the applications in the spring of 2004.

7.550 In the European Communities' view, these status reports demonstrate that the relevant approval procedures are "proceeding smoothly".[702] However, one of the three applications in question appears to have been delayed at the member State level as a result of a request by the competent member State authorities for additional information.[703] Another application, an application submitted to the United Kingdom, was apparently also delayed at the member State level at the time this Panel was established.[704] The report provided by the European Communities does not indicate any reason for this delay. The last of the three applications was submitted to Germany. This application was apparently assessed quickly, and favourably, by the competent German authorities. However, when the application moved to Community level, despite the favourable assessment by Germany, other member States appear to have raised objections to the placing on the market of this product.[705] The report provided by the European Communities does not contain any information about the basis for these objections.[706] In the light of the foregoing, the Panel does not consider that the information supplied by the European Communities in respect of the three above-mentioned applications is sufficient to support the inference that no general moratorium on final approvals was in effect before or in August 2003.

7.551 The eighth application which was mentioned only by the European Communities was submitted to Germany under Regulation 258/97 and apparently concerns the same product that was submitted to Germany under Directive 2001/18. In respect of this application, the European Communities provided neither a chronology with attachments nor a status report indicating the state of play. The European Communities merely indicates that the application was submitted in 2003 and

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[698] EC first written submission, para. 334. It should be recalled that the application concerning MON863 maize is not part of the eight applications mentioned by the European Communities. As explained previously, due to the fact that the Panel has no information on this application other than an EC letter stating that in September 2005 the application was approved by the Commission under Directive 2001/18, the Panel is not in a position to determine whether or not the history of the approval procedure concerning MON863 maize is consistent with the Complaining Parties' contention that a general moratorium on approvals was in effect between October 1998 and August 2003.

[699] Exhibits EC-103 (maize), -108 (rice) and -109 (cotton).

[700] Exhibit EC-107 (maize).

[701] Pursuant to Article 14(2) of Directive 2001/18, a member State has 90 days from the date of receipt of an application to prepare an assessment report on the application.

[702] EC first written submission, para. 336.

[703] Exhibit EC-104 (sugar beet).

[704] Exhibit EC-105 (maize). The United Kingdom took more than 13 months to prepare and forward its assessment report instead of the 90 days laid down in Article 14(2) of Directive 2001/18.

[705] Exhibit EC-106 (maize).

[706] The report suggests that the member States were unable to reach an agreement and that the application was therefore referred to an EC scientific committee for an opinion. However, this was after the present Panel had been established.

quickly moved up to the Community level, where it appears to have run into objections from other member States.[707] In respect of this application as well, the Panel does not consider that the information supplied by the European Communities is sufficient to support the inference that no general moratorium on final approvals was in effect until August 2003.

7.552 In the remainder of this Subsection, the Panel will examine the facts and histories of all other relevant applications with a view to determining whether they are consistent with the Complaining Parties' contention that during the relevant time period (October 1998 to August 2003) the European Communities applied a general moratorium on final approvals, or whether they are inconsistent with the Complaining Parties' contention and hence lead to the "collapse" of the Complaining Parties' claims in relation to the general moratorium, as the European Communities asserts. The structure of this examination reflects the arguments of the Complaining Parties. More specifically, the Panel's examination is structured according to the acts and omissions through which, in the Complaining Parties' view, the European Communities gave effect to the alleged general moratorium on approvals. The Panel will first address applications submitted under Directives 90/220 and/or 2001/18. Thereafter, the Panel will address applications submitted under Regulation 258/97.

7.553 Once the Panel has completed its analysis of individual approval procedures, it will focus on the conduct of Group of Five countries generally, notably their voting behaviour and their objections to favourable assessments by lead CAs. In addition, the Panel will address certain conduct by the Commission prior to the June 1999 declaration by the Group of Five countries.

(i) Deliberate Release – Applications submitted under Directive 90/220 and/or Directive 2001/18

7.554 The Panel first turns to address those of the relevant applications which were submitted and dealt with under the provisions of Directive 90/220 and, subsequently, Directive 2001/18 concerning the deliberate release of GMOs into the environment. It is useful to recall in this regard that in accordance with Article 36 of Directive 2001/18, Directive 90/220 was repealed on 17 October 2002. Furthermore, Article 35 of Directive 2001/18 provides that applications which were received pursuant to Directive 90/220 and in respect of which the procedures under Directive 90/220 were not completed by 17 October 2002, were subject to Directive 2001/18 as of that date. Pursuant to Article 35, such pending applications had to be complemented by the applicants in accordance with Directive 2001/18. The date by which applicants had to do so was 17 January 2003.

7.555 We further recall that this means that irrespective of the procedural stage reached by an application under Directive 90/220, an application which was updated in accordance with the requirements of Directive 2001/18 had to go through all procedural stages provided for in Directive 2001/18, beginning with the initial assessment by the lead CA.[708] However, according to the European Communities, any results and conclusions reached under the procedures of Directive 90/220 on the basis of the then-existing data and information were in principle still relevant under the procedures of Directive 2001/18 and hence did not need to be re-examined.

7.556 In reviewing the approval procedures conducted for the relevant applications, we will first focus on the Commission's conduct. Subsequently, we will also consider the conduct of individual member States acting as lead CAs.

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[707] EC first written submission, para. 337.

[708] It is useful to recall that the Complaining Parties did not challenge the obligation contained in Article 35 of Directive 2001/18.

7.557 Before commencing our examination of individual approval procedures, we should note that the European Communities acknowledges that delays occurred in some approval procedures which were pending under Directive 90/220. According to the European Communities, these delays occurred because of the adoption of Directive 2001/18. The European Communities argues, however, that after the entry into force of Directive 2001/18 all approval procedures have been proceeding normally. We will revert to this argument after reviewing all relevant applications.

Failure by the Commission to submit a draft measure to the Council

7.558 In support of their assertion that the European Communities applied a general moratorium on approvals the Complaining Parties have pointed to a number of approval procedures in which the Commission failed to submit to the Council a draft measure on the relevant applications. We consider these approval procedures below, recalling that Article 21 of Directive 90/220 provides in relevant part that "[i]f the measures envisaged [by the Commission] are not in accordance with the opinion of the [Regulatory] committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken".

Bt-531 Cotton (EC-65)

7.559 The application concerning Bt-531 cotton was first submitted to Spain (lead CA) in December 1996, and was provided to the Commission for circulation to all member States in December 1997. Following a positive opinion by the SCP on 14 July 1998, the Commission launched inter-service consultations on a draft measure to be submitted to the Regulatory Committee on 4 September 1998. The Regulatory Committee at its meeting of 22 February 1999 voted on the draft measure submitted by the Commission, but failed to reach the qualified majority necessary to deliver an opinion. Accordingly, on 7 May 1999, the Commission launched inter-service consultations on a draft measure to be submitted to the Council. But at no point prior to 17 October 2002, the date of repeal of Directive 90/220, did the Commission submit a draft measure to the Council.

7.560 The **United States** argues that the Commission was required under EC law to submit a draft measure to the Council "without delay". The United States submits that despite that legal obligation, the Commission failed to do so, with the result that the application languished for over three years without any activity other than purported inter-service consultations, until the application was updated in early 2003 to meet the requirements of Directive 2001/18. According to the United States, the "inter-service consultations" which the Commission launched in May 1999 and the Commission's failure to adhere to its legal obligation to act "without delay" confirm the existence of a moratorium.

7.561 **Canada** also argues that despite the positive opinion by the lead CA, the positive opinion by the SCP and the failure of the Regulatory Committee to deliver an opinion and despite an express legal obligation to do so, the Commission failed to submit to the Council a draft measure in order to break the deadlock at the Regulatory Committee in accordance with the legal obligation under Directive 90/220. According to Canada, the inter-service consultations following the Regulatory Committee vote and which were going on for close to four years resulted in a suspension of the approval procedure. In Canada's view, the only reasonable explanation for the time taken by the Commission to conduct inter-service consultations is the existence of a moratorium.

7.562 **Argentina** argues that instead of submitting a draft measure to the Council, the Commission intentionally stalled the approval procedure concerning Bt-531 cotton until the application had to be resubmitted under Directive 2001/18. Argentina maintains that the Commission did so by starting inter-service consultations, a phase not foreseen in the relevant EC legislation. In Argentina's view,

the Commission's inter-service consultations are evidence of the existence of a moratorium inasmuch as they reveal the European Communities' intention not to allow the final approval of applications.

7.563 The **European Communities** argues that the Regulatory Committee failed to reach a qualified majority because a number of member States raised legitimate scientific concerns which had not been addressed in any of the applicant's previous submissions. The European Communities submits that long after the vote in the Regulatory Committee, on 25 July 2001, the applicant provided the required additional information, and that the translation of this material was not made available until February 2002. According to the European Communities, if there was a three-year delay after the Regulatory Committee vote, it was because of the time taken by the applicant to provide the required additional information.

7.564 The **United States** responds that nothing in the record indicates that the applicant was ever requested to submit additional information to address the member State statements made at the Regulatory Committee meeting. According to the United States, the applicant was not responding to any request, but, on its own initiative, provided additional information to the lead CA as the state of scientific knowledge had advanced since the first submission of the application more than four years before. The United States submits that this information was submitted as part of the applicant's commitment to stewardship and initiatives to provide additional relevant new information as it becomes available.[709]

7.565 **Argentina** also considers that the additional information was provided by the applicant on its own initiative, as the record does not indicate that the applicant was specifically requested by the European Communities to provide that information.

7.566 The **European Communities** disagrees with the United States and Argentina, maintaining that the applicant was formally requested to submit the information in question.

7.567 The **Panel** begins its analysis by noting that on 25 July 2001, more than two years after the Commission launched inter-service consultations on a draft measure to be submitted to the Council, the applicant sent a letter to the lead CA providing an updated and extended molecular characterization of Bt-531 cotton and a safety assessment of Bt-531 cotton (analysis of flanking regions). The letter by the applicant does not state that the information it contains was provided in response to a specific request from the lead CA or another agency (another CA, the Commission, the SCP, etc.).[710] Nor does it indicate that the lead CA or the Commission had any knowledge that the applicant would be providing the additional information in question.

7.568 The European Communities has noted that at the Regulatory Committee meeting of February 1999, Austria, Sweden and the United Kingdom made written statements in support of their votes.[711] As also noted by the European Communities, these statements related to concerns about the presence of an antibiotic resistance marker gene, possible non-target effects on beneficial insects and the sufficiency of the monitoring plan to analyse indirect effects of Bt-531 cotton. None of these statements specifically call for an updated molecular characterization of Bt-531 cotton or a safety

[709] The United States submitted a statement from the applicant in which it confirms to the United States that it provided the information in question without a previous specific request from relevant authorities and that it did so to provide supplementary information that comes to light as a result of ongoing research and to help advance the approval process. Exhibit US-137.

[710] Exhibit EC-65/At. 61.

[711] Austria and the United Kingdom voted against, Sweden in favour of the proposed draft measure. Exhibit EC-65/At. 59.

assessment (analysis of flanking regions). There is therefore no indication that the applicant submitted the July 2001 information in response to the written statements made at the February 1999 meeting of the Regulatory Committee.[712]

7.569 Regarding the possibility that the information submitted by the applicant in July 2001 was in response to requests for information or concerns put forward prior to the February 1999 meeting of the Regulatory Committee[713], it should be observed that the lack of that information did not prevent the Commission from submitting a draft measure to a vote by the Regulatory Committee, and it did not prevent the Regulatory Committee from holding a vote on that measure. We therefore fail to see how the lack of the same information could provide a justification for the Commission's failure to submit a draft measure to the Council.

7.570 At any rate, based on the date of the applicant's letter (July 2001) and the type of information provided (an updated molecular characterization) we are not convinced that the applicant's July 2001 letter was intended as a direct response to a specific request for information from before February 1999.[714] The date of the letter and type of information provided rather suggest that the applicant sought to update its application in accordance with some of the requirements of Directive 2001/18, which had been adopted in March 2001. The European Communities itself advances this circumstance as constituting one of the reasons for the July 2001 letter, stating that by July 2001 "Directive 2001/18 had been adopted [...] and, as mentioned several times, applicants were updating their dossiers to match the new requirements".[715] In our view, the applicant in this approval procedure might well have done so in the hope that the updated information would make it possible for its application to be approved while Directive 90/220 was still in force.

7.571 It follows from the above remarks that there is no evidence to suggest that the Commission was waiting for the additional information provided by the applicant and that this was why the Commission did not submit a draft measure to the Council. Indeed, even after the applicant had provided the information, the Commission did not forward a draft measure to the Council, although Directive 90/220 remained in force for another seventeen months, until October 2002.

7.572 It appears that the European Communities also seeks to explain the Commission's failure to act by the fact that the draft measure which the Commission had submitted to a vote in the Regulatory Committee in February 1999 failed to achieve a qualified majority and that at that same meeting Austria, Sweden and the United Kingdom made statements in support of their votes. According to the

[712] It is also not clear that the content of the statements in question was ever brought to the attention of the applicant. According to the Complaining Parties, the minutes of Regulatory Committee meetings are confidential. The European Communities states that any request for information, comment or objection by a member State is automatically forwarded, through the lead CA, to the applicant (EC reply to Panel question No. 200). But the European Communities did not say that this also applies to comments or written statements made in the context of a Regulatory Committee meeting.

[713] The European Communities appears to make this point in its reply to Panel question No. 200.

[714] In its reply to Panel question No. 200, the European Communities suggests that the July 2001 information was provided in response to concerns raised by CAs other than the lead CA (*see* the references, e.g., to EC-65/At. 16-25). However, the Panel has seen no evidence, nor has it been informed, that the lead CA ever transmitted the July 2001 information to the Commission and other CAs. If, as it seems, this did not happen, then it would be difficult to accept the European Communities' suggestion that the information was provided in response to requests for information or concerns put forward by other CAs.

[715] EC reply to Panel question No. 200.

European Communities, these statements expressed legitimate scientific concerns that had not been previously addressed by the applicant.[716]

7.573 As no qualified majority was reached at the Regulatory Committee meeting, it seems reasonable to assume that the Commission used its inter-service consultations to analyse the reasons for the outcome of the vote in the Regulatory Committee and to determine, in the light of the results of such an analysis, whether it would be appropriate to modify the Commission's draft measure before it was sent on to the Council, and if so, how.[717] The statements by Austria and the United Kingdom could have been relevant to that task.[718]

7.574 In the present case, however, the Commission apparently never completed this task, even though the Commission launched its inter-service consultations more than three years before the date of repeal of Directive 90/220. It should be noted in this regard that in other approval procedures, the Commission was able to prepare and submit draft measures to the Council within a few months, despite the fact that some member States voted against the Commission's draft measure and that some made written statements.[719] Moreover, the European Communities does not assert that Austria and the United Kingdom raised new or particularly complex scientific concerns. We are therefore not convinced that either the absence of a qualified majority vote in the Regulatory Committee or the statements made by the aforementioned member States explain the Commission's failure, over a three-year period, to submit a draft measure to the Council.

7.575 The Complaining Parties consider that the Commission's failure to act rather reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. It is pertinent to note in this regard that the Commission launched its inter-service consultations with regard to Bt-531 cotton shortly before the June 1999 declaration by the Group of Five countries. At the time it conducted its inter-service consultations, the Commission thus had reason to believe that the Group of Five countries would act as a "blocking minority" in the Council, and that if that were to happen, the Commission would be required under Directive 90/220 to adopt the draft measure it submitted to the Council.[720] It is the contention of the Complaining Parties that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to discharge its responsibility under Directive 90/220 to complete approval procedures, in view of opposition of the Group of Five countries. In our view, the Commission's failure, over a three-year period, to submit a draft measure

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[716] As pointed out by the United States, however, the concerns referred to in the statements by Austria, Sweden and the United Kingdom were addressed in the SCP opinion. Exhibit EC-65/At. 47, paras. 6.2.1 and 6.3.3-6.3.4.

[717] The Panel does not agree with Argentina that the very fact that the Commission launched inter-service consultations is evidence of a *de facto* moratorium on approvals. We address this further *infra*, paras. 7.1254-7.1261.

[718] We note that Sweden voted in favour of the Commission's draft measure and that Sweden's statement suggests that its concerns were met.

[719] In the approval procedure concerning NK603 maize (Exhibit EC-76) and conducted under Directive 2001/18, the Commission submitted a draft measure to the Council little over one month after the Regulatory Committee had failed to reach a qualified majority. At that meeting, Austria made a statement in support of its negative vote. Exhibit EC-76/At. 72. In the approval procedure concerning Bt-11 maize (Exhibit EC-92) and conducted under Regulation 258/97, the Commission adopted a draft measure and referred it to the Council less than two months after the Regulatory Committee had failed to reach a qualified majority. At that meeting, several member States made statements in support of their votes. Exhibit EC-92/At. 70.

[720] Article 21 of Directive 90/220 states in relevant part that "[i]f, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measure shall be adopted by the Commission".

concerning Bt-531 cotton to the Council is consistent with the contention that the Commission made and followed such a decision.

7.576 In the light of the above considerations, we conclude that the Commission's failure after the February 1999 Regulatory Committee meeting to submit a draft measure concerning Bt-531 cotton to the Council is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

RR-1445 cotton (EC-66)

7.577 The application concerning RR-1445 cotton was first submitted to Spain (lead CA) in June 1997, and was provided to the Commission for circulation to all member States in December 1997. Following a positive opinion by the SCP concerning RR-1445 cotton on 14 July 1998, the Commission launched inter-service consultations on a draft measure to be submitted to the Regulatory Committee on 4 September 1998. The draft measure was submitted to the Regulatory Committee for a vote using a written procedure on 26 November 1998, with a deadline for the vote of 18 December 1998. The deadline for the vote was extended twice, following requests from various member States, until 22 February 1999. The Regulatory Committee failed to reach a qualified majority decision, and the Commission again launched inter-service consultations on 7 May 1999. At no point prior to 17 October 2002, the date of repeal of Directive 90/220, did the Commission submit a draft measure to the Council. The application was updated and re-submitted under Directive 2001/18 on 16 January 2003. As of 29 August 2003, no draft measure has been submitted by the Commission to the Council under Directive 2001/18.

7.578 The **United States** argues that the Commission was required under EC law to submit a draft measure to the Council "without delay" following the inability of the Regulatory Committee to reach a decision on 22 February 1999. The United States contends that the Commission refused to do so, however, and, as a result, further consideration of this application was indefinitely suspended as of February 1999. The Commission took no further action on this application for nearly four years, other than purported inter-service consultations, until the applicant was forced to update its application in January 2003 and to re-submit it under Directive 2001/18. The United States contends that only the existence of a moratorium explains the failure of the European Communities to move the application forward after its positive assessment by the relevant EC scientific body.

7.579 **Canada** argues that despite the positive opinion by the lead CA, the positive opinion by the SCP and the failure of the Regulatory Committee to deliver an opinion and despite an express legal obligation to do so, the Commission failed to submit to the Council a draft measure in order to break the deadlock at the Regulatory Committee in accordance with the obligation under Directive 90/220. Canada also argues that inter-service consultations had taken place earlier for this product, prior to the submission of a draft decision to the Regulatory Committee. Following the failure of the Regulatory Committee to reach a decision, the approval procedure for RR-1445 cotton was completely suspended for four years. Canada maintains that the only reasonable explanation as to why an additional four-year inter-service consultation was required is the existence of the moratorium.

7.580 **Argentina** argues that RR-1445 cotton, like other applications with a positive scientific opinion from 1998, was stalled by inter-service consultations. The lack of action on this product by the Commission for four years following the failure of the Regulatory Committee to reach a decision is further evidence of the de facto moratorium.

7.581 The **European Communities** notes that eight member States raised objections or had comments on issues related mainly to compositional analysis, molecular characterization, antibiotic

marker genes, safety and long-term effects on the environment – prior to the assessment and favourable opinion by the SCP. The European Communities argues that the Regulatory Committee failed to reach a qualified majority decision because a number of member States maintained objections, in particular because of concerns related to long-term effects of herbicide tolerant crops on the environment, to the presence of an antibiotic resistance marker gene, residue-limit levels, and to the effects on biodiversity of changes in herbicide tolerant crop management. The updated application submitted in January 2003 by the applicant under Directive 2001/18 was still incomplete with respect to a monitoring plan. The European Communities maintains, therefore, that any delay which has occurred is entirely legitimate and related to risk assessment and management considerations.

7.582 The **United States** responds that the four-year delay following the failure of the Regulatory Committee to reach a decision was not caused by a pending request to the applicant for additional information. The evaluation by the SCP had addressed all of the concerns raised by the member States at the level of the Regulatory Committee, including antibiotic resistance marker genes, toxicity to non-target organisms, and out-crossing from the transgenic plants, and came to the conclusion that the placing on the market of RR-1445 cotton with the purpose of being used as any other cotton was not likely to cause adverse effects on human health or the environment. None of the member States objecting at the Regulatory Committee offered any competing risk assessment or scientific evidence for their objections, nor did they identify any specific inadequacies in the SCP review. Nothing in the record indicates that the Commission communicated any scientific concerns to the applicant or identified any shortcomings in the application following the lack of a decision by the Regulatory Committee in February 1999.

7.583 **Argentina** also considers that all of the concerns identified by member States in their objections at the Regulatory Committee had been fully addressed by the SCP. Furthermore, this product had also received a favourable opinion under Regulation 258/97 on novel foods and food ingredients with respect to oil derived from RR-1445 cotton. The opinion of the Advisory Committee on Novel Foods and Processes was that oil from RR-1445 cotton is substantially equivalent to conventional cottonseed oil in terms of composition, nutritional value, metabolism, intended use and level of undesirable substances.

7.584 The **Panel** notes that, following the failure of the Regulatory Committee to reach a decision on 22 February 1999, and the re-launching of inter-service consultations on 7 May 1999, there is no record of any further action on this application before the repeal of Directive 90/220 in October 2002 and its replacement by Directive 2001/18. The record of the consultation of the Regulatory Committee by written procedure regarding a draft Commission Decision concerning the placing on the market of RR-1445 cotton does not contain any indication of a specific request to the applicant for further information.[721]

7.585 Four member States provided statements in support of their votes (Sweden, United Kingdom, Austria and Italy). All of the statements are very brief, and none includes a scientific evaluation or risk assessment in support of the views expressed. The UK competent authority voted against the draft measure stating that its disagreement is with respect to the marketing of the product for use in animal feed, due to the use of an antibiotic resistance marker gene in the product. Furthermore, while raising no concerns in terms of potential risks to the UK environment, the United Kingdom draws the attention of other member States where the cotton may be widely grown to potential negative impacts on biodiversity arising from changes in crop management methods. The Austrian competent authority abstained from voting indicating that the assessment of the risk especially from the use of the

[721] Exhibit EC-66/At. 57.

antibiotic resistance marker has not been sufficient for approval of a product which could be used as feed. Furthermore, Austria indicates that specific labelling requirements should be mentioned in the Commission Decision. The Swedish competent authority voted against the draft measure referring to earlier views that herbicide tolerant crops should not be placed on the market until the long-term effects of such crops on the environment have been better analysed, and common principles for evaluation and monitoring of potential risks connected to the cultivation of herbicide tolerant crops established. Italy, which voted in favour of the decision, stated that the use of Roundup-Ready herbicide on the cotton plant should be authorized only if the glyphosate metabolites and relevant residues were within the limits established by EC regulations.

7.586 We note that the evaluation of the SCP specifically addressed potential risks from the use of the antibiotic resistance marker gene in the product if used as animal feed. The SCP noted that it was "unlikely" that either gene which conferred resistance would survive processing. However, it went on to consider the potential risk if this "theoretically possible" and "extremely unlikely chain of events" occurred, and concluded that the introduction of either resistant gene would not increase existing risks to any significant effect, nor did they identify any potential risks from the "equally remote possibility" that the gene would be transformed and expressed. These findings were subsequently confirmed in a January 1999 report by the French CA, the Commission du Génie Biomoléculaire.

7.587 In response to a question from the Panel, one of the experts advising the Panel, Dr. Squire, observed that the issue of antibiotic resistance was considered in the SCP's opinion and found not to pose a risk. Furthermore, he notes that although there is now a widespread perception that antibiotic resistance should not be introduced through herbicide resistant products, cotton occupies a very small area in Europe and does not present potential problems of the type that might be associated with other crops.[722]

7.588 The SCP also specifically considered risks to non-target organisms and resistance and tolerance concerns. In response to a question by the Panel, another expert advising the Panel, Dr. Andow, stated his view that because the SCP considered that the risks of indirect effects or long-term and spatial scale effects on non-target organisms, and of effects associated with changes in the cropping system or the evolution of resistance in weeds to glyphosate, were inconsequential, the SCP did not propose a monitoring plan. Dr. Andow considered that the scientific issues raised by the objecting member States could be addressed in a monitoring plan, but that the necessity of a monitoring plan could not be determined from these objections.[723] Dr. Squire further noted that neither the applicant nor EC competent authorities had proposed suitable criteria on which to base monitoring.[724]

7.589 Although the European Communities stated that following the positive opinion of the Scientific Committee, the applicant entered into discussions with the lead CA on a further rat feeding study, no evidence was provided to the Panel with regard to these discussions or the possible outcome, nor with respect to whether these discussions were undertaken and/or concluded prior to the scheduled vote in the Regulatory Committee.[725]

7.590 As no qualified majority was reached by the Regulatory Committee, it is reasonable to assume that the purpose of the inter-service consultations launched by the Commission in May 1999 was to analyse the reasons for the outcome of the vote in the Regulatory Committee and to determine,

[722] Annex H, para. 480.
[723] *Ibid*, paras. 449-450.
[724] *Ibid*, para. 467.
[725] EC first written submission, para. 232.

in the light of such an analysis, whether it would be appropriate to modify the Commission draft measure before it was sent to the Council.[726]

7.591 However, in the case of RR-1445 cotton it appears that the Commission never completed this task, even though the inter-service consultations were started more than three years before the repeal of Directive 90/220. There is no evidence to suggest that there was any further contact with the applicant following the vote of the Regulatory Committee in February 1999, and even less that any further information was requested from the applicant. The Commission's failure to submit a draft measure to the Council before the repeal of Directive 90/220 contrasts with other approval procedures, in which the Commission was able to prepare and submit draft measures to the Council within a few months of a failure of the Regulatory Committee to reach a decision, despite the fact that some member States voted against the Commission's draft measure in those cases.[727] We are not convinced that either the absence of a qualified majority in the Regulatory Committee or the statements made by the above-mentioned member States explain the Commission's failure, over more than a three-year period, to submit a draft measure to the Council.

7.592 The Complaining Parties consider that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. It is pertinent to note in this regard that the Commission launched its inter-service consultations with regard to RR-1445 cotton shortly before the June 1999 declaration by the Group of Five countries. At the time it conducted its inter-service consultations, the Commission thus had reason to believe that the Group of Five countries would act as a "blocking minority" in the Council, and that if that were to happen, the Commission would be required under Directive 90/220 to adopt the draft measure it submitted to the Council.[728] We recall that it is the contention of the Complaining Parties that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to discharge its responsibility under Directive 90/220 to complete approval procedures, in view of opposition to final approvals by the Group of Five countries. In our view, the Commission's failure, over a three-year period, to submit a draft measure concerning RR-1445 cotton to the Council is consistent with the contention that the Commission made and followed such a decision.

7.593 In the light of the above considerations, we conclude that the Commission's failure after the February 1999 Regulatory Committee meeting to submit a draft measure concerning RR-1445 cotton to the Council is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

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[726] The Panel does not agree with Argentina that the very fact that the Commission launched inter-service consultations is evidence of a *de facto* moratorium on approvals. We address this further *infra*, paras. 7.1254-7.1261.

[727] In the approval procedure concerning NK603 maize (Exhibit EC-76) and conducted under Directive 2001/18, the Commission submitted a draft measure to the Council little over one month after the Regulatory Committee had failed to reach a qualified majority. At that meeting, Austria made a statement in support of its negative vote. Exhibit EC-76/At. 72. In the approval procedure concerning Bt-11 maize (Exhibit EC-92) and conducted under Regulation 258/97, the Commission adopted a draft measure and referred it to the Council less than two months after the Regulatory Committee had failed to reach a qualified majority. At that meeting, several member States made statements in support of their votes. Exhibit EC-92/At. 70.

[728] Article 21 of Directive 90/220 states in relevant part that "[i]f, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measure shall be adopted by the Commission".

MON809 maize (EC-83)

7.594 The application concerning MON809 maize was first submitted to the competent authority of France (lead CA) in December 1995, with the request for approval of both MON810 and MON809. In March 1996, a new application was submitted concerning only MON809. The application was forwarded to the Commission and to all member States in August 1996. A favourable opinion was issued by the SCP on 19 May 1998. Inter-service consultations were launched on 12 June 1998 and concluded on 19 July 1998. The consultation of the Regulatory Committee was launched on 4 September 1998, and closed on 23 October 1998 without a decision. On 22 April 1999, the Commission launched an internal procedure for the adoption by the Commission of a draft measure to be submitted to the Council, but this procedure was suspended on 29 April 1999. The application was withdrawn by the applicant on 4 October 2002.

7.595 The **United States** observes that this application was forwarded to the Commission with a favourable opinion from the lead CA, and that it received a positive opinion from the SCP. When the Regulatory Committee failed to reach a decision on the Commission's draft measure in October 1998, the Commission refused to submit the measure to the European Council as required by EC law. Because of the failure of the Commission to proceed with this application, the application was withdrawn in October 2002.

7.596 **Canada** notes that this product was assessed both under Directive 90/220 and under Regulation 258/97. The safety assessments undertaken by both the SCP and the Scientific Committee for Food (SCF) concluded that this product raised no concerns with respect to the environment or animal and human health.

7.597 The **European Communities** notes that after assessment by the SCP, the application was withdrawn by the applicant in October 2002. The applicant gave no reason for the withdrawal. The European Communities notes that an important number of applications have been withdrawn by the respective companies because of various commercial reasons and changes in strategies.

7.598 The **United States** argues that this failed application provides direct, compelling evidence of the existence of a general moratorium. This application languished in the approval process for years, for no apparent reason other than the moratorium, and the withdrawal evinces the applicant's frustration with the European Communities' suspension of its approval process. The United States further notes that there was no need to explicitly mention the delays in the notice of withdrawal. Over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Second, the companies have a strong incentive to maintain cordial relations with EC regulators, and saw no advantage of complaining to EC regulators about the length of the delays resulting from the moratorium.

7.599 **Canada** observes that given rapid advancements in the field of biotechnology, protracted delays in an approval process may cause products submitted for approval by 1998 to become obsolete. Also, given the considerable time and financial resources necessary to support an application, it may not be commercially justified to proceed with the application in the face of the legal uncertainty created by the moratorium. Canada argues that the sheer number of withdrawals (thirteen under Directives 90/220 and 2001/18 and six under Regulation 258/97) is evidence of the impact of the moratorium. Canada maintains that it is understandable in the circumstances that companies withdrawing applications did not cite undue delays in the processing of applications as reasons for the withdrawal. As companies have an interest in maintaining a good working relationship with the regulatory authorities responsible for approving their products, it is reasonable to expect companies to act with circumspection.

7.600 **Argentina** also argues that although applications received positive scientific opinions, favouring their approval, the procedure for their approval was stalled, and some had to be withdrawn. Argentina also considers that the silence of the applicants cannot be taken as evidence of satisfaction with the process, but rather was due to the applicants' concern with maintaining good relations with the approving authorities.

7.601 The **Panel** notes that six months following the failure of the Regulatory Committee to deliver an opinion on this application, on 22 April 1999, the Commission launched an internal written procedure for the adoption by the Commission of a draft measure to be submitted to the Council. This draft measure was for the approval of MON809. In circulating this proposal, the Commission noted that the applicant had undertaken to provide labelling of bags of seeds; to provide a detailed technical guide to purchasers of the seed; and to inform traders regarding the full product description of the modified seeds. Furthermore, the Commission noted that the applicant had developed a management strategy to minimize the development of insect resistance and had offered to inform the Commission and member States of the results of monitoring in this regard. However, one week later, on 29 April 1999, the Commission suspended the written procedure for approval, citing the need to verify the monitoring plan with respect to the development of insect resistance in light of the recommendations adopted in March 1999 by the SCP with respect to surveillance of resistance.[729]

7.602 The chronology of this application, as provided by the European Communities, indicates that additional questions were sent to the SCP, apparently in the context of the safeguard measure adopted by Austria with regard to MON810 maize.[730] Like MON809, MON810 is a modified Bt maize. No evidence has been provided of such additional questions, and by whom these questions were asked. However, in correspondence dated 15 June 1999, the applicant seeking the approval of MON809 maize submitted a further assessment of the likelihood of adverse effects on Lepidoptera species to the French competent authority, apparently in response to a request. The applicant noted that this evidence had previously been provided to the competent authorities of the United Kingdom in the context of the assessment of MON809 for food and feed safety.

7.603 On 24 September 1999, the SCP issued an opinion on Austria's safeguard measure on MON810. The Austrian competent authority had indicated that its safeguard measure was taken in light of a study which addressed possible adverse effects of pollen from genetically modified Bt maize on the monarch butterfly. The SCP considered the evidence available regarding potential undesired effects of the Bt toxin on non-target insects, including on the Lepidopteran species in Europe. The SCP evaluated this evidence not only with respect to MON810, but also with respect to other genetically modified maize lines which had previously been approved (Bt-176 and Bt-11), and with respect to products whose approval was pending, including MON809 and Bt-531 cotton. With respect in particular to MON809, the SCP noted that the protoxin had not been detected in pollen.

7.604 The SCP concluded that there was no reason to change its previous advice to the Commission on the Bt crops which it had previously evaluated. It recalled its previous statement that it would be sensible to conduct monitoring in post-release situations, and endorsed the practice of monitoring, with appropriate and adequately targeted methodology, the large-scale introduction of such crops in order to detect any deleterious impact on non-target insect populations. There was no specific reference in this regard to MON809.

7.605 Given this second favourable opinion by the SCP, it seems reasonable to assume that the Commission would rapidly have proceeded to submit a draft measure to the Council on MON809.

[729] Exhibit EC-83/At. 70.
[730] We discuss this safeguard measure below in Section VII.F of our Report.

This was not the case, however. Neither is there any indication that the applicant was requested to provide any further information on a monitoring plan for potential effects of MON809 on non-target insects. Indeed, there does not appear to have been any further action by the Commission on this application during the three years following the second favourable opinion of the SCP, and in October 2002 the applicant withdrew the application without citing a reason.

7.606 The Complaining Parties consider that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. It is pertinent to note in this regard that the Commission did not complete its suspended internal written procedure for the adoption of the draft measure to be submitted to the Council after the June 1999 declaration by the Group of Five countries. Following this declaration, and despite the favourable opinion of the SCP, the Commission had reason to believe that the Group of Five countries would act as a "blocking minority" in the Council, and that if that were to happen, the Commission would be required under Directive 90/220 to adopt the draft measure it submitted to the Council.[731] We recall that it is the contention of the Complaining Parties that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to discharge its responsibility under Directive 90/220 to complete approval procedures, in view of opposition to final approvals by the Group of Five countries. In our view, the Commission's failure, over a three-year period, to submit a draft measure concerning MON809 to the Council is consistent with the contention that the Commission made and followed such a decision.

7.607 We consider that the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application is not inconsistent with the Complaining Parties' assertion that the European Communities applied a general moratorium on approvals. As was pointed out by the Complaining Parties, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning MON809 maize.

7.608 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning MON809 maize to the Council after the September 1999 favourable opinion of the SCP is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

Transgenic tomato (EC-84)

7.609 The application concerning the Transgenic tomato is for the planting, growing, harvesting and processing of tomatoes into non-viable products and was first submitted to the competent authority of Spain (lead CA) in November 1996. In November 1997, the application was forwarded to the Commission with a favourable opinion from the lead CA, and circulated to all member States the following month. Another application regarding the same product was also submitted under Regulation 258/97 to the United Kingdom in March 1998 (EC-100). In June 1998, the SCP issued a favourable opinion indicating that there was no evidence that the production and consumption of the transgenic tomato was likely to cause adverse effects on human or animal health or the environment. According to the information provided by the European Communities, Commission inter-service consultations were concluded in October 1998. Consultation of the Regulatory Committee was launched in November 1998, and on 18 December 1998 the Regulatory Committee failed to reach a decision by qualified majority. In February 2002, the application was withdrawn.

[731] Article 21 of Directive 90/220 states in relevant part that "[i]f, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measure shall be adopted by the Commission".

7.610 The **United States** argues that despite favourable opinions from the lead CA and the SCP, when the Regulatory Committee failed to approve the Commission's draft measure, the Commission refused to submit the measure to the Council, as required by EC law. The United States maintains that this refusal to submit the measure to the Council is evidence of the existence of a general moratorium.

7.611 The **European Communities** notes that in the written procedure for a vote by the Regulatory Committee in December 1998, both Denmark and Italy voted in favour of approval of the transgenic tomato. The European Communities points to the fact that this application was withdrawn prior to the establishment of the Panel and that the applicant gave as the reason for the withdrawal "commercial re-positioning" following a merger with another company.

7.612 The **United States** argues that the application was withdrawn because of the European Communities' excessive delay in carrying out the approval process, despite the positive assessment from the SCP. The United States maintains that although a company may not have cited undue delays in its withdrawal letter, over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Furthermore, according to the United States, the companies had a strong incentive to maintain cordial relations with EC regulators and saw no advantage of complaining to EC regulators about the length of the delays, which the United States maintains results from the moratorium.

7.613 **Canada** argues that given rapid advancements in the field of biotechnology, protracted delays in an approval process may cause products submitted for approval by 1998 to become obsolete. Also, given the considerable time and financial resources necessary to support an application, it may not be commercially justified to proceed with the application in the face of the legal uncertainty created by the moratorium. Canada argues that the sheer number of withdrawals (thirteen under Directives 90/220 and 2001/18 and six under Regulation 258/97) is evidence of the impact of the moratorium. Furthermore, Canada maintains that it is understandable in the circumstances that companies withdrawing applications did not cite undue delays in the processing of applications as reasons for the withdrawal. As companies have an interest in maintaining a good working relationship with the regulatory authorities responsible for approving their products, it is reasonable to expect companies to act with circumspection.

7.614 **Argentina** argues that although applications received positive scientific opinions, favouring their approval, the procedure for their approval was stalled, and some had to be withdrawn. Argentina maintains that these withdrawals were the result of the moratorium. Argentina also considers that the silence of the applicants cannot be taken as evidence of satisfaction with the process, but rather was due to the applicants' concern with maintaining good relations with the approving authorities.

7.615 The **Panel** notes that although the Regulatory Committee failed to reach a decision by qualified majority in November 1998, the record of the votes (written procedure) indicates that no member State objected. France failed to submit a vote. Austria, Greece, Ireland, Luxembourg and Sweden abstained and statements were provided by Austria, Greece and Sweden. The Panel remarks that Austria's competent authority concurred that the "state-of-the-art" risk assessment "did not indicate any specific challenges to human health and the environment"; however, Austria suggested that any potential effects of large-scale cultivation be monitored "as generally agreed in discussions on the amendment of Directive 90/220/EEC", and that specific labelling requirements should be mentioned at least in the recitals.[732]

[732] Exhibit EC-84/At. 45.

7.616 On the other hand, the statement submitted by Greece consisted of a single sentence: "We support the idea of a 'Moratorium' for G.M.O.s as presented by some Member-States".[733] Sweden unsuccessfully requested an extension of the vote until the safety of the transgenic tomato as food had been assessed, to ensure co-ordination and coherence between decisions taken with regard to release into the environment and novel foods.

7.617 We note that within two months following the failure of the Regulatory Committee to reach a decision, the applicant provided clarification that the transgenic tomato was bred solely for the processing tomato industry and would not be available directly to consumers. Furthermore, on 23 September 1999, the Scientific Committee on Food (SCF) expressed a favourable opinion regarding the safety of processed products produced form the transgenic tomato in the context of Regulation 258/97 on novel foods.

7.618 We do not consider that any of the specific concerns identified by member States during the consultation of the Regulatory Committee pertain specifically to the safety assessment of transgenic tomatoes for cultivation and processing. Furthermore, all of the concerns previously identified by member States were addressed in the evaluations undertaken by the SCP and the SCF, and the European Communities has not argued that any substantive concerns were raised by any member State subsequent to these assessments. It could therefore be expected that the Commission would have submitted a draft measure to the Council "without delay" with respect to the applications for the cultivation and processing of transgenic tomatoes.

7.619 Indeed, the documentation provided to us indicates that the Commission began preparing a draft measure for submission to the Council in February 1999, and six months later, in August 1999, launched an internal written procedure for the adoption of the draft measure by the Commission. However, there is no indication that this draft measure was ever actually submitted to the Council, and no evidence of any Council action with regard to this application. The European Communities has provided no explanation for the failure to submit this draft measure to the Council, as required by Directive 90/220. No documentation has been provided with regard to any consideration of this application after the 23 September 1999 positive assessment by the SCF of the processed tomato products, until the withdrawal of the application under Directive 90/220 more than two years later, in February 2002.

7.620 The Complaining Parties consider that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. It is pertinent to note in this regard that the Commission did not complete its internal written procedure for the adoption of the draft measure to be submitted to the Council after the June 1999 declaration by the Group of Five countries. Following this declaration, and despite the favourable opinion of the SCP (and the SCF), the Commission had reason to believe that the Group of Five countries would act as a "blocking minority" in the Council, and that if that were to happen, the Commission would be required under Directive 90/220 to adopt the draft measure it submitted to the Council.[734] We recall that it is the contention of the Complaining Parties that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to discharge its responsibility under Directive 90/220 to complete approval procedures, in view of opposition to final approvals by the Group of Five countries. In our view, the Commission's failure, for a period of more than two years after launching its internal written

[733] *Ibid*.

[734] Article 21 of Directive 90/220 states in relevant part that "[i]f, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measure shall be adopted by the Commission".

procedure, to submit a draft measure to the Council is consistent with the contention that the Commission made and followed such a decision.

7.621 The European Communities points out that in November 1998, at the Regulatory Committee stage, Denmark and Italy voted in favour of approval of the transgenic tomato under Directive 90/220. In June 1999, these two member States became part of the Group of Five countries supporting a general moratorium. The votes by Denmark and Italy do not support the conclusion that there was systematic member State opposition to final approvals already as from October 1998, but they are not inconsistent with the application of a general moratorium at least as from June 1999.

7.622 Regarding the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application, we have already noted with respect to the application concerning MON809 maize that this is not inconsistent with the Complaining Parties' assertion that a general moratorium on approvals was in effect.

7.623 In light of the above considerations, we conclude that the Commission's failure after August 1999 to submit a draft measure concerning the cultivation and processing of the transgenic tomato to the Council is consistent with the Complaining Parties' assertion that at least as from June 1999 the European Communities applied a general moratorium on final approvals.

Failure by the Commission to re-convene the Regulatory Committee for a vote on a draft measure

7.624 In support of their assertion that the European Communities applied a general moratorium on approvals the Complaining Parties have pointed to a number of approval procedures in which the Commission failed to re-convene the Regulatory Committee for a vote on a draft measure, after the Regulatory Committee had met, but not taken a vote on the draft measure. We consider these approval procedures below, recalling that Article 21 of Directive 90/220 provides in relevant part that "[t]he representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter."

Falcon oilseed rape (EC-62)

7.625 The application concerning Falcon oilseed rape was first submitted to Germany (lead CA) in April 1996, and was provided to the Commission for circulation to all member States in December 1996. Following a positive opinion by the SCP concerning Falcon oilseed rape on 14 July 1998, the Commission launched inter-service consultations on a draft measure to be submitted to the Regulatory Committee on 4 September 1998. The Regulatory Committee met twice, on 29 October 1999 and on 9 March 2000, to consider the draft measure submitted by the Commission. At neither meeting was there a vote on the draft measure. The Regulatory Committee did not meet again to take a vote on the draft measure. On 17 October 2002, Directive 90/220 was repealed.

7.626 The **United States** initially argued that the Commission in this procedure did not submit a draft measure to the Regulatory Committee. Later, the United States argued that the Regulatory Committee twice failed to vote on a draft measure and that after the second attempt, the Commission never submitted a draft measure to the Regulatory Committee again. The United States also submits that in accordance with Article 21 of Directive 90/220, in the absence of action by the Regulatory Committee, the Commission was required to submit a draft measure, whether favourable or negative, to the Council. According to the United States, the Commission failed to do so for no other reason than the general moratorium.

7.627 **Canada** argues that this product was stalled at Community level for many years.

7.628 **Argentina** noted that the inter-service consultation phase effectively prevented all applications with positive scientific opinions in 1998, including Falcon oilseed rape, from moving forward. The application of Falcon oilseed rape was prevented from reaching the Regulatory Committee voting stage as of 4 September 1998 and until June and October 1999, where it was not voted on.

7.629 The **European Communities** argues that the United States is mistaken in saying that the Commission failed to submit a draft measure to the Regulatory Committee. The Commission launched a voting procedure in June 1999, and the Regulatory Committee met twice on the matter. The Regulatory Committee did not vote on 9 March 2000 because it came to the conclusion that further information was needed on the assessment of the effect of the new protein expressed by the GM plant on the biogeochemical cycle and the food chain, as well as the likelihood of spreading. The European Communities also states that in May 2001, the applicant modified the scope of its application, and that after that, the application proceeded with further submissions by the applicant of additional information.

7.630 The **United States** responds that the only information that could have been requested at the March 2000 Regulatory Committee meeting was the information requested by Italy concerning the effect of the transgenic product on the biogeochemical cycles, on the food chain and on the spreading of the gene due to the possibility of crossing between the GM and wild species. The United States points out in this respect that the applicant responded to Italy's request on 30 November 2000 even though, in the United States' view, Italy's request was not scientifically justified.

7.631 The **Panel** must first address the United States' understanding of Article 21 of Directive 90/220. Article 21 of Directive 90/220 states that if "no opinion is delivered" by the Regulatory Committee, the Commission must submit a draft measure to the Council. The United States suggests that after the March 2000 meeting of the Regulatory Committee, the Commission was required to submit another draft measure to the Regulatory Committee and/or was required to submit a draft measure to the Council.[735] The Commission in this case submitted a draft measure to the Regulatory Committee which was on the agenda of the October 1999 meeting. No vote was held on that measure at that meeting.[736] The record does not indicate that a different draft measure was on the agenda of the March 2000 meeting of the Regulatory Committee. Therefore, the Panel does not see what is the basis for the United States' argument that after the March 2000 meeting, there was a need for the Commission to submit another draft measure, or to re-submit the same draft measure, to the Regulatory Committee.

7.632 The Panel is also not persuaded that in the absence of a vote by the Regulatory Committee, the Commission was required to submit a draft measure directly to the Council. If that were the case, the Commission should have submitted a draft measure to the Council after the Regulatory Committee failed to vote on Falcon oilseed rape at its meeting in October 1999. Instead, the Commission convened another Regulatory Committee meeting in March 2000. In the Panel's understanding, the phrase "no opinion is delivered" is intended to refer to a situation where the

[735] US third written submission, paras. 107-108.
[736] Exhibit EC-62/At. 87.

Regulatory Committee votes on a draft measure, but fails to achieve the required qualified majority in favour or against the measure.[737]

7.633 The Panel agrees with the United States, however, that after the March 2000 meeting of the Regulatory Committee, it was for the Commission to take action. The next step indicated by Article 21 of Directive 90/220 was for the Commission to convene another meeting with a view to obtaining a vote on its draft measure.[738] Therefore, the question to be examined is why this did not happen.

7.634 There is no direct evidence on the record to show why the Regulatory Committee did not proceed to a vote on Falcon oilseed rape at the March 2000 meeting.[739] From other evidence before the Panel, two separate reasons can nevertheless be inferred. One reason appears to be a request for information from the Italian CA. That request was transmitted to the lead CA on 14 March 2000, and the lead CA forwarded it to the applicant.[740] The applicant provided the information requested to the lead CA on 13 November 2000. In its letter, the applicant notes that all the issues on which Italy requested more information "were indeed already addressed by the European Scientific Committee on Plants (SCP)" when evaluating the application in question and that they had also already been addressed in documents provided by the applicant in November 1999.[741]

7.635 The other reason for the Regulatory Committee's failure to vote appears to be a letter sent by the applicant to the Commission the day before the March 2000 Regulatory Committee meeting.[742] As can be gathered from a letter of 20 April 2000 by the German lead CA to the applicant[743], the applicant should have sent its letter to the lead CA rather than the Commission. The Commission apparently shared the applicant's letter with the lead CA at the March 2000 Regulatory Committee meeting, and the lead CA then distributed it to the other member States present at the meeting. According to the letter by the lead CA, the applicant's letter gave rise to confusion. The lead CA's letter states that it was unclear whether the applicant's letter sought to modify the application such that the product would no longer be placed on the market soon after the application was approved, but only as from 2003.[744] The lead CA notes that the uncertainty over the applicant's intentions meant that the decision had to be postponed so that clarification could be sought from the applicant. Consistent with this account, the lead CA's letter ends by asking the applicant for clarification. As

[737] *See* the result of the consultation of the Regulatory Committee by written procedure in the procedure concerning Bt cotton where member States voted, but the result was that the "Committee did not give an opinion on the measures" (emphasis omitted). Exhibit EC-65/At. 59.

[738] This is consistent with the "Summary of the Conclusions of the Committee at its [12th] Meeting on 29 October 1999" where it is stated that the "*Commission* informed delegates that the next meeting could be held on 8 December 1999". Exhibit EC-62/At. 87 (emphasis added). *See also* the Commission's note of 20 September 1999 to the member States, wherein it is stated that the "*Commission* is planning to hold the 12th meeting of the Regulatory Committee […] on 25 October 1999". Exhibit EC-63/At. 76 (emphasis added).

[739] The record contains a summary of the conclusions for the October 1999 Regulatory Committee meeting, but not for the March 2000 meeting.

[740] Exhibit EC-62/At. 95. This fax of 14 March 2000 from the Italian CA to the lead CA specifically "refer[s] to the conclusion of the last meeting of the Regulatory Committee meeting".

[741] Exhibit EC-62/At. 97.

[742] The record does not contain a copy of that letter.

[743] Exhibit EC-62/At. 96.

[744] According to the lead CA, the applicant's letter of 8 March 2000 expanded on a letter of 28 February 2000 which the applicant sent to the lead CA and which was subsequently forwarded to the other member States. The lead CA notes that while it had not itself understood the February 2000 letter as a request for a modification of the application, some uncertainty nevertheless arose in this respect once other member States became aware of the content of the letter. Exhibit EC-62/At. 96.

already pointed out, the lead CA's letter dates from 20 April 2000. From the record it appears that the applicant did not provide the requested clarification until 29 May 2001.[745] On the same date, the applicant provided the lead CA with a set of documents which it said confirmed that its application was already in line with the main provisions of Directive 2001/18, which had been adopted in March 2001.[746]

7.636 From the foregoing it would appear that as from the end of May 2001, when the applicant provided the clarification sought by the lead CA, the two above-mentioned reasons could no longer explain the Commission's failure to call another meeting of the Regulatory Committee for a vote on Falcon oilseed rape.[747] Directive 90/220 was not repealed until 17 October 2002. In the Panel's view, there would thus have been enough time to convene another Regulatory Committee meeting and for the Commission to adopt its draft measure in the event of a favourable vote.[748]

7.637 We note that the United States considers that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. It should be recalled that following the June 1999 declaration by the Group of Five countries, the Commission had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council. In this procedure, the Commission called two Regulatory Committee meetings after the June 1999 declaration by the Group of Five countries, but the Regulatory Committee did not vote on either occasion, and the Commission did not convene a third meeting. The Complaining Parties contend that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to discharge its responsibility under Directive 90/220 to complete approval procedures, in view of opposition to final approvals by the Group of Five countries. The Commission's failure to call a third Regulatory Committee meeting after May 2001 is consistent with the existence of such a decision by the Commission. The Commission could have considered that some member States simply did not wish to see the Commission call another vote on its draft measure. Or it could have considered that the Regulatory Committee would finally vote at the next meeting, but that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority and that the Commission would have to complete the procedure by adopting its draft measure.

7.638 In the light of the above considerations, we conclude that the Commission's failure to convene another Regulatory Committee meeting concerning Falcon oilseed rape after May 2001 is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

MS8/RF3 oilseed rape (EC-63)

7.639 The application concerning MS8/RF3 oilseed rape was first submitted to Belgium (lead CA) in September 1996, and was provided to the Commission for circulation to all member States in

[745] The applicant stated that once the application concerning Falcon oilseed rape was approved there would initially be large-scale releases in the European Communities that would remain limited to identified users. At the earliest as of 2003, there would be full commercial release of the product in question. Exhibit EC-62/At. 99.

[746] Exhibit EC-62/At. 98.

[747] As noted above, we are not aware of any other reasons.

[748] We note in this regard that the March 2000 Regulatory Committee meeting was held four months after the first Regulatory Committee meeting in October 1999 and that after that October meeting the applicant had also submitted additional information.

January 1997. Following a positive opinion by the SCP concerning MS8/RF3 oilseed rape on 19 May 1998, the Commission on 4 September 1998 launched inter-service consultations on a draft measure to be submitted to the Regulatory Committee . The Regulatory Committee met twice, on 29 October 1999 and on 9 March 2000, to consider the draft measure submitted by the Commission. At neither meeting was there a vote on the draft measure. The Regulatory Committee did not meet again to take a vote on the draft measure. On 17 October 2002, Directive 90/220 was repealed and replaced by Directive 2001/18.

7.640 The **United States** initially argued that the progress of the application concerning MS8/RF3 oilseed rape stalled when the Commission refused to submit a draft measure to the Regulatory Committee as required by the approval process. Later, the United States argued that the Regulatory Committee twice failed to vote on a draft measure, and that after the second attempt the Commission never submitted a draft measure to the Regulatory Committee again.

7.641 **Canada** argues that since the application went to the Community level, member States took approximately 12 months to put forth their objections to the application, and after the SCP issued its positive opinion on the application, the European Communities took another 12 months to address the recommendations contained in the SCP opinion, including a monitoring plan. Although the application was discussed at the Regulatory Committee in the summer of 1999, the Commission failed to submit a draft measure for a vote by the Regulatory Committee, and instead imposed the "interim approach". Canada notes that in August 1999 the applicant proposed to voluntarily agree to meet the requirements of the Council's June 1999 Common Position. On the basis of these commitments, the Commission invited the applicant to present its proposal to the Regulatory Committee in October 1999. However, while the Regulatory Committee again considered the proposal, it failed to hold a vote. Subsequently, the applicant made further proposals as a further attempt to address concerns expressed by member States. However, although the matter went yet again before the Regulatory Committee in March 2000, it failed to hold a vote.

7.642 Canada also points to the delay in the completion of the approval procedure following the failure of the Regulatory Committee to adopt the draft measure approving MS8/RF3 oilseed rape in March 2000. Canada notes in this regard the efforts made by the applicant to respond to further requests by the lead CA. Canada observes that while the lead CA finally accepted the applicant's proposed post-marketing monitoring plan and agricultural guidelines in May 2002, the European Communities provided no information to explain the delay between May 2002 and early January 2003, when the applicant submitted a further updated dossier under Article 35 of Directive 2001/18. As Directive 90/220 was repealed in October 2002, the application was effectively returned to the member State level, thus causing a 7.5- year delay in processing this application.

7.643 **Argentina** notes that the inter-service consultation phase effectively prevented all applications with positive scientific opinions in 1998, including MS8/RF3 oilseed rape, from moving forward. The application MS8/RF3 oilseed rape was prevented from reaching the Regulatory Committee voting stage until June and October 1999, where it was not voted on.

7.644 The **European Communities** argues that the United States is mistaken in saying that the Commission failed to submit a draft measure to the Regulatory Committee. The Commission launched a voting procedure in June 1999, and the Regulatory Committee met twice on the matter. The Regulatory Committee did not vote on 9 March 2000 because Italy raised scientific issues regarding the "effects of the transgenic product on the biogeochemical cycles and on food chains" and the likelihood of spreading. Italy's concerns reflected new information concerning the impact of herbicide regimes associated with cultivation of GM herbicide tolerant oilseed rape on biodiversity which had recently been made public at the time of the meeting. The European Communities further

states that in May 2001, the applicant modified the scope of its application, and that after that, the application proceeded with further submissions by the applicant of additional information.

7.645 **Canada** notes that Italy's questions had already been addressed in the application dossier and by the SCP. Further, the attempts to raise concerns about impacts of herbicide use on farmland biodiversity inappropriately linked concerns related to herbicide use to approval of a seed variety. Canada notes that 1) for all other seed varieties, seed approval legislation is distinct from the pesticide approval legislation; 2) herbicide use is one of many factors that may have an impact on farmland biodiversity; and 3) EC member States have actually authorized the use of glufosinate-ammonium for general use as well as for specific use on genetically modified herbicide-tolerant crops. Canada also counters that the European Communities fails to point out that the submission of further information by the applicant was necessary because the information requirements were either unclear or changing.

7.646 Canada further notes that at the same time that the Commission submitted a draft proposal to the Regulatory Committee in June 1999, the Environment Council adopted the "Common Position" and five EC member States issued their Declaration openly opposing the approval of any biotech product. The applicant voluntarily agreed to fulfill the requirements of the future legislation set out in the "Common Position".[749]

7.647 The **European Communities** maintains that in the summer of 1999, in view of the proposed modification of the legislation, and on the basis of the Common Position by the Environment Council, the applicant voluntarily committed to anticipate in its application a number of the additional requirements that the proposed modifications were meant to address. The applicant submitted undertakings and commitments on a number of issues including post-market monitoring, traceability and labelling. The lead CA, other member States' CAs and the Commission discussed commitments and undertakings by the applicant, and in particular monitoring plans, into 2002. By then, Directive 2001/18 had been approved and it was decided to continue the evaluation of the dossier under the old legislative regime provided that the provisions of the new Directive were taken into account by the applicant voluntarily and became legally binding. In February 2002, the lead CA asked the applicant to complete the dossier with required data on, *inter alia*, reference material concerning the events MS8 and RF3. The applicant did not reply in that year.

7.648 The **Panel** notes that after the March 2000 meeting of the Regulatory Committee, it was for the Commission to take action. The next step indicated by Article 21 of Directive 90/220 was for the Commission to convene another meeting with a view to obtaining a vote on its draft measure.[750] Therefore, the question to be examined is why this did not happen.

7.649 The record does not indicate why the Regulatory Committee did not proceed to a vote on MS8/RF3 oilseed rape at the March 2000 meeting.[751] One reason may have been a request for information from the Italian CA. Italy transmitted its request to the lead CA on 14 March 2000, and the lead CA then forwarded it to the applicant.[752] The applicant provided the information requested

[749] Exhibit EC-63/At. 72.

[750] This is consistent with the "Summary of the Conclusions of the Committee at its [12th] Meeting on 29 October 1999" where it is stated that the "Commission informed delegates that the next meeting could be held on 8 December 1999". Exhibit EC-62/At. 87 (emphasis added). *See also* the Commission's note of 20 September 1999 to the member States, wherein it is stated that the "Commission is planning to hold the 12th meeting of the Regulatory Committee […] on 25 October 1999". Exhibit EC-63/At. 76 (emphasis added).

[751] The record contains a summary of the conclusions for the October 1999 Regulatory Committee meeting, but not for the March 2000 meeting.

[752] Exhibit EC-63/At. 87. This fax of 14 March 2000 from the Italian CA to the lead CA specifically "refer[s] to the conclusion of the last meeting of the Regulatory Committee meeting".

by Italy to the lead CA on 13 November 2000. In its letter, the applicant notes that all the issues on which Italy requested more information "were indeed already addressed by the European SCP " when evaluating the application in question and that they were also already addressed in November 1999 documents provided by the applicant.[753] This communication was also circulated to all other CAs and the Commission. We further note that in response to a question from the Panel, one of the experts advising the Panel, Dr. Nutti, expressed the view that the request for further information was not necessary to ensure the conclusions for the safety assessment of the newly expressed protein in the food chain.[754]

7.650 In June 2001, the applicant sent a letter to the lead CA which clarified certain aspects of the application, including its scope. There is no indication that this clarification had been requested. However, the applicant's letter noted that following the March 2000 meeting of the Regulatory Committee the clarification appeared necessary.[755] In a separate letter of the same date, "following the revision of Directive 90/220/EEC", the applicant also submitted updated information to the lead CA, including an updated environmental risk assessment, a post-market monitoring plan, agricultural guidelines, additional information regarding identification and labelling and information for the public concerning the product in question.[756] The letter stated that this information confirmed that the application was already "in line with the main provisions" of Directive 2001/18, which had been adopted in March 2001. The letter requested the lead CA to inform the other member States about the new set of documents at the next Regulatory Committee meeting.[757] There is no indication that the lead CA ever forwarded the new documents to the other member States and to the Commission. A meeting of CAs was held two weeks after the applicant submitted the additional information, but the Panel has no information about what was discussed at that meeting. It is clear from the record, however, that the lead CA confirmed receipt of the new documents only in July 2001. The lead CA informed the applicant that it had forwarded the documents to the relevant scientific committee of the Belgian Biosafety Council (hereafter the "BBC") for an opinion.[758] No reason was given for why an opinion had been requested.

7.651 Regarding the clarification provided by the applicant in June 2001, we note that there is nothing in the record to suggest that the Commission was "waiting" for the June 2001 clarification. If the Commission was not waiting for that clarification, then it could not provide an explanation for the Commission's failure to re-convene the Regulatory Committee sometime between December 2000 and June 2001. On the other hand, if the Commission had been waiting for clarification from the applicant, it could be expected that the Commission would have inquired with the lead CA whether the applicant had provided clarification. There is no evidence that the Commission did so.

7.652 Regarding the updated information also provided by the applicant in June 2001, it is important to remember that the applicant provided that information, not pursuant to a requirement flowing from the provisions of Directive 90/220, but in an effort to convince member States to vote in favour of approving its application. Also, the lead CA had not been requested to offer an assessment of that additional information before transmitting it to the other member States and the Commission. Notwithstanding this, the lead CA requested an opinion of the BBC. However, it seems that for the BBC, it was not obvious that an opinion was needed. In November 2001, the BBC discussed the information in question. According to the minutes of the internal discussion, "no opinion on the part

[753] Exhibit EC-63/At. 88.
[754] Annex H, para. 331.
[755] Exhibit EC-63/At. 92.
[756] Exhibit EC-63/At. 91.
[757] *Ibid*.
[758] Exhibit EC-63/At. 93.

of the Biosafety Advisory Council was necessary prior to the forwarding of these documents to the European Commission; and in the past such additional information had already been sent straight to the Commission on several occasions."[759] However, as this was the first time a company had submitted a monitoring plan, agricultural guidelines and public dossier, the BBC "thought it advisable to ask the Biosafety Advisory Council to discuss these documents before forwarding them to the European Commission."[760] It was noted that in this way the relevant experts would have an opportunity to gain experience in the evaluation of such documents.[761]

7.653 We are not convinced that a lead CA assessment of the updated information was required before that information could be transmitted to the Commission and the other CAs, and that the Commission therefore needed to wait for the lead CA's assessment before re-convening the Regulatory Committee. Indeed, we recall that in the approval procedure concerning Falcon oilseed rape, a different lead CA did not find it necessary to make an assessment of additional information submitted by an applicant to document that its application was already in line with the main provisions of Directive 2001/18.

7.654 In any event, in the approval procedure concerning MS8/RF3 oilseed rape, the applicant replied to the last pending question of the BBC in early May 2002.[762] The record shows no further developments in this approval procedure until October 2002, when Directive 90/220 was repealed. Thus, there is no indication that the BBC ever provided its opinion on the June 2001 information to the lead CA. Even assuming that the Commission knew about the updated information of June 2001, and even assuming that it was justifiable in principle for the Commission to let the lead CA undertake some assessment of the information, it remained the Commission's responsibility to seek a vote by the Regulatory Committee on its draft measure. Yet even as the date of repeal of Directive 90/220 was approaching, the Commission apparently did not request the lead CA promptly to finish its assessment of the updated information and to circulate it together with that information so that a further attempt at completing the approval procedure under Directive 90/220 could be made.[763]

7.655 From the foregoing it would appear that at the very latest in the summer of 2002, once the applicant had replied to the last pending question of the BBC in May 2002, the Commission could have re-convened the Regulatory Committee for a vote on the application concerning MS8/RF3 oilseed rape. As Directive 90/220 was not repealed until 17 October 2002, we think there would have been enough time for the Commission to adopt its draft measure in the event of a favourable vote in the Regulatory Committee and for the lead CA to give its written consent.

7.656 The Complaining Parties consider that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium on the approval of biotech products. It should be recalled that following the June 1999 declaration by the Group of Five countries, the Commission had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council. In this procedure, the Commission called two Regulatory Committee meetings after the June 1999 declaration by the Group of Five countries, but the Regulatory Committee did not vote on either occasion, and the Commission did not convene a third

[759] Exhibit EC-63/At. 102.
[760] *Ibid*.
[761] *Ibid*.
[762] Exhibit EC-63/At. 108. The applicant also indicated readiness to follow a suggestion by the BBC regarding information to the public, subject to further clarification by the BBC.
[763] If the Commission did not know about the updated information submitted by the applicant in June 2001, then the existence of that information could not provide a justification for the Commission's failure to re-convene the Regulatory Committee after December 2000.

meeting. We recall that in the Complaining Parties' view, the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to discharge its responsibility under Directive 90/220 to complete approval procedures, in view of opposition to final approvals by the Group of Five countries. The Commission's failure to call a third Regulatory Committee meeting after May 2001 is consistent with the existence of such a decision by the Commission. The Commission could have considered that some member States simply did not wish to see the Commission call another vote on its draft measure. Or it could have considered that the Regulatory Committee would finally vote at the next meeting, but that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority and that the Commission would have to complete the procedure by adopting its draft measure.

7.657 In the light of the above considerations, we conclude that the Commission's failure to re-convene the Regulatory Committee for a vote on the application concerning MS8/RF3 oilseed rape in the summer of 2002 (at the latest) is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

RR fodder beet (EC-64)

7.658 The application concerning RR fodder beet was first submitted to Denmark (lead CA) in February 1997, and was provided to the Commission for circulation to all member States in October 1997. Following a positive opinion by the SCP concerning RR fodder beet on 23 June 1998, the Commission launched inter-service consultations on a draft measure to be submitted to the Regulatory Committee on 4 September 1998. The Regulatory Committee met twice, on 29 October 1999 and on 9 March 2000, to consider the draft measure submitted by the Commission. At neither meeting was there a vote on the draft measure. The Regulatory Committee did not meet again to take a vote on the draft measure. On 17 October 2002, Directive 90/220 was repealed.

7.659 The **United States** argues that the Commission failed to submit a draft measure to the Regulatory Committee. Later, the United States argues that the Regulatory Committee twice failed to vote on a draft measure and that after the second attempt, the Commission failed to re-submit a draft measure to the Regulatory Committee.

7.660 **Canada** argues that the Commission did not submit a draft measure for a vote by the Regulatory Committee, even though the lead CA issued a positive opinion on the application on 7 October 1997, the SCP issued a positive opinion on the application on 23 June 1998 and the applicant responded to all the questions posed by the lead CA on 27 April 1998.

7.661 **Argentina** noted that the inter-service consultation phase effectively prevented all applications with positive scientific opinions in 1998, including RR fodder beet, from moving forward. The application for RR Fodder beet was prevented from reaching the Regulatory Committee voting stage until October 1999, when it was not voted on.

7.662 The **European Communities** argues that the United States is mistaken in saying that the Commission failed to submit a draft measure to the Regulatory Committee. The Commission launched a voting procedure in June 1999, and the Regulatory Committee met twice on the matter – first in October 1999 and then in March 2000. The Regulatory Committee did not vote in October 1999 due to outstanding requests for information.

7.663 The **Panel** recalls that after the March 2000 meeting of the Regulatory Committee, it was for the Commission to take action. The next step indicated by Article 21 of Directive 90/220 was for the

Commission to convene another meeting with a view to obtaining a vote on its draft measure.[764] Therefore, we need to examine why the Commission did not do so.

7.664 There is no direct evidence on the record to show why the Regulatory Committee did not proceed to a vote on RR fodder beet at the March 2000 meeting.[765] One reason appears to be a request for information from the Italian CA. That request was transmitted to the lead CA on 14 March 2000, and the lead CA forwarded it to the applicant.[766] The applicant provided the requested information to the lead CA on 12 July 2000. In its letter, the applicant notes in regard to its answers to the questions raised by the Italian CA that "there are no new data in the document, only clarifications".[767] With its July 2000 letter, the applicant also provided data on molecular characterization which were apparently generated at the request of the United Kingdom's CA. The letter noted the applicant's understanding that the UK experts reached the conclusion that this data did not provide new information after they had reviewed a previously submitted data package which "addressed sufficiently the UK questions".[768]

7.665 The conclusion of the July 2000 letter states that, in the applicant's view, all objections raised by the CAs within the 60-day period provided for in Directive 90/220 had now been fully addressed. The applicant therefore requested the lead CA to inform all member States that the application dossier was complete and that a decision should be taken at Community level.[769] The applicant sent a copy of its July 2000 letter to the Commission.

7.666 There is no indication that the lead CA forwarded the new documents to the other member States. In fact, the issue of when the documents were to be forwarded was discussed in a meeting held between the lead CA and the applicant in January 2001.[770] In February 2001, the applicant suggested to the lead CA, in view of the "very volatile" EC regulatory context, that it forward the documents after the adoption of Directive 2001/18 (which came in March 2001) and the circulation of a Commission proposal on new EC rules concerning labelling and traceability (which came in July 2001).[771] However, the record shows that the lead CA did not follow the applicant's suggestion, and the documents were not provided to other member States while Directive 90/220 was still in force.

7.667 As noted earlier, the Commission received a copy of the applicant's July 2000 letter, and this letter addressed all outstanding issues. Notwithstanding this, even as the date of repeal of Directive 90/220 was approaching, the Commission apparently did not request the lead CA promptly to circulate the additional information provided by the applicant in July 2000 so that a further attempt at completing the approval procedure under Directive 90/220 could be made. We recall in this regard that it was the Commission's responsibility to seek a vote by the Regulatory Committee on its draft measure.

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[764] This is consistent with the "Summary of the Conclusions of the Committee at its [12th] Meeting on 29 October 1999" where it is stated that the "Commission informed delegates that the next meeting could be held on 8 December 1999". Exhibit EC-62/At. 87 (emphasis added). *See also* the Commission's note of 20 September 1999 to the member States, wherein it is stated that the "Commission is planning to hold the 12th meeting of the Regulatory Committee […] on 25 October 1999". Exhibit EC-63/At. 76 (emphasis added).

[765] The record contains a summary of the conclusions for the October 1999 Regulatory Committee meeting, but not for the March 2000 meeting.

[766] Exhibit EC-64/At. 116. This fax of 14 March 2000 from the Italian CA to the lead CA specifically "refer[s] to the conclusion of the last meeting of the Regulatory Committee meeting".

[767] Exhibit EC-64/At. 119.

[768] *Ibid*.

[769] *Ibid*.

[770] Exhibit EC-64/At. 120.

[771] *Ibid*.

7.668 From the foregoing it would appear that after July 2000, once the applicant had provided the additional information sought by the Italian CA, or at the latest as from the summer of 2001, when the Commission circulated its proposal for new EC rules on labelling and traceability, the Commission could have re-convened the Regulatory Committee for a vote on the application concerning RR fodder beet. Directive 90/220 was not repealed until 17 October 2002. In our view, there was thus enough time for the Commission to adopt its draft measure in the event of a favourable vote in the Regulatory Committee and for the lead CA to give its written consent.

7.669 The Complaining Parties consider that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium on the approval of biotech products. It should be recalled that following the June 1999 declaration by the Group of Five countries, the Commission had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council. In this procedure, the Commission called two Regulatory Committee meetings after the June 1999 declaration by the Group of Five countries, but the Regulatory Committee did not vote on either occasion, and the Commission did not convene a third meeting. We recall that, in the Complaining Parties' view, the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to discharge its responsibility under Directive 90/220 to complete approval procedures, in view of opposition to final approvals by the Group of Five countries. The Commission's failure to call a third Regulatory Committee meeting is consistent with the existence of such a decision by the Commission. The Commission could have considered that some member States simply did not wish to see the Commission call another vote on its draft measure. Or it could have considered that the Regulatory Committee would finally vote at the next meeting, but that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority and that the Commission would have to complete the procedure by adopting its draft measure.

7.670 In the light of the above considerations, we conclude that the Commission's failure to re-convene the Regulatory Committee for a vote on the application concerning RR fodder beet after July 2000 is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

Failure by the Commission to submit a draft measure to the Regulatory Committee

7.671 In support of their assertion that the European Communities applied a general moratorium on approvals the Complaining Parties have pointed to a number of approval procedures in which the Commission failed to submit to the Regulatory Committee a draft measure on the relevant applications. We consider these approval procedures below, recalling that Article 21 of Directive 90/220 provides in relevant part that "[t]he representative of the Commission shall submit to the committee a draft of the measures to be taken".

Transgenic potato (EC-67)

7.672 The application concerning Transgenic potato was first submitted to Sweden (lead CA) in August 1996, and was provided to the Commission for circulation to all member States in June 1998. Following a positive opinion by the SCP concerning the Transgenic potato on 18 July 2002, the Commission did not submit a draft measure to the Regulatory Committee. In October 2002, Directive 90/220 was repealed. The applicant submitted an updated application under Directive 2001/18 in January 2003, and it was provided to the Commission for circulation to all member States in May 2004.

7.673 The **United States** argues that after the Transgenic potato received a favourable opinion from the SCP, the Commission failed to submit a draft measure to the Regulatory Committee, with the consequence that the consideration of this application was suspended until the application was resubmitted under Directive 2001/18.

7.674 **Argentina** argues that the application concerning the Transgenic potato was stalled and hence never reached the Regulatory Committee stage. Argentina points out in this regard that after the favourable SCP opinion of July 2002, there was neither an inter-service consultation phase in the Commission nor any other movement until Directive 2001/18 entered into force.

7.675 The **European Communities** points out that the SCP in this procedure took more than three and a half years to assess the Transgenic potato. The European Communities submits that when the SCP issued its opinion in July 2002, Directive 2001/18 was about to enter into force and it was clear that the application had to be updated in the light of the new Directive.

7.676 The **Panel** understands the European Communities to argue that the Commission did not submit a draft measure to the Regulatory Committee because the SCP provided its opinion only three months before the date of repeal of Directive 90/220. This argument presents the issue whether the Commission could have reached the conclusion that three months would be insufficient to approve the application concerning the Transgenic potato.

7.677 Before the Transgenic potato could be approved, a number of procedural steps remained to be undertaken and completed. The Commission had to prepare a draft measure and submit it to the Regulatory Committee; the Regulatory Committee had to meet and vote on the draft measure; in the event of a favourable vote in the Regulatory Committee, the Commission had to adopt its draft measure; and finally, the lead CA had to give its written consent so that the product could be placed on the market[772]. In our assessment, it is possible that the Commission reached the conclusion that even if all relevant actors proceeded with a sense of urgency, the aforementioned steps could not all be completed within three months.[773] Similarly, it is possible that this was the reason why the Commission did not undertake any steps to move the process forward, *e.g.*, by launching inter-service consultations on a draft measure to be submitted to the Regulatory Committee.[774]

7.678 The United States and Argentina consider that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. The Complaining Parties contend that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to prevent the Group of Five countries from blocking the approval of applications. The fact that in the procedure concerning the Transgenic potato the Commission did not submit a draft measure to the Regulatory Committee is consistent with this contention. The Commission could have considered that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority and that the Commission would then have to complete the procedure by adopting its draft measure. As noted, however, the Commission's failure to forward a draft measure to the Regulatory

[772] Article 13(4) of Directive 90/220.

[773] We nevertheless note that in the procedure concerning NK603 maize, the Regulatory Committee voted on the application less than three months after EFSA issued its opinion. Exhibit EC-76/At. 72. This suggests that if indeed more than three months were necessary, in the best-case scenario, to complete the procedure, it might not have taken much more than that.

[774] From the evidence before us, it seems that unlike in other procedures (*see, e.g.*, Exhibits EC-62/At. 76; EC-65/At. 48), the Commission in this procedure did not launch inter-service consultations on a draft measure to be submitted to the Regulatory Committee.

Committee might also reflect the Commission's conclusion that even in the best of cases the application could not have been approved before the date of repeal of Directive 90/220.

7.679 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning the Transgenic potato to the Regulatory Committee following the issuance in July 2002 of the SCP's opinion is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

Liberator oilseed rape (EC-68)

7.680 The application concerning Liberator oilseed rape was first submitted to Germany (lead CA) in January 1998, and was provided to the Commission for circulation to all member States in January 1999. The SCP issued a favourable opinion on 30 November 2000. Following the issuance of the SCP opinion, the Commission did not submit a draft measure to the Regulatory Committee before Directive 90/220 was repealed. The applicant provided an updated application under Directive 2001/18 on 16 January 2003.

7.681 The **United States** argues that after Liberator oilseed rape received a favourable opinion from the SCP the Commission failed to submit a draft measure to the Regulatory Committee. The United States notes that this resulted in a two-year delay, since no action was taken on the application until November 2002 when the applicant was requested to provide an update in light of the entry into force of Directive 2001/18. The United States submits that there is no indication of any problem with the application during the two-year gap, nor of any additional information needed for final approval. According to the United States, the lengthy delay after the SCP opinion was issued provides compelling evidence of the existence of a general moratorium.

7.682 **Argentina** argues that the application concerning Liberator oilseed rape was stalled for two years and never reached the Regulatory Committee stage. Argentina points out in this regard that after the favourable SCP opinion of November 2000, there was neither an inter-service consultation phase in the Commission nor any other movement until November 2002.

7.683 The **European Communities** argues that the SCP opinion on Liberator oilseed rape recommended "an agreed code of practice for field management of the particular modified crop involving the active participation of the applicant to promote best practice by farmers".[775] The European Communities submits that contrary to what it had done in the parallel dossier on Falcon oilseed rape, the applicant did not present any proposal for a code of practice following the opinion of the SCP and that it did not manifest itself with the lead CA at all until the lead CA in November 2002 sent the applicant a letter reminding it of the need to up-date the application by January 2003.

7.684 The **Panel** understands the European Communities as asserting that the applicant in this case should on its own initiative and without a specific request by the lead CA have presented a code of practice for the field management of the Liberator oilseed rape and that the applicant's failure to do so explains the Commission's failure to submit a draft measure to the Regulatory Committee.

7.685 In considering the European Communities' assertion, the first thing to be noted is that it was the Commission, not the applicant, that requested an opinion from the SCP.[776] Accordingly, when the SCP stated that "[i]t is recommended that the introduction of herbicide tolerant crops should be

[775] Exhibit EC-68/At. 88.
[776] Exhibit EC-68/At. 86.

accompanied by […] an agreed code of practice for field management […]"[777], the SCP was in our understanding recommending that the Commission seek to agree on a code of practice with the applicant. However, there is no evidence that the applicant was ever requested by the Commission or the lead CA to propose a code of practice in accordance with the SCP's recommendation. We therefore see no reason to assume that it was for the applicant to take the initiative and prepare a response to the SCP recommendation.

7.686 The European Communities correctly points out that in the approval procedure concerning Falcon oilseed rape, the applicant wrote a letter to the Commission soon after the SCP had issued its opinion on the product in question. The applicant's letter refers to certain recommendations made by the SCP concerning optimal deployment in agriculture and indicates the applicant's intention to make available to users relevant information on management schemes.[778] However, there is nothing in the applicant's letter to suggest that the applicant was requested to respond to the SCP's recommendations. In the absence of a reference in the letter to a request or requirement, it may be assumed that the letter was sent at the applicant's own initiative. In our view, the letter at issue does not therefore support the EC argument that the applicant in the procedure concerning Liberator oilseed rape was supposed to present a proposal for a code of practice once the SCP had issued its opinion.

7.687 For the reasons set out above, we are not persuaded by the European Communities' explanation that the Commission did not submit a draft measure to the Regulatory Committee because it was waiting for the applicant to propose a code of practice. In any event, the fact that the applicant did not present a proposal in our view was not an obstacle to the Commission launching inter-service consultations on a draft measure. From the evidence before us, however, it seems that unlike in other procedures[779], the Commission in this procedure never even launched such consultations. This further undermines the EC assertion that the Commission was waiting for the applicant.

7.688 The SCP opinion in this procedure dates from November 2000. Directive 90/220 was not repealed until almost two years later. In our assessment, there was thus enough time for the Commission to launch and complete inter-service consultations on a draft measure to be submitted to the Regulatory Committee and for the Commission to adopt its draft measure in the event of a favourable vote in the Regulatory Committee.[780]

7.689 The United States and Argentina consider that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. The Complaining Parties contend that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to prevent the Group of Five countries from blocking the approval of applications. The fact that in the procedure concerning Liberator oilseed rape the Commission did not submit a draft measure to the Regulatory Committee is consistent with this contention. The Commission could have considered that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified

[777] Exhibit EC-68/At. 88.

[778] Exhibit EC-62/At. 75. In our view, it is doubtful that the applicant's statement of its intentions with respect to management schemes can be said to amount to a proposal for a code of practice, as the European Communities contends.

[779] *See, e.g.*, Exhibits EC-62/At. 76; EC-65/At. 48.

[780] We note, by way of example, that in the procedure concerning NK603 maize, the Regulatory Committee voted on the application less than three months after the EFSA issued its opinion. Exhibit EC-76/At. 72.

majority and that the Commission would then have to complete the procedure by adopting its draft measure.

7.690 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning Liberator oilseed rape to the Regulatory Committee following the issuance in November 2000 of the SCP's opinion is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

Bt-11 maize (EC-69)

7.691 The application concerning Bt-11 maize (EC-69) was first submitted to France (lead CA) in May 1996, and was provided to the Commission for circulation to all member States in May 1999. The SCP issued a favourable opinion on Bt-11 maize on (EC-69) 30 November 2000. Following the issuance of the SCP opinion, the Commission did not submit a draft measure to the Regulatory Committee. In October 2002, Directive 90/220 was repealed. Under the new Directive, the applicant submitted the updated application on 15 January 2003. As of the establishment of the Panel, the application was still under assessment under Directive 2001/18.

7.692 The **United States** argues that after Bt-11 maize (EC-69) received a favourable opinion from the SCP in November 2000, the Commission failed to submit a draft measure to the Regulatory Committee. The United States notes that, under the EC's approval system, the next step after the SCP favourable opinion should have been to submit the application for approval by the EC's Regulatory Committee, but that there is no action on the application for 2 years after the SCP opinion and instead the next entry is an "evaluation of updates by the lead CA" in October 2002, which is unexplained and unsupported by any exhibit or attachment. According to the United States, the lengthy delay after the SCP opinion was issued provides compelling evidence of the existence of a general moratorium.

7.693 **Argentina** argues that Bt-11 maize (EC-69) received a positive opinion from the SCP on 30 November 2000, but there was no further movement on the application until Directive 2001/18 took effect, and the application had to be resubmitted. The application was thus stalled for two years.

7.694 The **European Communities** argues that, after the SCP opinion, further discussions were held between the lead CA, the applicant and the Commission, and they went on until well into 2002. The European Communities notes in this respect that the SCP recommended a monitoring plan, and that the issue of the monitoring plan remained unsettled. The European Communities further points out that in May 2002 the applicant submitted additional information, including supplementary sequence information on the molecular characterisation of the Bt-11 line, taking into account the provisions of the new Directive, *inter alia* on monitoring, traceability and labelling.

7.695 The **United States** responds that the monitoring plan referred to in the SCP opinion is an Insect Resistance Management (IRM) plan, but that the SCP never recommended any changes to the applicant's proposed IRM plan. The United States also notes that the only other mention of monitoring was with respect to changes in field populations of non-target insects, but that the SCP did not request a monitoring plan on non-target insects, nor did it note any deficiency in the application. Moreover, the United States argues that nothing in the record indicates that EC regulators ever approached the applicant either to identify a problem, or to request additions to the application.

7.696 The **Panel** understands the European Communities as asserting that the Commission did not send a draft measure to the Regulatory Committee because, after the SCP opinion, the lead CA, the applicant and the Commission continued discussions on a monitoring plan well into 2002. The Panel

also understands the European Communities as asserting that the applicant submitted additional information in May 2002, just before the new Directive entered into force.

7.697 Regarding the monitoring plan, we note that the SCP, in its opinion concerning Bt-11 maize (EC-69), stated that "there is no evidence to indicate that the placing on the market for cultivation purposes of maize line Bt-11 […] is likely to cause adverse effects on human health and the environment", but nonetheless concluded that "[t]he SCP should be kept informed of the results of monitoring and research studies in Member States with particular regard to the development of insect resistance"[781]. The SCP, in another paragraph of its opinion, also states that "[s]uch monitoring [as developed by the Expert Group on Monitoring for Insect Resistance to Bt toxins] *should be* carried out in Bt-Maize and should provide an adequate framework to delay the onset of resistance in the target pest."[782]

7.698 Thus, while the European Communities is correct that the SCP recommended monitoring, it is important to recall that it was the Commission, not the applicant, that requested an opinion from the SCP. Accordingly, when the SCP expressed its interest in the implementation of a monitoring plan, the SCP was, in our understanding, addressing itself to the Commission, not the applicant. There is no evidence that the Commission or the lead CA ever requested the applicant to propose a monitoring plan in accordance with the SCP's opinion.

7.699 We note that the applicant submitted additional information in May 2002 which included a monitoring plan. However, as the European Communities itself has suggested, it appears this information was submitted with a view to updating the application in anticipation of the entry into force of the new requirements contained in Directive 2001/18.[783]

7.700 For the reasons set out above, we are not persuaded by the European Communities' explanation that the Commission did not submit a draft measure to the Regulatory Committee because the SCP recommended a monitoring plan and the proposal by the applicant remained unsettled. In any event, the fact that the SCP stated that monitoring should be carried out in our view was not an obstacle to the Commission launching inter-service consultations on a draft measure. From the evidence before us, however, it seems that unlike in other procedures, the Commission in this procedure never launched such consultations. This further undermines the EC assertion that the Commission did not forward a draft measure to the Regulatory Committee because the issue of the monitoring plan remained unsettled.

7.701 Regarding the additional information submitted by the applicant in May 2002, we have already observed that this information was apparently voluntarily submitted with a view to updating the application in anticipation of the entry into force of the new requirements contained in Directive 2001/18. There is no evidence that this additional information was submitted at the request of the Commission or the lead CA. In other words, there is no reason to believe that the Commission was waiting for this information. In our view, therefore, the May 2002 information does not explain the Commission's failure to submit a draft measure to the Regulatory Committee between November 2000 and May 2002.

7.702 We note that the SCP opinion in this procedure dates from November 2000. Directive 90/220 was not repealed until almost two years later. In our assessment, there was thus enough time for the

[781] Exhibit EC-69/At. 83.
[782] *Ibid*. (emphasis added).
[783] The European Communities provided the Panel with a list of the appendices submitted by the applicant, but not with the accompanying cover letter. Exhibit EC-69/At. 84.

Commission to launch and complete inter-service consultations on a draft measure to be submitted to the Regulatory Committee and for the Commission to adopt its draft measure in the event of a favourable vote in the Regulatory Committee.[784]

7.703 The United States and Argentina consider that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. The Complaining Parties contend that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to prevent the Group of Five countries from blocking the approval of applications. The fact that in the procedure concerning Bt-11 maize (EC-69) the Commission did not submit a draft measure to the Regulatory Committee is consistent with this contention. The Commission could have considered that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority and that the Commission would then have to complete the procedure by adopting its draft measure.

7.704 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning Bt-11 maize (EC-69) to the Regulatory Committee following the issuance in November 2000 of the SCP's opinion is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

GA21 maize (EC-78)

7.705 The application concerning GA21 maize (EC-78) (C/ES/98/01)[785] was first submitted to Spain (lead CA) in May 1998, and was provided to the Commission for circulation to all member States in June/July 1999. The SCP issued a favourable opinion on 22 September 2000. Following the issuance of the SCP opinion, the Commission did not submit a draft measure to the Regulatory Committee. In October 2002, Directive 90/220 was repealed. The applicant submitted an updated application to the lead CA under Directive 2001/18 on 15 January 2003. As of the establishment of the Panel, the application was still being assessed at Community-level deliberation under Directive 2001/18. On 15 September 2003, the application was withdrawn.

7.706 The **United States** argues that even though GA21 maize (EC-78) was forwarded by the lead CA to the Commission with a favourable opinion, and it also received a favourable risk assessment from the SCP, the consideration of this application was indefinitely suspended because the Commission refused to submit a draft measure to the Regulatory Committee.

7.707 **Canada** argues that GA21 maize (EC-78) received a positive opinion from the lead CA in May 1998 and the applicant answered all the questions posed by the lead CA. In addition, GA21 maize (EC-78) received positive opinion from the SCP in September 2000, the consultations with relevant member States were completed, and the scope of the application was reduced to exclude cultivation. Despite these facts, the Commission failed to submit a draft measure to the Regulatory Committee.

[784] We note, by way of example, that in the procedure concerning NK603 maize, the Regulatory Committee voted on the application less than three months after EFSA issued its opinion. Exhibit EC-76/At. 72.

[785] A separate application for approval of GA21 maize was submitted to the United Kingdom (*see* EC-85).

7.708 **Argentina** argues that once the SCP issued its favourable opinion on 22 September 2000, the procedure on this application was suspended. Upon the replacement of Directive 90/220 by Directive 2001/18, the application had to be re-submitted. However, the approval process has not made any progress since that time.

7.709 The **European Communities** argues that after assessment at both national and European Community level, the application was withdrawn by the applicant on 15 September 2003. The European Communities further notes that the applicant, in its withdrawal letter, gave three reasons for the withdrawal: *first*, the progress in the approval procedure of another Roundup Ready maize to a more advanced stage than the GA21 maize (EC-78) application; *second*, the introduction of the new regulations concerning commercialisation of GM products in the European Communities; and *third*, the change of the company's commercial priorities.

7.710 The **United States** responds that, once the SCP rendered a favourable opinion on 22 September 2000, all activity unexpectedly ceased at the Commission level and that there was no action or communication by the Commission on this application for the next 3 years, up to the time the application was finally withdrawn by the applicant on 15 September 2003. The United States adds that the only activity that occurred after the SCP's positive opinion was efforts by the applicant to re-start the process, including the applicant's voluntary offer in September 2001 to update the application (in the form of undertakings) to the requirements of the impending Directive 2001/18. Furthermore, the United States argues that although the applicant submitted all necessary supplementary information according to Directive 2001/18 to the lead CA on 15 January 2003, no action was taken in the following eight months, either by the lead CA or the Commission, to move the product towards consideration by the Regulatory Committee.

7.711 The United States argues that the application was withdrawn because of the European Communities' excessive delay in carrying out the approval process, despite the positive assessment from the SCP. The United States maintains that although a company may not have cited undue delays in its withdrawal letter, over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Furthermore, according to the United States, the companies had a strong incentive to maintain cordial relations with EC regulators and saw no advantage of complaining to EC regulators about the length of the delays, which the United States maintains results from the moratorium.

7.712 **Canada** argues that given rapid advancements in the field of biotechnology, protracted delays in an approval process may cause products submitted for approval by 1998 to become obsolete. Also, given the considerable time and financial resources necessary to support an application, it may not be commercially justified to proceed with the application in the face of the legal uncertainty created by the moratorium. Canada argues that the sheer number of withdrawals (thirteen under Directives 90/220 and 2001/18 and six under Regulation 258/97) is evidence of the impact of the moratorium. Furthermore, Canada maintains that it is understandable in the circumstances that companies withdrawing applications did not cite undue delays in the processing of applications as reasons for the withdrawal. As companies have an interest in maintaining a good working relationship with the regulatory authorities responsible for approving their products, it is reasonable to expect companies to act with circumspection.

7.713 **Argentina** likewise argues that although applications received positive scientific opinions, favouring their approval, the procedure for their approval was stalled, and some had to be withdrawn. Argentina maintains that these withdrawals were the result of the moratorium. Argentina also considers that the silence of the applicants cannot be taken as evidence of satisfaction with the

process, but rather was due to the applicants' concern with maintaining good relations with the approving authorities.

7.714 The **Panel** understands the European Communities to argue that after the SCP opinion, the application was being assessed according to the procedures. We recall that according to the procedures set out in Directive 90/220, after the issuance of the SCP opinion, it was for the Commission to submit a draft measure to the Regulatory Committee for a vote. The Commission did not do so, however. Indeed, it seems that unlike in other procedures[786], the Commission in this procedure never launched inter-service consultations on a draft measure.

7.715 We note that the SCP's favourable opinion stated that "[t]he applicant should however establish a monitoring plan to identify unexpected and unusual events and analyse grower experiences, in order to develop and implement any necessary changes in crop management practices in response to the results of monitoring."[787] However, as with the approval procedures we have considered earlier, there is no evidence that the Commission or the lead CA ever requested the applicant to propose a monitoring plan in accordance with the SCP's opinion. In January 2003, the applicant submitted an updated application, including a monitoring plan. But this information was submitted at the applicant's initiative, in anticipation of the entry into force of the new requirements contained in Directive 2001/18, and not because the applicant was requested to address the SCP opinion.[788] Therefore, there is no reason to believe that the Commission was waiting for the applicant to put forward a monitoring plan, or, indeed, to provide any of the other additional information submitted by the applicant in January 2003.

7.716 We note that four months after the SCP issued its opinion, in January 2001, the applicant sent a letter to the lead CA requesting that the scope of its application be limited to import only and no longer include cultivation.[789] In March 2001, the lead CA informed the Commission that it had no objection to the applicant's request.[790] There is no indication that the Commission opposed the applicant's request. While the scope of the application was relevant to the draft measure to be submitted by the Commission to the Regulatory Committee, the requested change of scope did not, in our view, present an obstacle to the Commission launching, or continuing, inter-service consultations on a draft measure.

7.717 Nor do we see a possible obstacle in the fact that Directive 90/220 was repealed in October 2002. Indeed, the SCP opinion in this procedure dates from September 2000. In our assessment, there was thus enough time for the Commission to launch and complete inter-service consultations on a draft measure to be submitted to the Regulatory Committee and for the Commission to adopt its draft measure in the event of a favourable vote in the Regulatory Committee.[791]

7.718 For the reasons set out above, we are not persuaded by the European Communities' assertion that the application concerning GA21 maize (EC-78) was being assessed according to the procedures until it was withdrawn by the applicant. The fact that the applicant's September 2003 letter withdrawing the application did not specifically state that the application was not being processed according to the procedures provided for in Directive 90/220, and that the letter did not specifically

[786] *See, e.g.*, Exhibits EC-62/At. 76; EC-65/At. 48.
[787] Exhibit EC-78+85/At. 90.
[788] Exhibit EC-78+85/At. 94.
[789] Exhibit EC-78+85/At. 91.
[790] Exhibit EC-78+85/At. 92.
[791] We note, by way of example, that in the procedure concerning NK603 maize, the Regulatory Committee voted on the application less than three months after the SCP issued its opinion. Exhibit EC-76/At. 72.

cite a general moratorium as a reason for the withdrawal of the application does not confirm the EC assertion. As we have noted in the context of our discussion of other approval procedures, the Complaining Parties have identified plausible explanations for why an applicant might not mention a moratorium in a withdrawal letter if a moratorium was in effect.

7.719 The Complaining Parties consider that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. We also recall that the Complaining Parties contend that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to prevent the Group of Five countries from blocking the approval of applications. The fact that in the procedure concerning GA21 maize (EC-78) the Commission did not submit a draft measure to the Regulatory Committee is consistent with this contention. The Commission could have considered that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority and that the Commission would then have to complete the procedure by adopting its draft measure.

7.720 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning GA21 maize (EC-78) to the Regulatory Committee following the issuance in September 2000 of the SCP's opinion is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

GA21 maize (EC-85)

7.721 The application concerning GA21 maize (EC-85) was first submitted to the United Kingdom[792] (lead CA) towards the end of 1997[793]. The lead CA forwarded the application to the Commission on 15 October 1999. The Commission circulated the application to all member States in December 1999. After receiving comments and objections from member States, the Commission did not submit a draft measure to the Regulatory Committee and the application was withdrawn by the applicant with a letter of 29 March 2001[794].

7.722 The **United States** argues that the Commission failed to submit a draft measure to the Regulatory Committee after completion of the MS consultation in February 2000.

7.723 **Canada** argues that the Commission failed to submit a draft measure to the Regulatory Committee after completion of the consultations with relevant member States in February 2000.

7.724 **Argentina** argues the procedure had taken 3 years and 5 months without the adoption of a definitive decision concerning its approval. According to Argentina, the application was submitted to the lead CA on 6 November 1997 under Directive 90/220 and still had not reached the Regulatory Committee stage when the Directive 2001/18 entered into force. The application was withdrawn on 29 March 2001.

7.725 The **European Communities** argues that after discussions between the lead CA and the applicant, the application was withdrawn by the applicant with its letter dated 29 March 2001. The

[792] *See also* the approval procedure concerning GA21 maize (Spain) (EC-78) above.
[793] The precise date on which the application was submitted to the United Kingdom is unclear from the information before the Panel.
[794] Exhibit EC-78/At. 93.

applicant referred to "the unexpected commercial constraints" and the parallel application for GA21 maize in Spain as justification for its withdrawal.

7.726 The **United States** maintains that although a company may not have cited undue delays in its withdrawal letter, over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Furthermore, according to the United States, the companies had a strong incentive to maintain cordial relations with EC regulators and saw no advantage of complaining to EC regulators about the length of the delays, which the United States maintains results from the moratorium.

7.727 **Canada** argues that given rapid advancements in the field of biotechnology, protracted delays in an approval process may cause products submitted for approval by 1998 to become obsolete. Also, given the considerable time and financial resources necessary to support an application, it may not be commercially justified to proceed with the application in the face of the legal uncertainty created by the moratorium.

7.728 Canada further argues that the sheer number of withdrawals (thirteen under Directives 90/220 and 2001/18 and six under Regulation 258/97) is evidence of the impact of the moratorium. Furthermore, Canada maintains that it is understandable in the circumstances that companies withdrawing applications did not cite undue delays in the processing of applications as reasons for the withdrawal. As companies have an interest in maintaining a good working relationship with the regulatory authorities responsible for approving their products, it is reasonable to expect companies to act with circumspection.

7.729 **Argentina** likewise argues that although applications received positive scientific opinions, favouring their approval, the procedure for their approval was stalled, and some had to be withdrawn. Argentina maintains that these withdrawals were the result of the moratorium. Argentina also considers that the silence of the applicants cannot be taken as evidence of satisfaction with the process, but rather was due to the applicants' concern with maintaining good relations with the approving authorities.

7.730 The **Panel** understands the European Communities to be asserting that the reason why the Commission did not forward a draft measure to the Regulatory Committee is that the applicant did not sufficiently respond to the comments and objections put forth by the member States.

7.731 The chronology provided to us by the European Communities indicates that some member States submitted comments, questions and objections on this application after it was circulated together with the lead CA's favourable assessment. The applicant on 17 February 2000 provided prompt responses to requests for additional information and for clarification from several member States.[795] On 18 February 2002, additional member States raised objections. These objections do not appear to have included new requests for information or clarification.[796] At any rate, there is no evidence that these objections were conveyed to the applicant and that the applicant indicated that it would respond to them. This is in contrast with the approval procedure concerning the GA21 maize application submitted to Spain (EC-78), in which the Commission sent to the applicant the substance of the objections by the member States and in which the applicant responded to them before the Commission sought an opinion from the SCP.[797]

[795] Exhibit EC-78+85/At. 41.
[796] Exhibit EC-78+85/Ats. 42-44.
[797] Exhibit EC-78+85/At. 77 and 79.

7.732 We note that in cases where member States raised objections to the approval of an application, the Commission routinely sought an opinion from the SCP before submitting a draft measure to the Regulatory Committee, even though there was no legal obligation under Directive 90/220 to do so.[798]. However, the Commission did not send this application to the SCP for review. In contrast, in February 2000, the parallel application submitted to Spain (EC-78) was already being reviewed by the SCP, for it had been sent to the SCP on 29 October 1999.[799] The SCP issued a favourable opinion on GA21 maize (EC-78) on 22 September 2000.[800] Even if it were assumed, *arguendo*, that the Commission saw no need to request an additional and separate SCP opinion on GA21 maize (EC-85) and was waiting for the SCP opinion on GA21 maize (EC-78), the fact remains that the Commission apparently did not launch inter-service consultations on a draft measure concerning GA21 maize (EC-85) even after the SCP had issued its opinion on GA21 maize (EC-78).

7.733 On 29 March 2001, the applicant withdrew its application. Since the last member State objections were filed already in mid-February 2000 and since, assuming it was relevant, the SCP opinion on GA21 maize (EC-78) was issued in September 2000, it is clear to us that the withdrawal of the application in March 2001 does not explain the Commission's failure to launch inter-service consultations and/or to forward a draft measure to the Regulatory Committee.[801]

7.734 The Complaining Parties consider that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. We also recall the Complaining Parties' contention that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to prevent the Group of Five countries from blocking the approval of applications. The fact that in the procedure concerning GA21 maize (EC-85) the Commission did not submit a draft measure to the Regulatory Committee is consistent with this contention. The Commission could have considered that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority and that the Commission would then have to complete the procedure by adopting its draft measure.

7.735 In our view, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application is not inconsistent with the Complaining Parties' assertion that the European Communities applied a general moratorium on approvals. As was pointed out by the Complaining Parties, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning GA21 maize (EC-85).

7.736 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning GA21 maize (EC-85) to the Regulatory Committee after the member States expressed their views on the dossier in February 2000 is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

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[798] EC reply to Panel question No. 133.

[799] Exhibit EC-78/At. 82.

[800] Exhibit EC-78/At. 90.

[801] We note, by way of example, that in the procedure concerning NK603 maize, the Regulatory Committee voted on the application less than three months after the SCP issued its opinion. Exhibit EC-76/At. 72.

T25 x MON810 maize (EC-86)

7.737 The application concerning T25 x MON810 maize was first submitted to the Netherlands (lead CA) in June 1998, and was provided to the Commission for circulation to all member States in May 1999. Following a positive opinion by the SCP concerning T25 x MON810 maize on 6 June 2000, the Commission did not submit a draft measure to the Regulatory Committee. In December 2002, the application was withdrawn.

7.738 The **United States** argues that, despite the SCP's favourable risk assessments, the Commission refused to submit a draft measure to the Regulatory Committee as required by EC law, which led to the withdrawal of the application on 12 December 2002.

7.739 The **European Communities** argues that, after assessment by the SCP, the application was withdrawn by the applicant by its letter dated 12 December 2002, which pointed to "entirely commercial reasons" as the justification for its withdrawal.

7.740 The **United States** argues that the application was withdrawn because of the European Communities' excessive delay in carrying out the approval process, despite the positive assessment from the SCP. The United States maintains that although a company may not have cited undue delays in its withdrawal letter, over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Furthermore, according to the United States, the companies had a strong incentive to maintain cordial relations with EC regulators and saw no advantage of complaining to EC regulators about the length of the delays, which the United States maintains results from the moratorium.

7.741 The **Panel** understands the European Communities as asserting that the Commission did not send a draft measure to the Regulatory Committee because, after the SCP opinion, the application was being assessed according to the procedures and then was withdrawn by the applicant.

7.742 We recall that according to the procedures set out in Directive 90/220, after the issuance of the SCP opinion, it was for the Commission to submit a draft measure to the Regulatory Committee for a vote. The Commission did not do so, however. Indeed, it seems that unlike in other procedures[802], the Commission in this procedure never launched inter-service consultations on a draft measure.

7.743 We further note that in contrast with other SCP opinions, the SCP opinion on T25 x MON810 maize did not contain any recommendation for monitoring.[803] Moreover, there is no evidence that the Commission had requested, and was waiting for, further information from the applicant. Accordingly, we are not persuaded by the European Communities' explanation that the application was being assessed according to the procedures until it was withdrawn by the applicant in December 2002.

7.744 The SCP opinion in this procedure dates from June 2000. Directive 90/220 was not repealed until more than two years later. In our assessment, there was thus enough time for the Commission to launch and complete inter-service consultations on a draft measure to be submitted to the Regulatory

[802] *See, e.g.*, Exhibits EC-62/At. 76; EC-65/At. 48.
[803] Exhibit EC-86/At. 66.

Committee and for the Commission to adopt its draft measure in the event of a favourable vote in the Regulatory Committee.[804]

7.745 The United States considers that the Commission's failure to act reflects the adoption by the European Communities of a general moratorium, that is to say, of a decision not to allow any application to proceed to final approval. We also recall the Complaining Parties' contention that the Commission was instrumental in the adoption and application of the alleged general moratorium and that it decided not to prevent the Group of Five countries from blocking the approval of applications. The fact that in the procedure concerning T25 x MON810 maize the Commission did not submit a draft measure to the Regulatory Committee is consistent with this contention. The Commission could have considered that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority and that the Commission would then have to complete the procedure by adopting its draft measure.

7.746 In our view, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application is not inconsistent with the Complaining Parties' assertion that the European Communities applied a general moratorium on approvals. As was pointed out by the United States, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning T25 x MON810 maize.

7.747 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning T25 x MON810 maize to the Regulatory Committee following the issuance in June 2000 of the SCP's opinion is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

Transgenic red-hearted chicory (EC-77)

7.748 The application concerning Transgenic red-hearted chicory was notified twice under Directive 90/220. The first application (C/NL/94/25) was submitted to the Netherlands (lead CA) in December 1994. This application was approved at the Community level in May 1996. In accordance with an agreement between the lead CA and the Commission, this approval covered only breeding activities, not food or feed uses. In March 2003, the applicant requested the withdrawal of the marketing approval for breeding activities and obtained the requested withdrawal on 24 April 2003.[805]

7.749 Following the 1996 approval for breeding activities, the applicant submitted an application (C/NL/94/25/A) under Directive 90/220 to the Netherlands and the Commission in September 1996 requesting that approval be extended to use of this product for human and animal consumption. At the time of the second application, the Regulation 258/97 had not been adopted, but subsequently, in April 1998, the applicant began the application process for this product under Regulation 258/97 as well, by submitting an application to the Netherlands. Under the Directive, the SCP issued a favourable opinion on Transgenic red-hearted chicory for food and feed use on 18 December 1998, whereas the Scientific Committee on Foodstuffs (SCF) did not complete its assessment.

[804] We note, by way of example, that in the procedure concerning NK603 maize, the Regulatory Committee voted on the application less than three months after the SCP issued its opinion. Exhibit EC-76/At. 72.

[805] Exhibit EC-77/Ats. 43 and 44.

7.750 The **European Communities** argues that the application concerning this product was introduced in the Netherlands in 1996 and that after assessment at both national and European Community level, the application was withdrawn by the applicant in April 2003. The applicant gave two reasons for the withdrawal: *first*, the absence of a market for these products; and *second*, the fact that the applicant preferred not to be associated with GMOs any longer.

7.751 The **United States** argues that in many cases the withdrawal of applications resulted from the applicant's frustration with the European Communities' suspension of its approval process, although the applicant may not have explicitly so indicated in it reasons for withdrawal. Over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. In addition, the companies have a strong incentive to maintain cordial relations with EC regulators, and saw no advantage of complaining to EC regulators about the length of the delays resulting from the moratorium.

7.752 **Canada** observes that given rapid advancements in the field of biotechnology, protracted delays in an approval process may cause products submitted for approval by 1998 to become obsolete. Also, given the considerable time and financial resources necessary to support an application, it may not be commercially justified to proceed with the application in the face of the legal uncertainty created by the moratorium. Canada argues that the sheer number of withdrawals (thirteen under Directives 90/220 and 2001/18 and six under Regulation 258/97) is evidence of the impact of the moratorium. Canada maintains that it is understandable in the circumstances that companies withdrawing applications did not cite undue delays in the processing of applications as reasons for the withdrawal. As companies have an interest in maintaining a good working relationship with the regulatory authorities responsible for approving their products, it is reasonable to expect companies to act with circumspection

7.753 **Argentina** also argues that although applications received positive scientific opinions, favouring their approval, the procedure for their approval was stalled, and some had to be withdrawn. Argentina also considers that the silence of the applicants cannot be taken as evidence of satisfaction with the process, but rather was due to the applicants' concern with maintaining good relations with the approving authorities.

7.754 The **Panel** begins its analysis by noting two factors which complicate the review of the procedure for the approval of the Transgenic red-hearted chicory under Directive 90/220. *First*, the food safety aspects of Transgenic red-hearted chicory were evaluated both under Directive 90/220 (EC-77) and under Regulation 258/97 (EC-97). A number of documents in the later stages of the application were filed in both approval procedures, which indicates that at a certain point in time, these applications began to be processed together. Many of the documents relating to the two applications are identical.[806] Hence, the evaluation of the approval procedure conducted under Directive 90/220 requires consideration of documentation submitted with the chronologies for both Exhibit EC-77 and EC-97.

[806] The following documents are identical: Exhibits EC-77/At. 93 and EC-97/At. 25 (on 14 November 2000); Exhibits EC-77/At. 94 and EC-97/At. 29 (on 11 June 2001); Exhibits EC-77/At. 95 and EC-97/At. 30 (on 18 June 2001); Exhibits EC-77/At. 97 and EC-97/At. 31 (24 July 2001). In addition, the document filed as Exhibit EC-97/At. 23 (on 10 July 2000) can be found amongst the documents filed as Exhibit EC-77/At. 93, and the document filed as Exhibit EC-77/At. 96 (12 July 2001) can be found amongst the documents filed as Exhibit EC-97/At. 31. Moreover, it appears that the entry "SCF review" (24 April 2001) in Exhibit EC-77 is the same as the entry "SCF additional request to the applicant" filed as Exhibit EC-97/At. 28.

7.755 *Secondly*, the same applicant submitted applications for Transgenic green-hearted chicory under both Directives 90/220 (EC-110) and Regulation 258/97 (EC-98) in parallel with the applications for Transgenic red-hearted chicory. The record for Transgenic red-hearted chicory overlaps substantially with that for Transgenic green-hearted chicory. In some cases the documentation submitted by the European Communities for a particular product actually provides information on two products. For example, on 23 April 1998, the Dutch Provisional Commission for Food Safety submitted to the European Commission a positive assessment[807] of both Transgenic green-hearted chicory and red-hearted chicory under the Directive 90/220. Yet this assessment was not included in the EC chronology for Transgenic red-hearted chicory.

7.756 Turning now to examine the procedure for the approval of the Transgenic red-hearted chicory under Directive 90/220, we note that the SCP evaluated feed and food safety aspects of this application under the Directive.[808] The SCP issued an opinion in December 1998, stating that "against the background of available knowledge, there is no evidence to indicate that the placing on the market of [red-hearted chicory] will cause adverse effects on human health and the environment".[809]

7.757 We recall that according to the procedures set out in Directive 90/220, after the issuance of the SCP opinion, it was for the Commission to submit a draft measure to the Regulatory Committee for a vote. The Panel notes that, in March 1999 after the SCP's favourable opinion, the Commission circulated an internal proposal for a draft measure to be submitted to the Regulatory Committee on which inter-service consultations were later launched.[810]. These consultations were closed on 26 May 1999.[811] The result of these consultations shows that one of the Commission services concerned expressed the view that the SCF needed to be consulted before the Regulatory Committee would be convened for a vote on the draft measure.[812] While it is clear from the record that the Regulatory Committee was not convened after the Commission completed its inter-service consultations, the record does not indicate that the Commission sought an opinion from the SCF.

7.758 However, documentation contained in Exhibit EC-97 concerning the procedure under Regulation 258/97 indicates that, in the meantime, the Commission had requested an evaluation by the SCF on 29 April 1999, as required by Article 11 of Regulation 258/97.[813] Exhibit EC-97 suggests that in September 2001 the applicant asked the SCF to suspend its assessment of the red-hearted chicory under Regulation 258/97.[814] Subsequently, in May 2003, the applicant requested the SCF to withdraw the dossier altogether.[815] Thus, it is clear that the SCF did not complete its assessment before September 2001, and it appears that it was no longer reviewing the application in question after that date.

7.759 There is no question that the Commission had enough time, once it had completed its inter-service consultations in May 1999, to submit its draft measure to the Regulatory Committee and to adopt its draft measure in the event of a favourable vote in the Regulatory Committee while Directive 90/220 was still in force. Based on the foregoing elements, it may be that the Commission decided not to convene the Regulatory Committee for a vote on its draft measure under

[807] Exhibit EC-110/At. 6.
[808] Exhibit EC-77/At. 86.
[809] *Ibid*., p. 5.
[810] Exhibit EC-77/Ats. 87 and 89.
[811] Exhibit EC-77/At. 90.
[812] *Ibid*.
[813] Exhibit EC-97/At. 19.
[814] Exhibit EC-97 contains no supporting document.
[815] Exhibit EC-97/At. 32.

Directive 90/220 until the SCF had completed its review of the Transgenic red-hearted chicory under Regulation 258/97.

7.760 Regarding the SCF's review of Transgenic red-hearted chicory, we note that in a communication to the SCF of 14 November 2000, the applicant expressed frustration with the progress of evaluation of the product, and in particular with a July 2000 request by the SCF for further information about substantial equivalence.[816] The applicant noted that much information had been provided to permit the determination of substantial equivalence between the transgenic chicory and conventional chicory, and expressed the view that "it does not make sense to continue year after year with experiments without having any indication that there is no substantial equivalence". The applicant also expressed concern that since the SCF had not indicated whether it would accept the new experiments as proposed by the applicant, "this might be a new reason for the SCF to ask the company to do new experiments after the proposed experiments have been finished". The total process would thus take at least three additional years, and the applicant indicated that the time necessary to conduct the required additional field trials would have negative financial implications. The applicant stressed that "the procedure, time, energy and costs are disproportionate compared to conventional breeding programs. This may lead to the conclusion that development and marketing of transgenic vegetable crops in the European Union do not have any opportunity." The applicant provided additional information from various years of field introductions to substantiate its claims of substantial equivalence, and requested that the SCF extract its conclusions and take decisions based on the information available at that time.

7.761 Five months after the communication from the applicant, in April 2001, the SCF informed the applicant that it would accept the data provided regarding field studies, and requested additional information regarding nutritional composition.[817] Dr. Nutti, one of the experts advising the Panel, considered that the information requested by the SCF regarding the nutritional composition was "important for the nutritional evaluation of the product".[818] The Panel accepts Dr. Nutti's view. But it is not convinced that the SCF's information request could not have been made at an earlier stage of the SCF's review. In response to the SCF's new request for information, the applicant indicated that it had not yet decided whether to execute additional experiments.[819] It expressed concern that the question regarding antibiotic resistance markers would need to be resolved before new experiments were started, and requested clarification regarding whether products containing antibiotic resistance markers would be permitted to enter the EC market after the entry into force of Directive 2001/18. In July 2001, the Commission indicated that the provisions of Directive 2001/18 did not include a general legal ban on antibiotic resistance marker genes as such but linked their phasing out to certain qualifiers.[820] The Commission also indicated that consideration of the applications for red-hearted chicory was suspended until the information requested by the SCF had been provided.[821] No further responses came from the applicant after the July 2001 clarifications by the Commission. As previously noted, in September 2001 the applicant asked the SCF to suspend its review of the red-hearted chicory.

7.762 We recall the Complaining Parties' assertion that the European Communities applied a general moratorium on final approvals between October 1998 and August 2003. We also recall the Complaining Parties' contention that the Commission was instrumental in the adoption and

[816] Exhibit EC-77/ At. 93.
[817] Exhibit EC-97/At. 28.
[818] Annex H, para. 762.
[819] Exhibit EC-77/At. 94. *See also* Exhibit EC-97/At. 29.
[820] Exhibit EC-77/At. 97. *See also* Exhibit EC-97/At. 31.
[821] *Ibid.*

application of the alleged general moratorium and that it decided not to prevent the Group of Five countries from blocking the approval of applications. It is pertinent to note in this regard that the Commission's failure to forward its draft measure concerning Transgenic red-hearted chicory to the Regulatory Committee coincided with the June 1999 declaration by the Group of Five countries. In this situation, the Commission could have considered that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure concerning Transgenic red-hearted chicory would not achieve the required qualified majority and that the Commission would then have to complete the procedure by adopting its draft measure. Therefore, the fact that in the procedure concerning Transgenic red-hearted chicory the Commission did not submit a draft measure to the Regulatory Committee is in principle consistent with the Complaining Parties' contention that a general moratorium on approvals was being applied.

7.763 We have said that the Commission may have decided not to convene the Regulatory Committee for a vote on its draft measure under Directive 90/220 until the SCF had completed its review of the red-hearted chicory under Regulation 258/97. If this was the case, this would neither confirm nor contradict the Complaining Parties' assertion that the Commission was instrumental in the application of a general moratorium on approvals. In our view, it would not confirm the Complaining Parties' assertion because the Commission might also have waited for the SCF opinion if no general moratorium was in effect at the time. We note in this respect the special and unusual circumstance that the food safety of Transgenic red-hearted chicory was being evaluated concurrently under both Directive 90/220 and Regulation 258/97. At the same time, we consider that the possibility that the Commission was waiting for the SCF opinion would not contradict the Complaining Parties' assertion because even if the SCF had completed its review, the Commission might still not have forwarded its draft measure to the Regulatory Committee.[822] This can be seen from the above-mentioned approval procedures, where the Commission failed to submit draft measures to the Regulatory Committee.

7.764 We note the European Communities' argument that the application concerning Transgenic red-hearted chicory was withdrawn in March 2003 without any reference to a moratorium. According to the information before the Panel, what the applicant did in March 2003 was to request the lead CA to withdraw its consent to the placing on the market of Transgenic red-hearted chicory. It is not clear why the applicant would have made a reference to a moratorium on approvals when it had already secured approval. Furthermore, we have seen no evidence of a withdrawal of the application submitted under Directive 90/220 for feed and food uses. At any rate, even if the application submitted under Directive 90/220 for feed and food uses had been withdrawn and the applicant had not specifically cited a general EC moratorium on approvals as a reason for the withdrawal, we think this would not be inconsistent with the Complaining Parties' assertion that the European Communities applied a general moratorium on approvals. As was pointed out by the Complaining Parties, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning Transgenic red-hearted chicory.

7.765 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning Transgenic red-hearted chicory to the Regulatory Committee following the completion of its inter-service consultations in May 1999 is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

[822] We note in this regard that after the applicant had asked the SCF in September 2001 to suspend its review of Transgenic red-hearted chicory under Regulation 258/97, the Commission did not transmit to the Regulatory Committee its draft measure in the approval procedure conducted under Directive 90/220. Exhibit EC-77 does not suggest that a similar request was made in the context of the procedure under Directive 90/220.

Delays at member State level

7.766 In support of their assertion that the European Communities applied a general moratorium on approvals the Complaining Parties have pointed to a number of approval procedures in which they say the member State to which the application was submitted – the lead CA – either did not complete its assessment of the relevant application or completed it with considerable delay. We consider these approval procedures below, recalling that Article 12(2) of Directive 90/220 provides that "[a]t the latest 90 days after receipt of the [application], the competent authority shall either: a) forward the dossier to the Commission with a favourable opinion, or b) inform the [applicant] that the proposed release does not fulfil the conditions of this Directive and that it is therefore rejected". Article 12(5) of Directive 90/220 further provides that "[f]or the purpose of calculating the 90-day period referred to in paragraph 2, any periods of time during which the competent authority is awaiting further information which it may have requested from the applicant shall not be taken into account".

7.767 Since some of the relevant lead CA assessments were made after the entry into force of Directive 2001/18, we further recall that Article 14(2) of Directive 2001/18 similarly provides in relevant part that "[w]ithin 90 days after receipt of the [application], the competent authority shall […] prepare an assessment report and send it to the [applicant]". Article 14(2) further provides that where the assessment report indicates that the product in question may be placed on the market, the competent authority shall "send its report […] to the Commission which shall, within 30 days of its receipt, forward it to the competent authorities of the other Member States". Article 12(4) provides in relevant part that "[f]or the purpose of calculating the 90 day period referred to in paragraph 2, any periods of time during which the competent authority is awaiting further information which it may have requested from the [applicant] shall not be taken into account".

Bt-531 cotton (EC-65)

7.768 In the approval procedure concerning Bt-531 cotton, the applicant submitted an updated application to the Spanish CA (lead CA) on 16 January 2003, in accordance with the requirements of Directive 2001/18. When the Panel was established on 29 August 2003, the lead CA had not yet forwarded the application to the Commission.

7.769 **Argentina** argues that although the applicant in January 2003 submitted an updated application in accordance with the requirements of Directive 2001/18, the application did not progress. Argentina submits that, as a result, as of the date of its first written submission – April 2004 – the application concerning Bt-531 cotton had been inactive for an additional period of 1 year and 3 months.

7.770 The **European Communities** submits that the application contained an incomplete monitoring plan. According to the European Communities, the lead CA is awaiting additional information on the post-marketing monitoring plan that it has requested with letters of August and October 2003. The European Communities argues that it cannot be responsible for the lack of diligence or failings of an individual applicant.

7.771 The **Unites States** responds that the argument by the European Communities that the applicant failed to provide an adequate monitoring plan under Directive 2001/18 is flatly wrong. The applicant had submitted an Insect Resistance Management (IRM) plan as part of its product stewardship, which was deemed "adequate" by the EC's own SCP back in 1998. According to the Unites States, that the application is being discussed at the "staff-level" under Directive 2001/18 – in this case at an arguably delayed pace and on questionable grounds – is entirely consistent with a moratorium adopted on a political level.

7.772 The **Panel** notes that the updated application was submitted to the lead CA in January 2003, and that more than seven months later, in August 2003, *i.e.*, when this Panel was established, the lead CA had not completed its initial assessment.

7.773 We recall that in accordance with Article 14(2) of Directive 2001/18, the lead CA should have prepared an assessment report within 90 days. The 90 days do not include any periods of time during which the lead CA is awaiting further information which it requested from the applicant. In the present case, the lead CA requested additional information in relation to the monitoring plan at the beginning of August 2003[823]. Before forwarding this request, the lead CA spent six and a half months evaluating the application without finishing its assessment report. As of the end of August 2003, the applicant had not provided the requested information.

7.774 The European Communities provides no explanation for the time taken by the lead CA in excess of the 90-day period, other than the assertion that the monitoring plan submitted by the applicant was incomplete. Moreover, the European Communities does not suggest that the alleged incompleteness somehow prevented the lead CA from evaluating other aspects of the application. Thus, the alleged incompleteness of the monitoring plan does not in any event explain why the evaluation of these other aspects led the lead CA to exceed the 90-day period.

7.775 As an additional matter, it must be kept in mind that the lead CA in this case was not examining the application concerning Bt-531 cotton for the first time. In November 1997, the lead CA forwarded the application to the Commission with a favourable assessment.[824] Moreover, in July 1998, the SCP provided its own assessment of the application.[825] While it is true that the lead CA in 2003 had to undertake an assessment in accordance with the partly new requirements of Directive 2001/18, it seems equally clear that the prior assessments rendered the lead CA's task considerably less complex than it would have been if the lead CA had had to undertake an assessment for the first time. Notwithstanding this fact, the lead CA in this case failed to complete its assessment within the prescribed 90-day period.

7.776 Furthermore, while there is no indication that Spain in 2003 was actively supporting a general moratorium on final approvals, we consider that the fact that by August 2003 the Spanish CA had already exceeded the 90-day period to complete its assessment under Directive 2001/18 is consistent with the existence of a moratorium on final approvals. Following the June 1999 declaration by the Group of Five countries, Spain had reason to believe that these countries would act as a "blocking minority" in the Regulatory Committee and the Council at least pending the adoption of new EC rules on labelling and traceability[826], and that, as in the case of some of the previously discussed approval procedures, the Commission might not complete the approval procedure in the face of systematic opposition by the Group of Five countries.

7.777 In the light of the above considerations, we conclude that the time taken by the Spanish CA to assess the application concerning Bt-531 cotton under Directive 2001/18 is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

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[823] Exhibit EC-65/At. 64.
[824] Exhibit EC-65/At. 4.
[825] Exhibit EC-65/At. 47.
[826] We note that Exhibit US-80, which contains an internal Commission note, suggests that several Group of Five countries in October 2001 expressed the view that new EC rules on labelling and traceability needed to enter into force before new biotech products could be approved. We note that Exhibit US-80 was also referred to by Argentina.

RR-1445 cotton (EC-66)

7.778 In the approval procedure concerning RR-1445 cotton, the applicant submitted an updated application to the Spanish CA (lead CA) on 16 January 2003, in accordance with the requirements of Directive 2001/18. When the Panel was established on 29 August 2003, the lead CA had not yet forwarded the application to the Commission.

7.779 **Argentina** argues that although the applicant in January 2003 submitted an updated application in accordance with the requirements of Directive 2001/18, the application did not progress. Argentina submits that, as a result, as of the date of its first written submission – April 2004 – the application concerning RR-1445 cotton had been inactive for an additional period of 1 year and 3 months.

7.780 The **European Communities** submits that the application contained an incomplete monitoring plan. According to the European Communities, the lead CA is awaiting additional information on the post-marketing monitoring plan that it has requested with letters of August and October 2003. The European Communities argues that it cannot be responsible for the lack of diligence or failings of an individual applicant.

7.781 The **Panel** notes that the updated application was submitted to the lead CA in January 2003, and that more than seven months later, in August 2003, *i.e.*, when this Panel was established, the lead CA had not completed its initial assessment.

7.782 We recall that in accordance with Article 14(2) of Directive 2001/18, the lead CA should have prepared an assessment report within 90 days. The 90 days do not include any periods of time during which the lead CA is awaiting further information which it requested from the applicant. In the present case, the lead CA requested additional information in relation to the monitoring plan at the beginning of August 2003.[827] Before forwarding this request, the lead CA spent six and a half months evaluating the application without finishing its assessment report. As of 29 August 2003, i.e. less than a month after that request, the applicant had not provided the requested information.

7.783 The European Communities provides no explanation for the time taken by the lead CA in excess of the 90-day period, other than the assertion that the monitoring plan submitted by the applicant was incomplete. Moreover, the European Communities does not suggest that the alleged incompleteness somehow prevented the lead CA from evaluating other aspects of the application. Thus, the alleged incompleteness of the monitoring plan does not in any event explain why the evaluation of these other aspects led the lead CA to exceed the 90-day period.

7.784 As an additional matter, it must be kept in mind that the lead CA in this case was not examining the application concerning RR-1445 cotton for the first time. In November 1997, the lead CA forwarded the application to the Commission with a favourable assessment.[828] Moreover, in July 1998, the SCP provided its own assessment of the application.[829] While it is true that the lead CA in 2003 had to undertake an assessment in accordance with the partly new requirements of Directive 2001/18, it seems equally clear that the prior assessments rendered the lead CA's task considerably less complex than it would have been if the lead CA had had to undertake an assessment for the first time. Notwithstanding this fact, the lead CA in this case failed to complete its assessment within the prescribed 90-day period.

[827] Exhibit EC-66/At. 64.
[828] Exhibit EC-66/At. 3.
[829] Exhibit EC-66/At. 43.

7.785 Furthermore, while there is no indication that Spain in 2003 was actively supporting a general moratorium on final approvals, we consider that the fact that by August 2003 the Spanish CA had already exceeded the 90-day period to complete its assessment under Directive 2001/18 is consistent with the existence of a moratorium on final approvals. Following the June 1999 declaration by the Group of Five countries, Spain had reason to believe that these countries would act as a "blocking minority" in the Regulatory Committee and the Council at least pending the adoption of new EC rules on labelling and traceability[830], and that, as in the case of some of the previously discussed approval procedures, the Commission might not complete the approval procedure in the face of systematic opposition by the Group of Five countries.

7.786 In the light of the above considerations, we conclude that the time taken by Spain to assess the application concerning RR-1445 cotton under Directive 2001/18 is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

RR oilseed rape (EC-79)

7.787 In the approval procedure concerning RR oilseed rape (EC-79), the applicant submitted an application to France (lead CA) on 21 May 1995. When Directive 90/220 was repealed on 17 October 2002, the lead CA had not yet forwarded the dossier to the Commission. The application was withdrawn on 15 January 2003.

7.788 The **United States** argues that this application was delayed at the member State level for more than 100 months. The United States submits that although the applicant in this procedure provided answers to all of the questions raised by the lead CA, the lead CA failed to approve the product under Directive 90/220. More specifically, the United States argues, based on the applicant's letter of withdrawal, that the lead CA refused to consider the application after February 1996, the date of the lead CA's last request for information.

7.789 **Canada** asserts that after responding to three iterations of questions, the applicant was informally advised that the lead CA would not be proceeding further with the assessment of the application. More particularly, Canada argues that since 1996, the lead CA has taken no further action to complete the approval procedure, meaning that this application was delayed at the member State level for more than 100 months. Canada acknowledges that some of the delays occurred prior to October 1998. Canada submits in this respect that whatever the motivation of France prior to October 1998, RR oilseed rape was the victim of the moratorium after October 1998. Canada further asserts that it was due to the inaction of the lead CA that the applicant on 7 July 1998 submitted a second application, this time to the Netherlands (application concerning RR oilseed rape (EC-70)). According to Canada, this demonstrates that if the delay caused by a particular lead CA is long enough, it has the effect of discouraging applicants from continuing with their applications.

7.790 The **European Communities** notes that the applicant in 2003 gave two reasons for the withdrawal of its application in January 2003: the prolonged inaction by the lead CA with respect to this application and the applicant's consequent focus on commercial activities outside of the European Communities. The European Communities also confirms, however, that a second application was filed in the Netherlands in 1998.

[830] We note that Exhibit US-80, which contains an internal Commission note, suggests that several Group of Five countries in October 2001 expressed the view that new EC rules on labelling and traceability needed to enter into force before new biotech products could be approved.

7.791 The **Panel** notes that in August 1996 the applicant provided additional information in response to a request of February 1996 from the French "Commission du génie biomoléculaire" (hereafter CGB).[831] The CGB apparently delivered a favourable opinion at the end of 1996.[832] There is no indication that after receiving the CGB's opinion at the end of 1996 the lead CA was waiting for further scientific advice or for additional information from the applicant. In fact, in mid-1997, the applicant wrote to the lead CA to inquire about the progress of the procedure, the modalities of transmission of the dossier to the Commission and the advisability of supplementing the dossier with further information prior to its forwarding to the Commission.[833] It appears that the lead CA never provided a formal response to the applicant's inquiry.[834]

7.792 The United States and Canada argue that the lead CA's failure to complete its assessment of RR oilseed rape (EC-79) is consistent with their view that as of October 1998 the European Communities applied a general moratorium, that is to say, a decision not to allow any application to proceed to final approval. The Panel considers that as of June 1999 the unexplained failure by the lead CA to complete its assessment supports the view of the United States and Canada. It is important to recall in this context that France is one of the Group of Five countries. The countries making up the Group of Five in June 1999 declared that they would use their powers under Directive 90/220 to prevent the approval of applications, pending the adoption of new EC legislation on labelling and traceability. The fact that France as the lead CA in this procedure delayed the completion of the assessment at member State level for several years is in accordance with the June 1999 declaration.[835]

7.793 In the light of the above considerations, we conclude that the failure by France to complete its assessment of RR oilseed rape (EC-79) is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

RR oilseed rape (EC-70)

7.794 In the approval procedure concerning RR oilseed rape (EC-70 – incidentally the same product as in EC-79 where the lead CA is the French CGB), the applicant submitted an application to the Netherlands ((lead CA) on 7 July 1998. When Directive 90/220 was repealed on 17 October 2002, the lead CA had not yet forwarded the dossier to the Commission. The dossier was forwarded to the Commission with a favourable assessment report on 16 January 2003, after the applicant had provided an updated application in accordance with Directive 2001/18.

7.795 The **United States** argues that this application was delayed at the member State level for more than four years. The United States submits that although the applicant in this procedure provided answers to all of the questions raised by the lead CA, the lead CA failed to approve the product under Directive 90/220. More specifically, the United States argues that the total time taken at the member State level for the initial review was 54 months (7 July 1998 to 22 January 2003), of

[831] Exhibit EC-79/At. 15.
[832] Exhibit EC-79/At. 30.
[833] Exhibit EC-79/At. 28.
[834] Exhibit EC-79/At. 30.
[835] In the approval procedure concerning Bt-11 maize (EC-69), France was also the lead CA. In that procedure, which was initiated in June 1996, France completed its assessment and forwarded the application to the Commission in early April 1999. Thus, that application was forwarded before the June 1999 declaration by the Group of Five countries. France was also the lead CA in the case of two other oilseed rape applications under Directive 90/220 – MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape. These applications were approved at Community level, but France subsequently withheld its consent to the placing on the market of the two products concerned.

which 12 months were taken by the applicant to respond to questions. The United States asserts that an additional 10 months of the total time taken were spent resolving confidentiality issues in relation to detection methods. Thus, according to the United States, the lead CA in this procedure took 32 months for its review instead of the 90 days referred to in Article 12 of Directive 90/220.

7.796 **Canada** notes that in February 2000, the Dutch State Institute for Quality Control of Agricultural Products (hereafter RIKILT-DLO), responsible for providing scientific opinions relating to feed safety, issued a favourable assessment of RR oilseed rape (EC-70). On 10 January 2001, the Dutch Committee on Genetic Modification (COGEM), responsible for providing scientific advice relating to human health and the environment, concluded its assessment with a favourable conclusion. In January 2003, the Netherlands CA published a favourable overall assessment report. Canada submits that the two-year delay by the Netherlands CA in completing its overall assessment report and forwarding it to the Commission is unjustified.

7.797 Canada further argues that the total time taken by the Netherlands to review this file was 54 months (7 July 1998 to 22 January 2003). Out of these 54 months, the applicant took a total of 12 months to respond to questions. Another 10 months were used for discussions of the confidentiality status of certain information submitted by the applicant beyond the legal requirements of the approval legislation then in force. Canada submits that even if the latter period of time were not taken into account in this calculation, the remaining 32 months are in stark contrast to the 90 days foreseen in Directive 90/220 for this procedural step. In Canada's view, it is reasonable to infer from this that in the light of the moratorium, the Dutch authorities were taking a decidedly go-slow approach.

7.798 The **European Communities** argues that in this procedure there was a continuous exchange of correspondence between the lead CA and the applicant until December 2002, when the applicant updated its application in accordance with the requirements of Directive 2001/18. The lead CA requested additional information on molecular characterization and on certain feed safety aspects, and exchanges regarding these issues continued until the year 2000. After the adoption of Directive 2001/18 in March 2001, the lead CA asked the applicant to provide information on a detection method as required under the new legislation. The applicant requested confidentiality status for the information to be provided. The lead CA initially did not accept the reasons provided for requesting that status and several letters were exchanged on the issue. The lead CA also requested reference material which again triggered a debate on confidentiality. The European Communities notes that these issues were only settled in the autumn of 2002. By that time, Directive 2001/18 had entered into force and the lead CA and applicant worked on up-dating the application according to Directive 2001/18. The European Communities points out that once the applicant had provided an update, the application moved immediately to the Community level. This indicates that all relevant steps had already been completed, and is inconsistent with the notion that a moratorium was in place.

7.799 The **Panel** understands from the record that in evaluating applications for placing on the market at the time in question, the Netherlands generally took into consideration the application submitted by the applicant, the advice from the COGEM, the opinion of the RIKILT-DLO, where applicable, and comments from other relevant parties. Based on this evaluation, a draft assessment report was then published and was open for public comments for a period of four weeks.[836] In the procedure concerning RR oilseed rape (EC-70), the RIKILT-DLO submitted its favourable opinion in February 2000[837]; the applicant was advised in March 2000 in an e-mail that no further technical

[836] Exhibit EC-70/At. 66, Summary of the evaluation carried out by the Netherlands Competent Authority (GT73), p. 3; *see also* Exhibit CDA-57.

[837] Exhibit EC-70/At. 66, Summary of the evaluation carried out by the Netherlands Competent Authority (GT73), p. 5; *see also* Exhibit CDA-57.

information for the risk assessment needed to be supplied[838]; and the COGEM provided its favourable advice on 10 January 2001.[839]

7.800 By January 2001 the Netherlands had spent over seven months evaluating RR oilseed rape (EC-70).[840] In other words, the Netherlands had already exceeded the 90 day time-period envisaged for this process in Directive 90/220. The European Communities suggests that all of the time taken until December 2002 when the applicant complemented its application in accordance with the requirements of Directive 2001/18 was necessary to resolve scientific and technical issues.[841] However, there is no indication that the COGEM provided its advice only in January 2001 because it needed to resolve scientific or technical issues. The COGEM met in September 1998 to discuss the application in question. This led to a request for additional information on molecular characterization, which was transmitted to the applicant also in September 1998.[842] The applicant provided the requested information in December 1998.[843] Yet the COGEM did not meet again to discuss the application and the additional information for another two years. The relevant meeting took place in December 2000, a month before the COGEM provided its final advice.[844]

7.801 In the light of the foregoing, the Panel considers that at the latest in March 2000, when the Netherlands CA confirmed to the applicant by e-mail that no further technical information needed to be submitted, the Netherlands CA could have had all the elements to complete its assessment report. The European Communities notes that the applicant submitted additional information in April and May 2000. It is correct that in the aforementioned e-mail of March 2000, the Dutch CA also noted that the legal name and registration of the applicant would need to be confirmed, and that the original application would need to be modified to take into account the additional information submitted in the course of the assessment process.[845] However, the Panel does not consider that the March 2000 e-mail from the Netherlands CA constituted a formal request for information which triggered a clock-stop.[846] In any event, in April 2000, the applicant did confirm its legal name and registration.[847] And in mid-May 2000, the applicant sent a draft document to the Netherlands CA to indicate how it intended to modify the original application and to ask for comments and suggestions.[848] The

[838] Exhibit EC-70/At. 18; Exhibit CDA-132.

[839] Exhibit EC-70/At. 66, Summary of the evaluation carried out by the Netherlands Competent Authority (GT73), p. 5; *see also* Exhibit CDA-57.

[840] The evidence on the record does not permit a precise determination of the period during which the clock was stopped. Nevertheless, it is clear from Exhibit EC-70 that the lead CA was assessing the application between 13 August 1998 and 25 September 1999; between 2 April 1999 and 17 August 1999; and between 18 November 1999 and 21 January 2000 when the RIKILT-DLO appears to have requested additional information (Exhibit EC-70/At. 17). These periods of time alone during which the clock was not stopped and which are but examples already add up to more than seven months.

[841] EC second written submission, para. 199.

[842] Exhibit EC-70/At. 7.

[843] Exhibit EC-70/Ats. 9 and 10.

[844] Exhibit EC-70/At. 17, p. 2 (in Dutch), Letter of 10 January 2001 by the COGEM to the Netherlands CA, p. 2. *See also* Exhibit EC-70/At. 66, Summary of the evaluation carried out by the Netherlands Competent Authority (GT73), p. 5.

[845] Exhibit EC-70/At. 18.

[846] Indeed, the chronology provided to the Panel by the European Communities does not describe the communication as such, which is in contrast to other entries in the chronology. Exhibit EC-70/At. 18.

[847] Exhibit EC-70/At. 19. In addition, the applicant sent some information which the European Communities acknowledges had already been transmitted to the lead CA. EC reply to Panel question No. 152.

[848] Exhibit EC-70/At. 21. The Panel fails to see a basis for the European Communities' contention that the relevant draft document was "a new element in the authorization process because it change[d] the terms of the application". Nor does the Panel think that Exhibit EC-70/At. 23 supports the conclusion that the lead CA was still "analys[ing] the update" in November 2000. EC reply to Panel question No. 152.

Netherlands CA replied that it would communicate its "findings" as soon as possible, probably within less than a fortnight.[849] This estimate demonstrates that the document submitted in mid-May 2000 did not call for a lengthy analysis by the Netherlands CA. Thus, it cannot be said that the additional information submitted in April and May 2000 precluded the Netherlands CA from proceeding to finalize its assessment report as from March 2000.

7.802 Even assuming that the COGEM could not have provided its advice before January 2001, once the COGEM had done so, the Netherlands CA had all the elements to complete its assessment report. Notwithstanding this, the Netherlands CA did not finalize its report at that point. Instead, on 12 March 2001 – on the day Directive 2001/18 was adopted – the Netherlands CA wrote to the applicant saying that in accordance with Directive 2001/18 a detection method "should be provided" to complete the dossier, "to be able to forward the dossier to the EU member states".[850] Although Directive 2001/18 was not to enter into force until October 2002, the applicant provided a detection method on 16 March 2001.[851] The applicant requested, however, that the detection method be treated as confidential. In May 2001, the lead CA asked the applicant to reconsider its request or else provide further substantiation. The lead CA also stated that in the absence of further substantiation by June 2001, it would take a decision with respect to the request.[852] In September 2001, after providing further clarification at the request of the lead CA and "in order to keep the approval process moving forward", the applicant agreed to disclose the protocol for the detection of RR oilseed rape (EC-70). But the applicant requested that the primer sequences in the protocol remain confidential until the first patent application was published.[853] In response, the lead CA again sought further substantiation. After receiving additional substantiation, the lead CA in January 2002 granted the request that the primer sequences should be treated as confidential. As is clear from the foregoing, 8 months were spent clarifying the confidentiality status of the detection method and primer sequences. While the applicant took a total of 3 and a half months to reply to the several requests for further substantiation, it must also be noted that in June 2001 the lead CA waited for more than a month after receiving further substantiation before it followed up with a request for yet more substantiation.[854] A similar situation arose in September 2001 when the lead CA waited for more than two months before following up with another request.[855]

7.803 In January 2002, the lead CA made a request, "according to the conditions as laid down in Directive 2001/18/EC", that the applicant should provide reference material to verify the primer sequences and detection method.[856] Two weeks later, the applicant informed the lead CA that it was sending the requested materials.[857] According to a statement by the Netherlands, the assessment report was completed before 17 October 2002 but was not forwarded to the Commission due to a change of government following general elections.[858]

7.804 It is clear from the foregoing that there are a number of elements which support the conclusion that the Netherlands could have completed its assessment much earlier than it did: (i) the COGEM apparently did not review information submitted at its request for more than two years, which delayed the finalization of the lead CA's assessment report since the lead CA as of March 2000

[849] Exhibit EC-70/At. 22.
[850] Exhibit EC-70/At. 23.
[851] Exhibit EC-70/At. 24.
[852] Exhibit EC-70/At. 26.
[853] Exhibit EC-70/At. 30.
[854] Exhibit EC-70/At. 28.
[855] Exhibit EC-70/At. 33.
[856] Exhibit EC-70/At. 35.
[857] Exhibit EC-70/At. 36
[858] Exhibit EC-70/At. 66, Statement of the Competent Authority of the Netherlands.

had all other technical information needed for its risk assessment; (ii) when the COGEM finally provided its advice in January 2001, the lead CA did not complete its assessment report but requested additional information based on the provisions of Directive 2001/18, even though the Directive had not yet entered into force; and (iii) during the eight-month exchange with the applicant over confidentiality issues, the lead CA caused delays by not following up promptly with its additional requests for clarification.

7.805 The United States and Canada do not assert that the Netherlands itself was an active participant in the alleged moratorium on approvals and that the time taken by the Netherlands to complete its assessment is a reflection of the Netherlands' support for the moratorium. Rather, their assertion is that the time taken by the Netherlands reflects the impact of the moratorium. The United States and Canada contend that the Netherlands was placed in a position of having to recognize the moratorium as a reality and that this affected the speed with which it conducted its assessment. In the view of the United States and Canada, the Netherlands knew that because of the alleged moratorium the speed of its assessment would have little impact on the eventual date of approval.[859]

7.806 Following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council. It is reasonable to assume that the Netherlands was also aware that in the approval procedures concerning Bt-531 cotton and RR-1445 cotton the Commission after May 1999 failed to discharge its responsibility inasmuch as it did not submit a draft measure to the Council. Consequently, the Netherlands could in our view have come to the conclusion that there was no realistic prospect that RR oilseed rape (EC-70) could be approved under Directive 90/220 in 1999 or at any point thereafter until the date of repeal of the Directive. The Netherlands' conduct is consistent with such a view. The COGEM did not provide its advice until shortly before the adoption of Directive 2001/18. Instead of completing its assessment report at that point, the Netherlands on the day of adoption of Directive 2001/18 requested the applicant to provide a detection method, even though the Directive would not enter into force for another 19 months. During the subsequent exchange with the applicant over the confidentiality of the detection method and primer sequences, there were further delays attributable to the lead CA. And even when the applicant provided the requested reference material in early February 2002, the assessment report was not promptly completed and forwarded to the Commission so that the application might still have been approved in the event of no objections within 60 days from other member States.

7.807 The European Communities correctly points out that once the applicant had provided an updated application in December 2002, the application was quickly forwarded to the Commission together with the lead CA's favourable assessment report. We also agree with the European Communities that this indicates that the assessment report was up-to-date in terms of the requirements of Directive 2001/18. But we do not agree that this undermines the claim that a moratorium on approvals was in place. In our view, the fact that under Directive 2001/18 the application promptly moved to the Community level rather supports the opposite view. This is the view that the Netherlands considered that for as long as Directive 2001/18 was not in force, the Group of Five countries and the Commission would prevent the final approval of the application in question, whereas after the entry into force of the new Directive, the application might eventually be approved, after the adoption of new EC rules on labelling and traceability.

7.808 In the light of the above considerations, we conclude that the time taken by the Netherlands to complete its assessment of RR oilseed rape (EC-70) is consistent with the Complaining Parties'

[859] US reply to Panel question Nos. 193-195; Canada's reply to Panel question No. 189.

assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

LL soybeans (EC-71)

7.809 In the approval procedure concerning LL soybeans (EC-71), the applicant submitted an application to Belgium (lead CA) on 28 September 1998. In September 1999, the applicant submitted an application for this same product to Portugal. We will discuss the latter application separately below. When Directive 90/220 was repealed on 17 October 2002, Belgium as the lead CA in the procedure here at issue had not yet forwarded the dossier to the Commission. The applicant updated the application on 15 January 2003. The applicant withdrew the application to Portugal in January 2003. The application to Belgium was withdrawn by the applicant on 29 June 2004. It is important to note as well that in November 1998 the applicant submitted to Belgium an application concerning LL soybeans (EC-93) for approval as a novel food under Regulation 258/97.

7.810 The **United States** submits that although the applicant in this procedure provided answers to all of the questions raised by the lead CA, the lead CA failed to approve the product under Directive 90/220.

7.811 **Argentina** claims that the application was delayed at the member State level for 68 months without a final decision on its approval. Argentina asserts that the European Communities neither processed the application nor conducted the required risk assessment. Argentina argues that there is no scientific justification for the suspension of the approval procedures, as the "initial reports" were not prepared, and considers this to be a "failure to consider" the application for LL soybeans (EC-71).

7.812 The **European Communities** provides three explanations for the delay at the member State level: (1) requests by the lead CA for further information during the period from September 1998 to 2001; (2) procedural problems arising from the fact that the applicant submitted an application for the same product in Portugal; and (3) delays caused by the applicant's lack of response to requests for additional information on 25 February 2003.

7.813 The **Panel** considers that in relation to Belgium's assessment of LL soybeans (EC-71) three separate time periods can be usefully distinguished: (1) the time period between the submission of the application to the Belgian CA and the concurrent submission in Portugal; (2) the time period between the submission of the concurrent application in Portugal and the repeal of Directive 90/220; and (3) the time period between the submission of the application under Directive 2001/18 and the applicant's withdrawal of the application.

7.814 In considering the first time period, we understand that in evaluating applications for placing on the market at the time in question, Belgium generally took into consideration the application submitted by the applicant and the advice from the Biosafety Council. Two months after the application was first submitted to the Belgian CA, the Biosafety Council requested a substantial amount of information[860] and the Belgian CA indicated that the approval process would be suspended until the requested information was provided.[861] In a response to this request the applicant noted that some information which was being requested by the Biosafety Council had already been submitted to the Ministry of Public Health.[862] In a later letter dated March 1999, the Biosafety Council acknowledged that the applicant had apparently submitted much of the requested information

[860] Exhibit EC-71/At. 4.
[861] Exhibit EC-71/At. 5.
[862] Exhibit EC-71/At. 12.

regarding herbicides and stated that the Belgian CA had passed this information directly to the High Health Council for evaluation.[863] In this same letter, the Biosafety Council stated that it was "of the opinion that the file [concerning the application submitted under Directive 90/220] in its present form (with addition of molecular data and after minor corrections) can be passed on to the European Commission with a positive opinion". Based on the advice by the Biosafety Council the Belgian CA in May 1999 asked for more information, including information on molecular characterization, nutritional analysis (concerning the approval procedure for LL soybeans (EC-93)) and herbicide aspects.[864] The applicant did not respond to the May 1999 request until July 2001.

7.815 The second time period begins with the submission by the applicant of a second application concerning LL soybeans (EC-81) to Portugal in September 1999. We note that in a communication to Belgium dated 1 December 2000, the applicant explicitly indicated its intention of maintaining dual applications.[865] In this letter the applicant also stated it would take all necessary measures to ensure that only one application would circulate at the Community level. On 5 December 2000, the Biosafety Advisory Council of the Belgian CA confirmed the continuation of the evaluation process in Belgium and requested that the applicant forward the questions posed by the Portuguese CA in the approval procedure concerning LL soybeans (EC-81) in order to complete the application dossier in Belgium.[866] On 5 September 2001, ten months after confirming the continuation of the evaluation process in Belgium, the lead CA (Belgium) indicated to the applicant that further evaluation of the application would be suspended until the applicant specified a single country to handle the application.[867] The applicant responded by asserting the maintenance of double concurrent applications.[868] No further exchanges appear to have occurred between the applicant and the lead CA until January 2003, when the applicant updated the application submitted to Belgium under Directive 2001/18. While there is no evidence on the record to confirm this, it appears that in view of the applicant's response the lead CA did not further assess the application concerning LL soybeans (EC-71) between October 2001 and January 2003.

7.816 In relation to the third time period, we note that after the applicant updated its application under Directive 2001/18 (15 January 2003) and withdrew its application in Portugal (27 January 2003), the Belgian CA acknowledged receipt of the updated application and requested further information regarding molecular characterization, detection methods and reference materials. The applicant provided preliminary informal answers regarding information for labelling requirements and detection methods in March 2003. There is no record of further exchanges between the applicant and the lead CA until the applicant withdrew the application in July 2004.

7.817 It is clear from the foregoing that the progress of this application was adversely affected notably by two elements. *First*, the applicant took more than two years to provide the information requested by the lead CA in May 1999. *Secondly*, the consideration of the application appears to have been suspended as from September 2001 as a result of the applicant's refusal to discontinue one of the two applications submitted under Directive 90/220.

7.818 Regarding the first element, we note that the United States and Argentina do not assert that at the time of the May 1999 request for additional information, Belgium was an active participant in the alleged moratorium on approvals. Indeed, we recall that in June 1999 Belgium was one of the Group

[863] Exhibit EC-71/At. 16.
[864] Exhibit EC-71/Ats. 17 and 22.
[865] Exhibit EC-71/At. 23.
[866] Exhibit EC-71/At. 24.
[867] Exhibit EC-71/At. 28.
[868] Exhibit EC-71/At. 29.

of Seven countries which declared, not that they would take steps to suspend further approvals, but that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. We consider that Belgium's May 1999 request for additional information could be a reflection of the precautionary approach referred to in the June 1999 declaration of the Group of Seven countries.

7.819 Regarding the second element, we note that the applicant was of the view that Directive 90/220 did not prevent it from filing identical applications to different lead CAs. It nevertheless acknowledged that this approach could give rise to procedural problems, and it therefore indicated that it would withdraw one of the two applications as soon as one of the applications was ready for transmission to the Commission. The Belgian CA appears to have considered that the approach followed by the applicant was either not permitted by Directive 90/220 or otherwise inappropriate. From the information before us it is not apparent that Belgium's position on this issue, which appears to have led it to suspend consideration of the application concerning LL soybeans (EC-71) under Directive 90/220, was a mere pretext for delaying the consideration of the application. We recall in this regard that Belgium indicated to the applicant that it would continue considering the relevant application if the applicant decided to discontinue the application submitted to Portugal. At the same time, it must be noted that a similar issue of parallel applications arose in the approval procedure concerning Bt-11 maize (EC-80). In that procedure, however, the lead CA (Spanish CA) did not appear to consider this a problem.[869]

7.820 Taking account of the foregoing, we consider that the aforementioned two elements do not in themselves provide direct confirmation of the existence of a general moratorium on final approvals. However, we note that the application concerning LL soybeans (EC-71) did not reach the Community level phase of the EC approval process prior to its withdrawal in April 2004. In other words, it never reached the procedural stage where the Group of Five countries and/or the Commission could have taken action to delay or prevent its final approval. Therefore, while it is recognized that the two above-mentioned elements which affected the progress of the application concerning LL soybeans (EC-71) at the member State level do not directly confirm that a general moratorium was in effect, the record on this case does not demonstrate that no moratorium on final approvals was in effect during the relevant time period.

7.821 In the light of the above considerations, we conclude that Belgium's failure to complete its assessment of the application concerning LL soybeans (EC-71) prior to August 2003 is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

LL soybeans (EC-81)

7.822 The application concerning LL soybeans (EC-81) was introduced in Portugal (lead CA) in 1999. The applicant withdrew the application on 27 January 2003. As already discussed, an application for the approval of LL soybeans under Directive 90/220 had been previously submitted to Belgium (EC-71, see above) and the evaluation of that application by Belgium was ongoing when the application in Portugal was withdrawn.

7.823 The **United States** claims that this application was delayed at the member State level.

7.824 **Argentina** asserts that in this case, the European Communities blocked the marketing of the product, given the suspension of, or failure to consider, the application. Argentina further notes that

[869] Exhibit EC-80/At. 12.

in the case of this product the European Communities neither processed the application nor conducted the required risk assessment. Argentina asserts that there is no scientific justification for the suspension of the approval procedures, as the "initial reports" were not prepared, and considers this to be a "failure to consider" the application for LL soybeans (EC-81).

7.825 The **European Communities** notes that after discussions between the lead CA and the applicant, the application was withdrawn by the applicant's letter of 27 January 2003. The product had been previously notified in Belgium, and the evaluation of that application in Belgium was ongoing.

7.826 The **Panel** notes that no dossier was submitted as evidence for this application with regard to the approval procedure in Portugal. We understand from the record that in evaluating applications for placing on the market at the time in question, Portugal's CA generally took into consideration the application submitted by the applicant and the advice from the Ministry of Agriculture, the Ministry of Health and the Institute for Experimental and Technological Biology (IBET).

7.827 In a December 1999 opinion on the application concerning LL soybeans (EC-81), the Ministry of Agriculture noted lack of information on environmental impacts and lack of region-specific studies.[870] In January 2000, the Ministry of Health noted that the application was not clear about whether there was an intention to cultivate this product, and that the molecular characterization provided was insufficient.[871] The Ministry of Health also noted the need to have a toxicological study of the associated herbicide. The Ministry of Health asked Portugal's CA to obtain clarification, and so in January 2000 Portugal's CA requested additional information from the applicant. In May 2000, the IBET, in the opinion it provided to Portugal's CA, noted several areas in which the analyses presented were somewhat incomplete and concluded that "having due regard to the grounds for caution and the need to clarify the abovementioned points in doubt, there do not, however, appear to be any objective reasons for regarding these soybeans as 'unsafe' to use, at least when compared with other equivalent products currently on the market".[872] Following IBET's advice, the Portuguese CA sought further clarification from the applicant in May 2000.

7.828 After a 16-month delay, in September 2001, the applicant responded to questions from the Ministry of Health and IBET, providing additional information on nutritional composition and molecular characterization.[873] In October 2001, the Portuguese CA acknowledged receipt of the information and indicated that the information would be assessed by the Ministry of Health and IBET.[874]

7.829 In November 2001, the Portuguese CA proposed to the applicant that it updates the application under Directive 2001/18, which had been adopted in March 2001. The Portuguese CA pointed out that its initiative was in accordance with a July 2000 proposal by the Commission whose aim it was "to allow the different Member States to vote on and approve, where appropriate, the Commission's proposals for decisions authorizing the placing on the market of notified products before the new Directive enters into force." The Portuguese CA's letter further notes that "although the requested reformulation of the application is voluntary, given the complex situation currently prevailing in Europe with regard to authorizations for the placing on the market of new genetically modified products we consider it to be absolutely necessary" in order to present the application for

[870] Exhibit EC-81/At. 2.
[871] Exhibit EC-81/At. 3.
[872] Exhibit EC-81/At. 6
[873] Exhibit EC-81/Ats. 7 and 8.
[874] Exhibit EC-81/At. 9

assessment by the member States.[875] The letter asked the applicant to let the Portuguese CA know whether it accepted the CA's proposal. The applicant responded that it would be providing the requested documentation as soon as possible.[876]. However, the applicant does not appear to have done so.

7.830 In January 2002, the Ministry of Health raised further questions particularly related to molecular characterization.[877] There is no record of a response from the applicant addressing this request for information. In January 2003, one year after the last request for information from the lead CA, the applicant withdrew the application citing "various reasons" for the withdrawal.[878]

7.831 It is clear from the foregoing that the progress of this application was adversely affected notably by two elements: (i) the time taken by the applicant to respond to the January and May 2000 requests for information and (ii) the failure of the applicant to update the application under Directive 2001/18, as proposed by the Portuguese CA in November 2001.

7.832 In considering Portugal's conduct, we note that the United States and Argentina do not assert that at the time of the January and May 2000 requests for additional information or in November 2001, Portugal was an active participant in the alleged moratorium on approvals. Indeed, Portugal was not one of the Group of Five countries. We also note that Portugal was not part of the Group of Seven countries which declared that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products.

7.833 Concerning Portugal's 2001 proposal that the applicant update its application in accordance with the requirements of Directive 2001/18, the first thing to be noted is that Portugal made it clear that doing so was voluntary. However, Portugal also indicated its view that, in view of the "complex situation currently prevailing in Europe", the update was "absolutely necessary" in order for the application to be approved at Community level. The reference to a "complex situation currently prevailing in Europe" could be a reference to a general moratorium on final approvals. Indeed, Portugal suggested that compliance with certain Directive 2001/18 requirements was a necessary condition for approval; it did not suggest that this would lead to approval. But the reference to a "complex situation" could also be a reference to the fact that there was opposition among member States to approving under Directive 90/220 applications which did not meet the main requirements of Directive 2001/18. We recall in this regard that already before Directive 2001/18 had been adopted, in June 1999, the Group of Seven countries stated that to the extent legally possible they wished to see applied the principles, especially regarding traceability and labelling, laid down in the Council's Common Position of June 1999 concerning the revision of Directive 90/220. Therefore, we consider that the November 2001 proposal of the Portuguese CA does not provide confirmation of the asserted fact that the European Communities at the time applied a general moratorium on final approvals. However, it is consistent with that assertion.

7.834 It should be added that as of January 2003, when it was withdrawn by the applicant, the application concerning LL soybeans (EC-81) had not reached the Community level phase of the approval procedure under Directive 90/220. In other words, it had not yet reached the procedural stage where the Group of Five countries and/or the Commission could have taken action to delay or prevent its final approval.

[875] Exhibit EC-81/At. 11.
[876] Exhibit EC-81/At. 12.
[877] Exhibit EC-81/At. 13.
[878] Exhibit EC-81/At. 15.

7.835 In the light of the above considerations, we conclude that the failure of Portugal to complete its assessment of the application concerning LL soybeans (EC-81) prior to January 2003, when the application was withdrawn, is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium on final approvals during the relevant period of time.

LL oilseed rape (EC-72)

7.836 The application concerning LL oilseed rape was submitted to the United Kingdom (lead CA) on 28 January 1999. When Directive 90/220 was repealed on 17 October 2002, the United Kingdom had not yet forwarded the dossier to the Commission. The applicant submitted an updated application on 13 January 2003 in accordance with Directive 2001/18. The application was still pending at the time of establishment of the Panel. It was withdrawn by the applicant on 26 March 2004.

7.837 The **United States** argues that this application was delayed at the member State level for more than four years. The United States submits that although the applicant provided answers to all of the questions raised by the lead CA, the lead CA nonetheless delayed and ultimately suspended consideration or failed to approve the product.

7.838 The **European Communities** argues that the lead CA requested some additional information after having initially received the application. After having received that information, the lead CA forwarded the dossier for a preliminary view to its scientific committee, the Advisory Committee on Releases to the Environment (hereafter ACRE). The ACRE found that the dossier not only showed inconsistent data on molecular characterization but was also generally "rather impenetrable". In December 1999, the dossier was sent back to the applicant for "substantial revision and clarification".

7.839 According to the European Communities, the applicant did not get back to the lead CA on this dossier for almost two years. Contact was only re-established towards the end of 2002 when the applicant inquired about what was needed to up-date the dossier under the new Directive 2001/18. The applicant sent some up-dated documents in January 2003, but not the full dossier. The lead CA requested completion of the up-dated application and the applicant provided further data, which required further clarifications and led the lead CA to suggest that the full dossier should be re-submitted. In March 2004, the applicant withdrew the pending application and submitted a new application a few days later. According to the European Communities, at the time of establishment of the Panel the new dossier was in the course of being assessed by the lead CA. The European Communities maintains that it cannot be responsible for delays arising at the instigation of the applicant.

7.840 The **Panel** understands from the record that the lead CA made some preliminary requests for additional information in the months following receipt of the application. Some, but not all, of the additional requests from the lead CA are included in the information provided to the Panel. For example, a letter from the lead CA dated 20 July 1999 requests that the applicant provide further information and clarification on points raised in an annex to the letter; however the annex has not been provided.[879] There is, moreover, no record of a response from the applicant to this request.

7.841 In November 1999, the lead CA apparently requested the ACRE to provide guidance to the lead CA as to where the application needed improvement and noted that the ACRE would be asked for formal advice only at a later stage. The preliminary advice by ACRE was that there were a number of inconsistencies in the molecular data provided, some deficiencies in the molecular studies

[879] Exhibit EC-72/At. 11.

and too much important material was in annexes rather than being in the core dossier. It was noted that the appropriate experimental data may have been supplied somewhere in the application dossier but it was not immediately obvious where it might be.[880] As advised by ACRE, the lead CA in December 1999 requested that the applicant undertake substantial revision and clarification of the dossier. The lead CA suggested a meeting with the applicant later in the same month to provide the applicant with some guidance. There is no evidence in the information before the Panel that such a meeting took place, and that the applicant provided what was requested in December 1999.

7.842 On 16 January 2003, the applicant submitted an updated application under Directive 2001/18 to the lead CA.[881] In acknowledging receipt of the updated application, the lead CA indicated, on 27 January 2003, that the dossier was still incomplete and information requested in July and December 1999 was still missing.[882] Further requests for clarifications or modification of the application were made by the lead CA in the first half of 2003, with responses apparently provided by the applicant in May 2003.[883] On 13 June 2003, the lead CA requested further clarifications and suggested that a complete version of the application be re-submitted.[884] On 26 March 2004, the applicant withdrew the application, saying that certain elements of that application were incomplete or out-of-date, and submitted a new one (C/GB/04/M5/4).[885] No information was provided to the Panel regarding the assessment of the new application.

7.843 It is clear from the foregoing that the consideration of the application concerning LL oilseed rape was delayed for almost two years between 2 December 1999 and the repeal of Directive 90/220 in October 2002, following a letter from the lead CA advising the applicant that the dossier required substantial revision and clarification. Based on the information submitted to us, we understand that this gap was caused by the failure of the applicant to provide the additional information and clarification requested in July and December 1999. However, the precise reasons for the failure of the applicant to respond to the information solicited by the lead CA in July and December 1999 are unclear.

7.844 We asked the experts advising us whether the information requested by the lead CA up to and in December 1999 was necessary to ensure that conclusions of the safety assessment were valid.[886] Dr. Nutti, the only expert who responded to this question, concurred that the deficiencies in the application as identified by the ACRE were such that the requested information was necessary for the safety assessment.[887]

7.845 Nonetheless, the circumstance that the applicant apparently never responded to the July and December 1999 requests for additional information is consistent with the existence of a moratorium on final approvals. Following the June 1999 declaration by the Group of Five countries and the failure by the Commission to complete some of the previously discussed approval procedures, we think the applicant could have believed that the application concerning LL oilseed rape would not be approved while Directive 90/220 was still in force.

7.846 Taking account of the aforementioned elements, we consider that the gap between December 1999 and October 2002 does not in itself provide direct confirmation of the existence of a general

[880] Exhibit EC-72/At. 12.
[881] Exhibit EC-72/At. 15.
[882] Exhibit EC-72/At. 16.
[883] Exhibit EC-72/Ats. 18 and 19.
[884] Exhibit EC-72/At. 28.
[885] Exhibit EC-72/At. 29.
[886] Annex H, Panel Question 29.
[887] Annex H, para. 600.

moratorium on final approvals. But in our view the gap is consistent with the contention that a general moratorium was in effect at the time.

7.847 Regarding the assessment of the application concerning LL oilseed rape under Directive 2001/18, we recall our earlier summary of relevant facts. These facts do not lead us to believe that the lead CA was deliberately delaying the consideration of this application. We also note in this respect that the United States does not assert that the United Kingdom was an active participant in the alleged moratorium on approvals. Indeed, the United Kingdom was not part of the Group of Five countries. However, as of August 2003, when this Panel was established, the application concerning LL oilseed rape had not reached the Community level phase of the approval procedure under Directive 2001/18. In other words, it had not yet reached the procedural stage where the Group of Five countries and/or the Commission could have taken action to delay or prevent its final approval.

7.848 In the light of the above considerations, we conclude that the failure of the United Kingdom to complete its assessment of the application concerning LL oilseed rape prior to August 2003 is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium on final approvals during the relevant time period.

BXN cotton (EC-73)

7.849 The application concerning BXN cotton was submitted to the Spanish CA (lead CA) in April 1999. When Directive 90/220 was repealed on 17 October 2002, the lead CA had not yet forwarded the dossier to the Commission. An updated application was submitted on 16 January 2003, in accordance with Directive 2001/18. According to the European Communities, the application was withdrawn after the establishment of the Panel.[888]

7.850 The **United States** argues that this application was delayed at the member State level for more than four years. The United States submits that although the applicant provided answers to all of the questions raised by the lead CA, the lead CA nonetheless delayed and ultimately suspended consideration or failed to approve the product.

7.851 The **European Communities** argues that the lead CA forwarded the dossier to its scientific committee, the National Biosafety Committee, which found that the dossier needed to be improved. A considerable amount of information was missing on issues such as compositional analysis, environmental impact, toxicity, nutritional analysis, and a number of points, such as scope, labelling proposal, etc., had to be clarified. The lead CA forwarded these comments to the applicant in July 1999.

7.852 According to the European Communities, after a first exchange of correspondence, the applicant did not respond to the lead CA for three years, until January 2003, when the company which produced the herbicide to which the cotton is tolerant informed the lead CA that it had assigned this pending application to another company. The new applicant company submitted an up-dated application in accordance with Directive 2001/18 on 16 January 2003.

7.853 The European Communities maintains that the lead CA forwarded the new dossier to the National Biosafety Committee, which found that there were deficiencies in the molecular characterization of the product. The lead CA forwarded these comments to the applicant in October 2003. In November 2003, the lead CA was asked by another company to clarify its request for

[888] There is nothing in the record to confirm this EC assertion.

additional information. The lead CA has provided these clarifications and asked for an explanation of the identity of the applicant. The European Communities notes that a response is still awaited.

7.854 The **Panel** begins its analysis by noting that despite its request in June 2004 that the European Communities provide complete documentation relating to the scientific assessments of all applications, the documentation provided in relation to this application is incomplete. None of the substantive information provided by the applicant, either with respect to the original application in May 1999 or with the resubmission of the application in January 2003, has been made available. This makes it very difficult to put into context the requests for clarification and for further information from the lead CA.

7.855 We note that the application was first submitted in May 1999, and in July 1999 the lead CA submitted questions and requested further information from the applicant. The applicant responded in September 1999, clarifying, *inter alia*, that the application was both for the import and processing of seeds of BXN cotton as well as for the cultivation of BXN cotton. Following the further examination of the application in January 2000 by the Spanish National Biosafety Committee, the lead CA requested further clarifications on some of the same issues in a communication dated 2 February 2000.[889] The applicant did not respond to this request before an updated application was submitted in January 2003 under Directive 2001/18.[890]

7.856 The communication from the lead CA in February 2000 made five points. One was to note that the National Biosafety Committee saw fit to request the Ministry of Agriculture to register the associated herbicide for use on this cotton product. Another was to instruct that references to the OECD in relation to the certification of varieties be deleted as not relevant. Two of the remaining points appeared to be related to food and feed safety concerns: that new analyses be conducted regarding the nitrilase level in cottonseed oil, and that the studies proposed on animals fed on feed derived from this product be conducted under normal livestock feeding conditions in Spain. The remaining point was to request rewording of the text with reference to gentamicine resistance. Although this would appear to be a concern about potential risks to human or animal health arising from antibiotic resistance, without the text of the application it is not possible to confirm that this is indeed a food safety issue.

7.857 The Panel asked the experts advising it whether the information requested by the lead CA up to and in February 2000 was necessary to ensure that conclusions of the safety assessment were valid.[891] The experts noted that only the table of contents of the actual submission by the applicant had been provided, and the response from the applicant. On the basis of this limited information, Dr. Nutti was of the view that the responses provided by the applicant in September 1999 appeared to be satisfactory as far as food safety was concerned. These responses provided clarification or explanations of information that presumably was contained in the original application.[892] Dr. Andow noted that the information previously requested by the lead CA was normally necessary to assess environmental risks, particularly those related to the cultivation of the plant. However, without the application itself, he could not determine to what extent relevant information may have already been provided by the applicant, or how much additional information might be necessary. Dr. Andow further observed that, according to the table of contents, only two pages of the text of the application were devoted to issues relating to environmental impact studies, herbicide or residue toxicity or

[889] Exhibit EC-73/At. 6.
[890] This is confirmed by Exhibit EC-73/At. 12.
[891] Annex H, Panel Questions 30 and 31.
[892] Annex H, para. 601.

ecotoxicity tests or proposals to manage, monitor and handle the crop to reduce the risk of herbicide resistance in weeds.[893]

7.858 An updated application was submitted in January 2003 under Directive 2001/18 and completed in March 2003. Again, the application itself has not been provided to the Panel. It seems that the application now concerned the importation of seed for processing, but not cultivation.[894] In August 2003, when this Panel was established, the application appears to have been under review by the National Biosafety Committee.[895]

7.859 It is clear from the foregoing that in this procedure a delay of more than two and a half years occurred between February 2000, when the lead CA requested clarifications, and October 2002, when Directive 90/220 was repealed. Based on the information submitted to us, we understand that this gap was caused by the failure of the applicant to provide the requested clarifications. However, the precise reasons for the failure of the applicant to respond to the lead CA's February 2000 request are unclear.

7.860 We recall that, due to incomplete information, the experts advising us were unable to express definitive views on whether the clarifications requested by the lead CA in February 2000 were necessary to ensure that conclusions of the safety assessment were valid. Nonetheless, the circumstance that the applicant did not respond to the February 2000 request is consistent with the existence of a moratorium on final approvals. Following the June 1999 declaration by the Group of Five countries and the failure by the Commission to complete some of the previously discussed approval procedures, we think the applicant could have believed that the application would not be approved while Directive 90/220 was still in force.

7.861 The European Communities has surmised that the failure to pursue this application may be due to the numerous changes in the ownership of the producing company as well as in the rights on the pending application. From information provided by the European Communities it appears that in 1999 and 2001, the applicant from the EU was merged with or taken over by other EU companies. Subsequently, in 2003, the lead CA was informed that the rights to the application had been transferred to a US company. It is unclear when the application was assigned to the relevant US company. Based on the information before us, we think it is conceivable that the aforementioned changes in ownership had an impact on the efforts made by the applicant in pursuit of its application.

7.862 Taking account of the aforementioned elements, we consider that the gap between February 2000 and October 2002 does not in itself provide direct confirmation of the existence of a general moratorium on final approvals. But in our view the gap is consistent with the contention that a general moratorium was in effect at the time.

7.863 Turning to Spain's assessment of the application concerning BXN cotton under Directive 2001/18, we note that the updated notification was submitted to Spain on 16 January 2003.[896] It was not until 14 February 2003, *i.e.*, almost one month later, that the lead CA requested the applicant to submit a summary of the application as required by Directive 2001/18.[897] The applicant provided such a summary on 19 March 2003, and thus the updated application appears to

[893] Annex H, paras. 604-612.
[894] Exhibit EC-73/At. 12.
[895] There is no information about when the application was submitted to the National Biosafety Committee.
[896] Exhibit EC-73/At. 8.
[897] Exhibit EC-73/At. 9.

have been complete as of that date.[898] The application was apparently forwarded to the National Biosafety Committee for an assessment, but as of August 2003 that assessment had not yet been completed. The record shows that the assessment was completed in September 2003.[899] From the record of the consideration of this application by the National Biosafety Committee, it is clear that the Committee had also been reviewing the applications concerning Bt-531 cotton and RR-1445 cotton, for which Spain was also the lead CA. However, we recall that pursuant to Directive 2001/18, the lead CA is to prepare an assessment report within 90 days after receipt of an application. It should also be noted in this connection that the National Biosafety Committee's assessment concerning BXN cotton is quite short *i.e.*, there is no indication that the preparation of the report itself required much time.

7.864 While there is no indication that Spain in 2003 was actively supporting a general moratorium on final approvals, we consider that the fact that by August 2003 Spain had already exceeded the 90-day period to complete its assessment under Directive 2001/18 is consistent with the existence of a moratorium on final approvals.[900] Following the June 1999 declaration by the Group of Five countries, Spain had reason to believe that these countries would act as a "blocking minority" in the Regulatory Committee and the Council at least pending the adoption of new EC rules on labelling and traceability[901], and that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries.

7.865 In the light of the above considerations, we conclude that the failure of the Spanish CA to complete its assessment of the application concerning BXN cotton under Directive 90/220 is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period. We further conclude that the time taken by Spain to assess the application concerning BXN cotton under Directive 2001/18 is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

Bt-1507 maize (EC-74)

7.866 The application concerning Bt-1507 maize (EC-74) was first submitted to the Netherlands CA (lead CA) in November 2000. The scope of the application was for import of maize for processing and for use as food and feed. A separate application was submitted to the Spanish CA for the cultivation of the product, which we hereafter refer to as the application concerning Bt-1507 maize (EC-75). We will discuss that application separately below. When Directive 90/220 was repealed on 17 October 2002, the Netherlands CA had not yet forwarded the dossier to the Commission. An updated application was submitted in November 2002 under Directive 2001/18. The lead CA completed its initial assessment of the application and submitted the application to the Commission on 15 August 2003.

7.867 The **United States** argues that this application was delayed at the member State level for several years, and was not submitted for a decision by the Regulatory Committee. The United States

[898] Exhibit EC-73/At. 10.
[899] Exhibit EC-73/At. 12.
[900] Since the application was not complete until March 2003, it would appear that the 90-day period started to run as of that time.
[901] We note that Exhibit US-80, which contains an internal Commission note, suggests that several Group of Five countries in October 2001 expressed the view that new EC rules on labelling and traceability needed to enter into force before new biotech products could be approved.

submits that although the applicant provided answers to all of the questions, the lead CA nonetheless delayed consideration of the product. The United States explicitly contests the justifiability of one of the information requests by the lead CA, as well as of a number of the objections raised by other member States following the circulation of the application by the Commission.

7.868 The **European Communities** argues that following receipt of this application, the lead CA requested additional information on molecular characterization, allergenicity and toxicity of CRY1F, and on labelling. Exchanges with the applicant on these issues went on until almost the end of 2002. In two instances, the applicant requested an extension of the time granted by the lead CA to submit further data or information. The applicant updated the application just after the entry into force of Directive 2001/18. After a further exchange on compositional data, a monitoring plan, and confidentiality of the detection method, the lead CA submitted the full application and its assessment report to the Commission in August 2003. Once the application reached the Community level, a considerable number of objections were raised by member States, including on environmental effects, the monitoring plan, molecular characterisation, sampling and detection methods, allergenicity and toxicity. The Commission forwarded the dossier to EFSA for an opinion in February 2004, together with a summary of the remaining objections from seven member States. The European Communities argues that the facts demonstrate that there was neither a suspension of consideration nor a failure to approve this product.

7.869 The **Panel** notes that there was frequent communication between the lead CA and the applicant on this application from the time the application was initially submitted under Directive 90/220 until the lead CA sent its assessment report to the Commission on 15 August 2003. Although extensive documentation was provided to us, it was presented in a manner which did not facilitate its consideration (some documents were reproduced up-side down or sideways, others mislabelled or duplicated, for others only the tables of content were provided).

7.870 The United States explicitly questions the justifiability of only one of the requests for additional information made by the lead CA, a request of 13 December 2001 for additional field trial data. Other US arguments concern objections and requests for additional information from other member States which were made subsequent to the establishment of the Panel and hence are not specifically taken into account.

7.871 We note that in response to the March 2001 request from the lead CA the applicant on 16 October 2001 provided field trials from Chile, France and Italy, which it considered representative for the cultivation areas exporting maize to the European Communities.[902] On 13 December 2001, the lead CA indicated that it was not convinced by the response and maintained its request. Specifically, the lead CA indicated that it was not convinced that these locations would be representative of locations exporting maize to the European Communities. It therefore requested that the applicant conduct additional field trials and provide compositional data for two consecutive growing seasons.[903] The applicant addressed this further request for additional field trials in its responses of 21 November 2002. It provided arguments as to why the results of the field trials for 1998/1999 from Chile, France and Italy should be considered to be sufficient, and also submitted the results of field trials for 1999/2000 from Bulgaria, France and Italy.[904] On 10 February 2003, the lead CA indicated that it accepted this response, but requested that the data provided from the field trials in Chile be

[902] Exhibit EC-74/At. 33.
[903] Exhibit EC-74/At. 52.
[904] Exhibit EC-74/At. 65, response to Panel Question 3.

presented in the same detail and manner as for France and Italy, and suggested a format.[905] This was apparently done by the applicant on 24 March 2003.[906]

7.872 The United States argues that when the lead CA on 13 December 2001 rejected the applicant's compositional data from field trials that had been conducted in France, Italy and Chile, on the grounds that these locations were insufficiently representative of locations exporting maize to the European Communities, the lead CA provided no explanation for its conclusion that the locations were "insufficiently representative." The United States argues that the data provided by the applicant in October 2001 would generally be considered "representative" and relevant for evaluating maize that might be imported into the European Communities. The United States maintains that, in the absence of some further explanation, such as an anomaly in the submitted data, the only explanation for the lead CA's request for additional field trials of 13 December 2001 appeared to be the resulting two-year delay caused by the time it would take for the applicant to generate the data.

7.873 We sought advice from the experts advising us as to whether the field trials in France, Italy and Chile would provide compositional data on maize kernels that would be relevant to evaluating cultivation areas exporting maize to the European Communities. Dr. Nutti drew attention to the Codex Alimentarius *Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*[907] which state that the location of the trials sites should be representative of the range of environmental conditions under which the plant varieties would be expected to be grown. The number of trial sites should be sufficient to allow accurate assessment of compositional characteristics over this range. Similarly, trials should be conducted over a sufficient number of generations to allow adequate exposure to the variety of conditions met in nature.

7.874 Dr. Nutti considered that the field tests in France, Italy and Chile could be considered as supplementary information to previous tests carried out by the applicant, although she did not consider that they were necessary, in particular since the maize in question was for importation and processing and not for cultivation.[908] Dr. Andow noted that it was likely that for some industrial uses of maize, *e.g.*, as biofuel, there was little need to distinguish among regional sources. However, without data supporting this lack of need to distinguish geographic sources, it was not possible, in his view, to determine if maize from Chile would in fact be representative of maize from other regions of the world. He further observed that the scientific rationale for the request for compositional data was not evident from the written record. He considered it essential that the lead CA provide such a rationale concomitant with the request for information, because many of the possible reasons for requesting such information were not necessary for completing a scientific risk assessment.[909]

7.875 In considering the December 2001 request by the lead CA for further field trials, we note that the United States does not assert that, at that time, the Netherlands was an active participant in the alleged moratorium on approvals. However, the United States contends that the Netherlands was placed in a position of having to recognize the moratorium as a reality and that this affected how it assessed applications.

7.876 We consider that following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on

[905] Exhibit EC-74/At. 84.
[906] Exhibit EC-74/Ats. 87-88.
[907] CAC/GL 45-2003, para. 45.
[908] Annex H, para. 626.
[909] Annex H, para. 635

labelling and traceability. The Commission made a proposal for such rules in July 2001. In our view, the Netherlands also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries. Consequently, the Netherlands could in our view have come to the conclusion in 2001 that there was no realistic prospect that the application concerning Bt-1507 maize (EC-74) could be approved prior to the repeal of Directive 90/220.

7.877 Against this background, we accept that it is possible that the lead CA's December 2001 request for further field trials could, as the United States argues, be explained as a way to delay consideration of the application concerning Bt-1507 (EC-74) so that it would not be forwarded to the Commission and the other member States until the entry into force of Directive 2001/18, under which the application might eventually be approved, after the adoption of new EC rules on labelling and traceability. The fact that the applicant's response to the December 2001 request did not come until after the repeal of Directive 90/220 is consistent with this explanation. However, the applicant's response was provided together with responses to a request of March 2002 for other additional information which has not been questioned by the United States. It is therefore not clear that the resulting delay is attributable solely to the request for additional field trials.

7.878 It must also be noted that the Netherlands was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. In our view, the December 2001 request for additional field trials could also reflect a precautionary approach to evaluating applications. The views expressed by the experts advising us do not appear to rule out this possibility.

7.879 Taking account of the aforementioned elements, we consider that the December 2001 request by the Netherlands for additional field trials does not in itself provide direct confirmation of the existence of a general moratorium on final approvals. But in our view the request is consistent with the contention that a general moratorium was in effect at the time.

7.880 We note that after the applicant had provided an updated application in November 2002, the lead CA requested further information from the applicant on 10 February 2003 with respect to a surveillance plan and the confidentiality of the proposed detection method. Furthermore, as noted, in February 2003 the lead CA dropped its request for the additional field trials, but requested that the data be presented in a uniform manner. The responses to these requests were provided by the applicant on 24 March 2003, and on 28 May 2003 the applicant withdrew the request for confidentiality with respect to the detection method.

7.881 In the light of the foregoing, we consider that by the end of March 2003 the lead CA had all the elements to complete its safety assessment. The outstanding clarification of the confidentiality issue should not have delayed the completion of the safety assessment itself. In any event, as we have noted, the confidentiality issue was resolved in May 2003. Notwithstanding this, the lead CA did not send its completed assessment report to the Commission until 15 August 2003.

7.882 We recall that in accordance with the requirements of Directive 2001/18 the lead CA was to have transmitted its completed assessment report at the latest 90 days after receipt of the updated application. As we have already pointed out, following the receipt of the application in November 2002, the lead CA reviewed the application for more than two and a half months before forwarding its request for additional information. After receiving the applicant's response in March 2003, the lead CA took an additional period of time of more than four and a half months to complete its assessment report and transmit it to the Commission. Thus, by the time the lead CA sent its assessment report to

the Commission it had taken more than seven months to evaluate the updated application instead of the 90 days envisaged in Directive 2001/18.

7.883 We have observed earlier in respect of the 90-day deadline stipulated in Directive 2001/18 that that deadline provides a useful indicator for determining how much time might be needed to complete an assessment. As we have said, in the case of the application concerning Bt-1507 maize (EC-74), by the end of March 2003 the lead CA had all the elements to complete its safety assessment. Even if the lead CA at that point in time had taken a full 90-day period to complete its assessment, it would have completed its assessment before the end of June 2003. By that time, as noted, the confidentiality issue had also been resolved.

7.884 While there is no indication that the Netherlands in 2003 was actively supporting a general moratorium on final approvals, we consider that the fact that the Netherlands exceeded the 90-day period even after it had received all necessary information is consistent with the existence of a moratorium on final approvals. Following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that these countries would act as a "blocking minority" in the Regulatory Committee and the Council at least pending the adoption of new EC rules on labelling and traceability[910], and that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries.

7.885 Moreover, we note that it was not until 15 August 2003 that the application concerning Bt-1507 (EC-74) reached the Community level phase of the approval procedure under Directive 2001/18. As we have said before, it is only at the Community level that the Group of Five countries and/or the Commission could take action to delay or prevent the final approval of this application.

7.886 In the light of the above considerations, we conclude that the failure of the Netherlands to complete its assessment of the application concerning Bt-1507 maize (EC-74) earlier than in August 2003 is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

Bt-1507 maize (EC-75)

7.887 Neither the date of the initial submission of the application concerning Bt-1507 maize (EC-75) to the Spanish CA (lead CA), nor the application itself, have been made available to the Panel. However, the lead CA acknowledged receipt of the application in a letter dated 11 July 2001. The application was for all uses including cultivation. When Directive 90/220 was repealed on 17 October 2002, the lead CA had not yet forwarded the dossier to the Commission. The application was updated in December 2002 under Directive 2001/18. On 5 August 2003, the lead CA submitted the application and its assessment report to the Commission; it was circulated to all member States on 20 August 2003.

7.888 The **United States** argues that this application was delayed at the member State level for several years, and was not submitted for a decision by the Regulatory Committee. The United States submits that although the applicant provided answers to all of the questions, the lead CA nonetheless delayed consideration of the product. The United States contests the justifiability of some of the

[910] We note that Exhibit US-80, which contains an internal Commission note, suggests that several Group of Five countries in October 2001 expressed the view that new EC rules on labelling and traceability needed to enter into force before new biotech products could be approved.

information requested by the lead CA, and particularly of a number of the objections raised by other member States following circulation of the lead CAs' assessment report by the Commission.

7.889 The **European Communities** argues that following a preliminary assessment of this application by the Spanish National Biosafety Committee, the lead CA requested further additional information on molecular characterization, allergenicity and toxicity of CRY1F, environmental impact and a monitoring plan. These requests were dealt with by the applicant during the following 12 months, until 17 July 2002.[911] After the entry into force of Directive 2001/18, the applicant updated the application in line with the requirements of the new legislation. Exchanges between the applicant and the lead CA continued until the 28 May 2003. The lead CA submitted the full application and its assessment report to the Commission on 5 August 2003.

7.890 The European Communities notes that the Commission circulated the application to the member States and received comments and objections from ten of them. These concern issues such as molecular characterization, detection methods, non target organisms, monitoring plans, toxicity, allergenicity and agricultural practices.

7.891 The **Panel** notes that there appeared to be at least two exchanges between the applicant and the lead CA regarding requests for further information before the repeal of Directive 90/220. Unfortunately, although a considerable amount of documentation was provided to us, it was presented in a manner which did not facilitate its consideration. Many of the documents were mislabelled or misrepresented in the chronologies provided by the European Communities; or they did not correspond to the requests for information identified but rather to requests that occurred considerably later.

7.892 As far as we have been able to determine, following the receipt of the application in July 2001, the lead CA consulted with its National Biosafety Committee and on 30 October 2001 requested additional information from the applicant based on the advice received from the Committee. This request was apparently repeated in a communication of 28 November 2001. First and foremost, the lead CA requested that field studies of Bt-1507 maize (EC-75) be conducted in Spain. Other requests concerned molecular characterization, protein expression, effects on target and non-target species, and monitoring of resistance. A response was provided by the applicant on 14 February 2002, including information on field studies undertaken in Spain. Following further advice from the National Biosafety Committee of 13 May 2002, on 17 June 2002, the lead CA submitted requests for additional field studies and other additional information about molecular characterization and protein expression to the applicant. The applicant responded to these requests on 17 December 2002, providing, *inter alia*, information on additional field studies undertaken in Spain. This was after the date of repeal of Directive 90/220.

7.893 The application was apparently updated and re-submitted under Directive 2001/18 on 13 February 2003. The lead CA requested a specific recalculation on the molecular characterization, additional information regarding toxicity studies, and information on herbicide use on 17 February 2003. Following a meeting between the applicant and lead CA on 28 February 2003, the applicant provided the requested information on 7 April 2003. Following another meeting between the applicant and lead CA, the applicant submitted a revised updated application on 28 May 2003. The updated application was forwarded along with a positive assessment by the lead CA to the Commission on 5 August 2003. It was circulated by the Commission to member States on 20 August 2003, with a deadline for comments of 19 October 2003. On the date of establishment of the Panel, the application was thus being reviewed by the member States.

[911] Exhibit EC-75/Ats. 1-3.

7.894 It is clear from the foregoing that the assessment of the application concerning Bt-1507 maize (EC-75) under Directive 90/220 was delayed as a consequence of two requests for information from the lead CA in November 2001 and June 2002, respectively. We sought advice from the experts as to whether the information requested by the lead CA in November 2001 on molecular characterization, allergenicity, toxicity and environmental impact were necessary to ensure that the conclusions of the safety assessment were valid.[912] The experts were unable to assess the original application as it was not provided to the Panel. Dr. Nutti noted, however, that the subsequent explanations and information provided by the applicant with regard to protein toxicity and allergenicity were correct, very well detailed and comprehensive.[913] Dr. Andow opined that the requests for further information on toxicity, including the toxicity of degradation products of Cry1F or PAT proteins, were necessary to ensure that the conclusions of the safety assessment were valid. He also considered that there could be a legitimate basis for requesting studies on non-target species of particular concern to Spain. He noted that there was no scientific consensus regarding the need for field trials to be conducted in the actual location of concern, but he considered the question from the lead CA to be insufficiently specific to guide the applicant in providing a response and therefore concluded that the particular question which was put forward by the lead CA was not necessary to ensure that the conclusions of the safety assessment were valid .[914]

7.895 In connection with the November 2001 and June 2002 requests for information, we further note that on both occasions the lead CA waited for more than one month before forwarding the questions suggested by the National Biosafety Committee. This contrasts with other approval procedures where Spain was also the lead CA and where the Spanish CA forwarded requests for information from the National Biosafety Committee more promptly.[915]

7.896 In examining the lead CA's November 2001 and June 2002 requests for information, we note that the United States does not assert that, at that time, Spain was an active participant in the alleged moratorium on approvals. However, the United States contends that Spain was placed in a position of having to recognize the moratorium as a reality and that this affected how it assessed applications.

7.897 We consider that following the June 1999 declaration by the Group of Five countries, Spain had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability. The Commission made a proposal for such rules in July 2001. In our view, Spain also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries. Consequently, Spain could in our view have come to the conclusion in 2001 that there was no realistic prospect that the application concerning Bt-1507 maize (EC-75) could be approved prior to the repeal of Directive 90/220. Spain's conduct, notably the time taken by the lead CA to forward questions from the National Biosafety Committee, is consistent with such a view, in that it contributed to the application not being forwarded to the Commission and the other member States until after the entry into force of Directive 2001/18.

7.898 We recognize that the application in this case was submitted and acknowledged just fifteen months before the date of repeal of Directive 90/220. However, we do not consider that in September 2001, when the lead CA received the suggested questions from the National Biosafety Committee, the lead CA could have legitimately concluded that it was impossible to complete the required steps and

[912] Annex H, Questions No. 36 and 36(a).
[913] Annex H, paras. 636-637.
[914] *Ibid*, paras. 639-651.
[915] *See, e.g.*, the approval procedure concerning BXN cotton. Exhibit EC-73/Ats. 2-3 and 5 and 6.

have the application approved or rejected while Directive 90/220 was still in force. It should also be noted that Spain was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, even if we were to accept, taking account of the views expressed by the experts advising us, that the November 2001 request for information might reflect a precautionary approach to evaluating applications, the delayed transmission of that request cannot, in our view, be said to reflect such an approach.

7.899 We note that under Directive 2001/18, in February 2003, the lead CA requested further information in response to the applicant's replies to the lead CA's request for information of June 2002. The applicant provided a response in April 2003 and a revised updated application in May 2003. The updated application was then forwarded to the Commission together with the lead CA's favourable assessment report within three months, as required by Directive 2001/18. The fact that after obtaining yet further information, the application under Directive 2001/18 appears to have moved promptly to the Community level in our view does not disprove the claim that a moratorium on approvals was in place. As we have said, Spain could have considered that while Directive 90/220 was still in force, the Group of Five countries and the Commission would prevent the final approval of the application in question, whereas after the entry into force of Directive 2001/18, the application might eventually be approved, after the adoption of new EC rules on labelling and traceability.

7.900 In the light of the above considerations, we conclude that Spain's failure to complete its assessment of the application concerning Bt-1507 maize (EC-75) earlier than in August 2003 is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

Bt-11 maize (EC-80)

7.901 The application concerning Bt-11 maize (EC-80) was first submitted to the CA of Spain (lead CA) on 29 May 1998. On 30 April 1999, the lead CA forwarded the application with a positive assessment to the Commission. The application was withdrawn by the applicant on 20 May 1999. In withdrawing the application, the applicant referred to the parallel application which had been submitted to France on 28 May 1996 (Bt-11 maize (EC-69)), and which had been forwarded by the French CA to the Commission on 4 April 1999 with a positive assessment.

7.902 The application concerning Bt-11 maize (EC-80) was for approval of the cultivation of this product. It should be noted that Bt-11 maize (EC-163) had been approved in the European Communities as of 22 April 1998 under Directive 90/220 for import and for processing.

7.903 The **United States** argues that this application was delayed at the member State level and was not forwarded for consideration at the Community level. The United States submits that although the applicant provided answers to all of the questions, the member State nonetheless delayed and ultimately suspended consideration or failed to approve the product. The United States considers that the delays in the consideration by the lead CA are evidence of the existence of a moratorium.

7.904 The **European Communities** argues that after discussions between the lead CA and the applicant, this application was withdrawn on 20 May 1999. The applicant gave as the reason for its withdrawal the existence of a parallel application made in France.

7.905 The **United States** argues that the companies had a strong incentive to maintain cordial relations with EC regulators and saw no advantage of complaining to EC regulators about the length of the delays, which the United States maintains results from the moratorium.

7.906 The **Panel** begins by noting the United States' argument that the application concerning Bt-11 maize (EC-80) was not forwarded for consideration at the Community level. This is incorrect. This application was submitted by the lead CA to the Commission in April 1999 and thus did reach the Community level; however, the applicant withdrew the application within a month of this referral.

7.907 The United States further argues that the delays in the consideration by the lead CA are evidence of the existence of a moratorium. In considering this argument, we first recall that it is the United States' contention that the European Communities applied a general moratorium as of October 1998. From the information provided to us, it appears that between October 1998 and April 1999 the application was under assessment by Spain's National Biosafety Committee and by the Spanish CA. There is no indication that in the period from October 1998 to April 1999 further information was to be submitted by the applicant in response to requests for information. This period exceeds the 90-day assessment period provided for in Directive 90/220. We therefore agree with the United States that between October 1998 and April 1999 there were delays in the consideration of the application concerning Bt-11 maize (EC-80).

7.908 No explanation has been offered by the European Communities of the failure of the lead CA to consider this application within the period of time foreseen in Directive 90/220. The United States does not assert that Spain itself was an active participant in the alleged moratorium on approvals and that the time taken by Spain to complete its assessment is a reflection of Spain's support for the moratorium. Rather, its assertion is that the time taken by Spain reflects the impact of the moratorium.

7.909 We note that the relevant delay in the consideration of this application occurred between October 1998 and April 1999, *i.e.*, before the June 1999 declaration by the Group of Five countries. Spain was not a part of the Group of Five countries. Spain was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. Taking into account these elements, we consider that the delay which occurred between October 1998 and April 1999 neither contradicts nor confirms the existence of a moratorium on final approvals as of October 1998. In our view, a general EC moratorium on final approvals as of October 1998 could explain Spain's conduct after 1998. Spain could have considered that strict compliance with the 90-day deadline was effectively not necessary since in any event a final approval of the application concerning Bt-11 maize (EC-80) would not be granted while the alleged moratorium was in effect. On the other hand, since Spain in June 1999 formally declared that it would take a thoroughly precautionary approach, we think it is also possible that Spain reviewed the application particularly carefully and that this resulted in unintended delays.

7.910 In our view, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application is not inconsistent with the United States' assertion that the European Communities was applying a general moratorium on approvals as from October 1998. As was pointed out by the Complaining Parties, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning Bt-11 maize (EC-80).

7.911 In the light of the above considerations, we conclude that the failure by Spain to complete its assessment of the application concerning Bt-11 maize (EC-80) earlier than in April 1999 is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

NK603 maize (EC-76)

7.912 In the approval procedure concerning NK603 maize, the applicant submitted an application to Spain (lead CA) in August 2000. When Directive 90/220 was repealed on 17 October 2002, the lead CA had not yet forwarded the dossier to the Commission. The application was forwarded with a positive assessment to the Commission on 14 January 2003. The scope of the application covered import and industrial use, including use as animal feed.

7.913 The **United States** argues that the application was delayed at the first stage of the approval process under 90/220 because the lead CA declined to forward the application to the Commission. Although the applicant provided answers to all of the questions raised by the lead CA, the lead CA nonetheless delayed this product under Directive 90/220. The application remained at member State level for a period of 25 months. This product was resubmitted under Directive 2001/18, and received favourable initial assessments from the Spanish CA.

7.914 **Canada** argues that the total time taken by the lead CA for its review was 25 months, and that only 13 of the 25 months were taken by the applicant to respond to questions. The difference of 12 months exceeds the 3-month period provided for in Directive 90/220.

7.915 **Argentina** notes that a risk assessment of NK603 maize was initiated under Directive 90/220 and re-initiated under Directive 2001/18. This was concluded with a favorable opinion from the scientific panel. Argentina notes that, as of April 2004, the approval procedure concerning NK603 maize, which was initiated on 4 August 2000, had lasted 3 years and 8 months and no final decision had been reached on the application for approval.

7.916 The **European Communities** claims that the only delays in the application for NK603 maize arose due to questions on additional information; otherwise the application process has proceeded smoothly. In addition, the European Communities asserts that the application submitted in August 2000 was incomplete and therefore not considered as received until January 2001. The European Communities further claims that 44 days after the application was submitted, the clock was stopped because the scientific committee of the lead CA requested additional information on issues such as molecular characterization, nutritional composition, and environmental impact.[916]

7.917 The **United States** notes that using the January 2001 date of receipt suggested by the European Communities, and taking account of the "clock stop" when requested information was awaited from the applicant, out of the total 25 months for which the application was at the CA level, the European Communities had delayed action on the application for NK603 maize under Directive 90/220 for 12 months.

7.918 The **European Communities** responds that, given that the applicant had taken 13 months to gather additional information, it was not unreasonable that the lead CA required 12 months to digest and process that information.

7.919 The **Panel** understands from the record that the applicant sent the first application to the Spanish CA on 4 August 2000. Four months later, on 20 December 2000, the applicant resubmitted the application in Spanish and apparently with additional studies added to the application.[917] We note that there is no record of these additional studies. The Spanish CA subsequently acknowledged receipt of the letter on 2 January 2001.

[916] Exhibit EC-76/At. 1.
[917] Exhibit EC-76/At. 3.

7.920 It is clear from the record that the progress of this application was adversely affected notably by two elements. *First*, the applicant took more than six months to provide information requested by the lead CA in February 2001. *Secondly*, the applicant took more than five months to provide information requested by the lead CA in October 2001.

7.921 Regarding the February 2001 request for information, we note that the lead CA requested additional information concerning molecular characterization, nutritional analysis and environmental impact of the product in question. We asked the experts advising us whether the information requested by the lead CA in February 2001 was necessary to ensure that conclusions of the product's safety assessment were valid.

7.922 Given that the application was for import and industrial use in the European Communities and not for cultivation, Dr. Andow indicated that "some information is necessary to consider how gene escape can occur either during processing, storage or transport, but detailed information is not necessary." Thus, he concluded that requests for additional detailed environmental studies were not justified.[918]

7.923 Dr. Nutti noted that the food safety information available to the lead CA seemed sufficient given that substantial equivalence had been demonstrated in several feeding studies.[919] Dr. Nutti stated that "whatever studies were further requested by the lead CA [...] were not necessary to ensure that conclusions of the safety assessment were valid since all the relevant information had already been provided."

7.924 Regarding the October 2001 request for information, we understand from the record that one month after the applicant had submitted new information in response to the request of February 2001, in October 2001, the Spanish CA requested that a Polymerase Chain Reaction (PCR) be conducted, and sought additional information on molecular characterization and details of the potential environmental impact of accidental dissemination or germination.[920] More than five months passed before the applicant responded with additional information. After the applicant had submitted new information in March 2002, the Spanish CA communicated persistent doubts.[921]

7.925 The United States notes that the Spanish CA had stressed that PCR should be used to detect small DNA insertions because PCR provides a greater degree of sensitivity.[922] The United States argues that the use of some PCR-based method to detect additional fragments potentially too small to be seen by a Southern blot analysis was scientifically unjustified.

7.926 The European Communities claims that the request from the lead CA was scientifically valid.[923] According to the European Communities, the additional data provided by the applicant indicates that the use of PCR improved the sensitivity of the molecular characterization in comparison to the data previously provided in the application. Therefore, although the applicant stressed that the conclusion in relation to safety provided in the application was not altered, the European Communities maintains that the lead CA's request for additional information was necessary to ensure that conclusions of the safety assessment were valid.

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[918] Annex H, Dr. Andow's response to Panel Question 37.
[919] Annex H, Dr. Nutti's response to Panel Question 37.
[920] Exhibit EC-76/At. 10.
[921] Exhibit EC-76/At. 14.
[922] Exhibit EC-76/At. 10.
[923] EC Comments on the experts replies, para. 462.

7.927 In relation to PCR, the Panel recalls that Dr. Nutti expressed the view that the initial information regarding food safety seemed sufficient.[924] The Panel understands from the record, however, that the Spanish CA emphasized that the PCR is also considered "essential for product traceability".[925]

7.928 In relation to the additional October 2001 requests for environmental information, Dr. Andow noted that the applicant had not addressed this question of potential environmental impact of any accidental dissemination or germination. He commented that the applicant "believes, probably rightly, that the likelihood of accidental dissemination and germination (exposure to the environment) is small. If this is true, the applicant is arguing that when exposure is small, risk is small. Consequently, the applicant may believe that it was not necessary to address this question."[926] However, Dr. Andow noted that the lead CA could believe that the potential risk associated with accidental dissemination and germination could be large. Dr. Andow therefore concluded that this request for information to be provided by the applicant was justified.

7.929 In considering the lead CA's February 2001 and October 2001 requests for information, we note that the United States and Argentina do not assert that, at the time of these requests, Spain was an active participant in the alleged moratorium on approvals. Indeed, Spain was not part of the Group of Five countries. However, following the June 1999 declaration by the Group of Five countries, Spain had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability.[927] In our view, Spain also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries. Consequently, Spain could in our view have come to the conclusion in 2001 that there was no realistic prospect that the application concerning NK603 maize could be approved prior to the repeal of Directive 90/220.

7.930 Against this background, we consider that Spain could have been requesting information which it would not otherwise have requested, and that it was not concerned about any delays such requests would entail, as it saw no possibility of the application being approved while Directive 90/220 was still in force. The views expressed by the experts advising us are not inconsistent with this possibility. As indicated previously, notably in the case of the February 2001 request the experts questioned the need for the information that was requested.

7.931 It must also be remembered, however, that Spain was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. In our view, the fact that the experts questioned the need for the information that was requested in February 2001 does not rule out the possibility that Spain was taking a precautionary approach to evaluating applications. Therefore, we think the February 2001 and October 2001 requests for additional information could also be a reflection of the June 1999 declaration by the Group of Seven countries.

7.932 Taking account of the aforementioned elements, we consider that Spain's February 2001 and October 2001 requests for additional information do not in themselves provide direct confirmation of the existence of a general moratorium on final approvals. But in our view these requests are consistent with the contention that a general moratorium was in effect at the time.

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[924] Annex H, Dr. Nutti's response to Panel Question 37.
[925] Exhibit EC-76/At. 10.
[926] Annex H, Dr. Andow's response to Panel Question 38.
[927] We recall that the Commission made a proposal for such rules in July 2001.

7.933 We note that at a very early stage, in August 2002, the applicant submitted an updated application to satisfy the new requirements of Directive 2001/18. The applicant appears to have done so at its own initiative.[928] In August 2002, it was already clear, however, that the approval procedure concerning NK603 maize could not be completed under Directive 90/220. Consistent with the fact that the update was submitted early on, the updated application was promptly forwarded to the Commission with the lead CA's favourable assessment report on 14 January 2003.[929] However, the fact that under Directive 2001/18 the application moved to the Community level very quickly in our view does not disprove the claim that a moratorium on approvals was in effect. As we have said, Spain could have considered that while Directive 90/220 was still in force, the Group of Five countries and the Commission would prevent the final approval of the application in question, whereas after the entry into force of Directive 2001/18, the application might eventually be approved, after the adoption of new EC rules on labelling and traceability.

7.934 In the light of the above considerations, we conclude that the failure of Spain to complete its assessment of NK603 maize earlier than in January 2003 is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

GA21 maize (EC-85)

7.935 The application concerning GA21 maize (EC-85) was initially submitted to the United Kingdom (lead CA) on 12 December 1997, for the import of grain and of derived products for animal feed and processing. On 15 October 1999, the lead CA submitted the application to the Commission with its favourable assessment.[930] The application was withdrawn on 27 June 2001.

7.936 The **United States** argues that this application was delayed at the member State level for seven months. In February 1999, the Advisory Committee on Release into the Environment (ACRE) notified the applicant that it would forward the application to the Commission following some amendments to the application.[931] On 23 March 1999 the applicant submitted the final and complete amended application, as agreed between the applicant and the lead CA, which was ready to be forwarded to the Commission as of that date.[932] The application, however, was delayed for more than seven months for no discernible reason before it was finally sent to the Commission on 15 October 1999. More than four months after the positive ACRE opinion, the applicant explicitly inquired about this delay in a letter dated 8 July 1999 to the Minister of the Environment, only to receive a reply back four months later, on 2 November 1999, noting, without explanation, that the application "had recently been forwarded" to the Commission.[933]

7.937 The United States observes that the chronology provided by the European Communities gives the false impression that activity actually occurred on this application after April 1999 by referencing an ACRE meeting on 16 September 1999.[934] As the minutes of that meeting show, however, GA21 maize (EC-85) was not on the agenda and was not discussed. There was no activity during this time period on the side of the lead CA. The United States maintains that these seven months of inaction following the lead CA's positive risk assessment were politically motivated. The exact application as

[928] Exhibit EC-76/At. 18.
[929] Exhibit EC-76/At. 27.
[930] We recall that an application for the same product was submitted to Spain on 29 May 1998 (EC-78).
[931] EC Exhibit 78 + 85/At. 22.
[932] Exhibit US-145.
[933] Exhibit US-146.
[934] Exhibit EC-78 + 85/At. 24.

submitted by the applicant on 23 March 1999 was finally forwarded to the Commission without further discussion or amendment.

7.938 **Canada** argues that the lead CA failed to submit the application to the Commission until November 1999, well after the applicant had made certain amendments to the original application in March 1999 in accordance with the agreement with the lead CA made in February 1999. That is, the lead CA failed to forward the application to the Commission for 7.5 months. Canada argues that this should be considered together with the fact that the lead CA had already spent 15.5 months for its review with regard to the application since the application was submitted by the applicant in November 1997.

7.939 The **European Communities** argues that the delays at the member State level relating to this application were due to the numerous requests for additional information. Furthermore, when the application was withdrawn, the applicant cited as reasons for its withdrawal "unexpected commercial constraints" and the parallel application in Spain.

7.940 The **United States** argues that the application was withdrawn because of the European Communities' excessive delay in carrying out the approval process. The United States maintains that although a company may not have cited undue delays in its withdrawal letter, over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Furthermore, according to the United States, the companies had a strong incentive to maintain cordial relations with EC regulators and saw no advantage of complaining to EC regulators about the length of the delays, which the United States maintains results from the moratorium.

7.941 The **Panel** notes that on 16 February 1999 the lead CA informed the applicant that, in light of some of the new data provided by the applicant in response to requests from the lead CA, ACRE had re-reviewed the application, and requested some amendments in order to permit the dossier to be forwarded to the Commission. ACRE indicated that subject to these amendments being made, it was content for the dossier to be forwarded to the Commission with a favourable opinion.[935] The applicant provided an amended application to the lead CA in March 1999.[936] The chronology provided by the European Communities indicates that a meeting of ACRE was held on 16 September 1999. However, as correctly noted by the United States, the minutes of this meeting make no reference to any discussion of the GA21 maize (EC-85) application.[937] The EC chronology shows no further action on this application until it was forwarded to the Commission with a positive assessment report on 15 October 1999. Evidence submitted by the United States shows, however, that on 8 July 1999, the applicant inquired with the lead CA why the application was not being forwarded.[938] The lead CA replied on 2 November 1999, almost four months later, indicating only that the application had meanwhile been forwarded to the Commission.[939]

7.942 The United States does not assert that the United Kingdom itself was an active participant in the alleged moratorium on approvals and that the delay in question is a reflection of the United Kingdom's support for the moratorium. Nevertheless, the United States contends that the fact that the lead CA did not forward the application to the Commission for almost seven months after receiving an amended version was politically motivated. In response to a request for elaboration from the

[935] Exhibit EC78+85/At. 22.
[936] Exhibit EC-78+85/At. 26. Evidence submitted by the United States confirms that the revised application was submitted on 23 March 1999. Exhibit US-145.
[937] Exhibit EC-78+85/At. 24.
[938] Exhibit US-146.
[939] *Ibid*.

Panel, the United States observed that many EC member States, including the United Kingdom, were divided internally on their position related to biotechnology. On the one hand, elements of the UK government have, in the United States' view, been supportive of agricultural biotechnology. On the other hand, the United States argues that certain political figures were not supportive, including the UK Environment Minister at the time of the delay in question. According to the United States, the conduct of the United Kingdom shows that countries other than the Group of Five countries recognized the political reality of the moratorium, and that this reality at times affected the manner in which they conducted their assessments of biotech applications.

7.943 In considering the United States' arguments, we note that it is reasonable to assume that the lead CA needed some time to review the amended application submitted in March 1999 before it could be forwarded to the Commission with a favourable opinion. Nevertheless, the lead CA had previously indicated that there were no other outstanding issues, and so we agree with the United States that a delay did occur between March 1999 and October 1999. Indeed, this period alone resulted in the consideration of this application at the member State level far exceeding the 90-day assessment period allowed under Directive 90/220.

7.944 The precise reasons for the lead CA's temporary inaction are unclear. We note that during the period from March to October 1999, in June, the Environment Council agreed on a Common Position in relation to the revision of Directive 90/220 and the Group of Five countries made their declarations. It may be that the United Kingdom considered that it was not appropriate to forward the application concerning GA21 maize (EC-85) to the Commission and the other member States with a favourable opinion shortly before this important Council meeting, and that after the meeting the United Kingdom took time to evaluate the impact of the Council meeting on the EC approval process, and to see the reaction of the Commission. It may also be that the delay reflects an internal UK policy debate, as suggested by the United States.

7.945 What is clear, though, is that the United Kingdom completed its assessment and in October 1999 forwarded the application to the Commission with a favourable opinion. This is consistent with the circumstance that the United Kingdom was not part of the Group of Five countries which stated that they would take steps to suspend further approvals. The fact that the United Kingdom completed its assessment does not, however, contradict the claim that a general moratorium on final approvals was in effect in October 1999. If a moratorium was in effect, it was only after the application concerning GA21 maize (EC-85) reached the Community level that the Group of Five countries and/or the Commission could take steps to prevent the final approval of the application concerning GA21 maize (EC-85).

7.946 In our view, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application in 2001 is not inconsistent with the United States' assertion that the European Communities was applying a general moratorium on approvals. As was pointed out by the United States, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning GA21 maize (EC-85).

7.947 In the light of the above considerations, we conclude that the time taken by the United Kingdom to complete its assessment of the application concerning GA21 maize (EC-85) is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

MON810 x GA21 maize (EC-82)

7.948 The application concerning MON810 x GA21 maize was initially submitted to Spain (lead CA) on 4 August 1999. This maize is produced by conventionally hybridizing two "parental" biotech products, MON810 maize and GA21 maize. This application was withdrawn by the applicant on 15 September 2003. At that time, the lead CA had not yet submitted the application to the Commission.

7.949 The **United States** argues that this application never reached the Community level stage of review due to the moratorium. On 30 November 1999, the lead CA requested that the applicant provide several additional studies to support the application for this product.[940] The applicant responded in August 2001 to all requests, except for a scientifically unjustified study on the nutritional composition of milk from dairy cows fed this product.[941] Given the demonstrated safety of maize in feed generally, as well as the substantial data submitted to support the feed safety of both transgenic parents, there is no scientific basis to suggest a concern. One of the parental lines (MON810 maize) was approved by the European Communities several years prior to this application, and the feed safety was established as part of that process.[942] In addition, as part of its original submission, the applicant had relied on substantial compositional analyses of the other parent (GA21 maize), as well as feeding studies.[943] None of these studies identified anything that would provide any basis for the concern raised by the member State.

7.950 The United States notes that the lead CA also requested additional studies of the hybrid in order to verify the stability of both events jointly. In the view of the United States, there was no logical basis for this request, which implies some interaction between the MON810 and GA21 events. The United States submits that the applicant had already shown the stability of these transformation events in each parental line. The insertions, having been shown to be stable in the parental lines, would be no more likely to be affected by crossing than any other gene already present in either parent.

7.951 The United States notes that the applicant provided translations in January 2002 of various studies it had previously submitted. Following that, the only activity by the lead CA was a meeting held in April 2002.[944] No further action was taken on this application for over 18 months, until the applicant volunteered to update the application under Directive 2001/18 on 16 January 2003.[945] The applicant, however, subsequently withdrew the application on 15 September 2003, at the same time it withdrew the application for GA21 maize (EC-78), as the delays caused by the moratorium had rendered the applications for GA21 maize (EC-78) and MON810 x GA21 maize commercially obsolescent.[946]

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[940] Exhibit EC-82/At. 8.

[941] Exhibit EC-82/ Ats. 9, 10 and 11. According to the United States, conducting the dairy cattle feeding study would have involved considerable cost and delay to the applicant. Such a test would require the applicant to obtain approval for further experimental plantings to generate sufficient maize for the feeding study; employ external consultants to undertake the required study; grow maize for the feeding study in the 2000 season; harvest, transport and ensile the maize under rigorous experimental conditions; undertake the cow-feeding phase; analyse the milk samples; and produce all reports to the Standards of Good Laboratory Practice.

[942] Commission Decision concerning the placing on the market of genetically modified maize (zea mays L. line MON810) pursuant to Council Directive 90/220/EEC, (98/294/EC), April 22, 1998, Official Journal of the European Communities, L 131/32, May 5, 1998 (Exhibit US-131).

[943] Exhibit EC-82/Ats. 2 and 5.

[944] Exhibit EC-82/At. 18.

[945] Exhibit EC-82/At. 20.

[946] Exhibit EC-82/At. 21.

7.952 The **European Communities** argues that the delays identified by the United States can be explained by the fact that the safety of one of the parental lines of this hybrid product, GA 21 maize, had not yet been assessed. The lead CA was awaiting that assessment. The European Communities maintains that it is obvious that the assessment of a hybrid cannot be concluded as long as the assessment of one of its parental lines is still open. Furthermore, according to the European Communities, the United States acknowledges that the delays were caused by the applicant when it stated in response to a question from the Panel that "the applicant was unable to devote resources to respond to the questions posed by the [lead CA] in a timely fashion".[947]

7.953 The European Communities further observes that after discussions between the lead CA and the applicant, the application was withdrawn with a letter of 15 September 2003. The applicant gave three reasons for the withdrawal: first, the progress in the procedure of NK603 maize to a more advanced stage than the GA21 maize (EC-78) application; second, the introduction of the new regulations concerning commercialisation of GM products in the European Communities; and third, the change of the company's commercial priorities.

7.954 The **United States** denies acknowledging that the delays were caused by the applicant. The summary table of the US response to question 47 from the Panel was not intended to indicate that delay was the fault of the applicant. Rather, the applicant recognized that the application for MON810 x GA21 maize would not move forward as long as consideration of the application for the single trait parent GA21 maize (EC-78) remained suspended under the moratorium. The United States contends that it was pointless for the applicant to devote resources to pursue the application for MON810 x GA21 maize when the approval of GA21 maize (EC-78) had been stalled for years under the moratorium. Thus, the delay in the application for MON810 x GA21 maize was a direct consequence of the delay in the application for GA21 maize (EC-78) under the moratorium.

7.955 The United States points out that because of the delay in the approval procedure concerning GA21 maize (EC-78), that product, as well as MON810 x GA21 maize, have been superseded by a second generation Roundup Ready maize product (NK603 maize and NK603 × MON810 maize, respectively). The United States maintains that the applicant may not have cited undue delays in its withdrawal letter because it had a strong incentive to maintain cordial relations with EC regulators and saw no advantage of complaining to EC regulators about the length of the delays.

7.956 The **Panel** begins by noting that much of the information provided to it has been incorrectly identified. In particular, translations into Spanish of information previously submitted in English have been identified as "additional data", and at times the same document was included as several different attachments. Furthermore, it should be recalled at the outset that the Spanish CA in May 1999 had given a favourable assessment to the application concerning GA21 maize (EC-78) and forwarded that application to the Commission. When the application concerning MON810 x GA21 maize was submitted, the application concerning GA21 maize (EC-78) was under assessment at Community level.[948]

7.957 Turning now to Spain's assessment of the application concerning MON810 x GA21 maize under Directive 90/220, we note that the most significant delay in the consideration of this application appears to be due to the time taken by the applicant to provide information in response to a request for additional information from the Spanish CA in November 1999. The applicant did not provide the

[947] The European Communities refers to the United States' response to question 47 of the Panel, table in Annex I.

[948] We recall that the application concerning GA21 maize (EC-78) was withdrawn by the applicant in 2003.

information requested until August 2001, and a translation into Spanish of the documents submitted in the August 2001 response was provided to the Spanish CA in January 2002. The United States has pointed out that the applicant did not comply with the Spanish CA's request that it provide a study on the nutritional composition of milk from dairy cows which had been fed the product in question.

7.958 In April 2002, the Spanish National Biosafety Committee reviewed the January 2002 Spanish translation of the applicant's documents. The National Biosafety Commission concluded that it still needed the results of feeding studies on cows, and other information.[949] However, there is no indication in the record that a further request for information was ever sent to the applicant prior to the repeal of Directive 90/220 in October 2002.

7.959 We note that after receiving the additional information requested from the applicant, it was incumbent on the Spanish CA either to seek further clarifications or to complete its assessment within the 90-day period provided for in Directive 90/220. As indicated, there is no evidence that the Spanish CA requested additional or missing information once the National Biosafety Commission had reviewed the Spanish version of the applicant's documents of August 2001. Nor did the Spanish CA complete its assessment after receiving further advice from the National Biosafety Commission in April 2002. From the information before us, it would appear that the 90-day period had already been exceeded by April 2002.

7.960 According to the European Communities, the failure of the lead CA to forward the application concerning MON810 x GA21 maize to the Commission in 2002 can be explained by the fact that the lead CA was waiting for the result of the Community level assessment of one of the parental lines of this hybrid product, GA 21 maize (EC-78). The European Communities maintains that it is obvious that the assessment of a hybrid cannot be concluded as long as the assessment of one of its parental lines is still open. We are not convinced by this explanation.

7.961 To begin with, as previously noted, the Spanish CA had already favourably assessed the application concerning GA21 maize (EC-78). Furthermore, the SCP in September 2000 had issued a favourable opinion on the application concerning GA21 maize (EC-78).[950] It is not clear, therefore, why the same Spanish CA would not be in a position to reach a conclusion also with regard to the application concerning the hybrid product, *i.e.*, MON810 x GA21 maize. Indeed, the record does not indicate that the Spanish CA ever indicated to the applicant that it was unable to proceed due to the failure of the European Communities to approve the GA21 maize (EC-78) parent. As a general matter, it may be correct that "the assessment of a hybrid cannot be concluded as long as the assessment of one of its parental lines is still open". However, it would seem that the assessment of the parental lines could also be made in the context of the assessment of the hybrid. At any rate, the Spanish CA could not "conclude" the assessment of the application concerning MON810 x GA21 maize completely on its own. If other member States had concerns with Spain's assessment of GA21 maize (EC-78), even though that assessment appears to have been confirmed by the SCP, they could have raised an objection and the assessment would then have been "concluded" at Community level. Thus, it is not apparent to us that the Spanish CA needed to keep the application at the member State level in order to avoid the possibility of conflicting assessments of GA21 maize.

7.962 The United States argues that this application never reached the Community level stage due to the alleged general moratorium on final approvals. More particularly, the United States contends that the delay in the application for MON810 x GA21 maize was a direct consequence of the delay in the application for GA21 maize (EC-78) under the moratorium. We recall that the United States does not

[949] Exhibit EC-82/At. 18.
[950] Exhibit EC-78+85/At. 90.

assert that Spain itself was an active participant in the alleged moratorium on approvals or that the time taken by Spain in its assessment is a reflection of Spain's support for the moratorium. Rather, it asserts that Spain was placed in a position of having to recognize the moratorium as a reality, and that this affected the speed with which it conducted its assessment.

7.963 We consider that following the June 1999 declaration by the Group of Five countries, Spain had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability.[951] In our view, Spain also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries. We note in this regard that the single trait parent application concerning GA21 maize (EC-78) did not progress at Community level after the SCP had issued its favourable opinion in September 2000.[952] In relation to that application, we have previously concluded that the Commission's failure to submit a draft measure concerning GA21 maize (EC-78) to the Regulatory Committee following the issuance in September 2000 of the SCP's opinion is consistent with the United States' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

7.964 Against this background, and in particular in view of the situation with regard to the single trait parent application concerning GA21 maize (EC-78), we consider that Spain could have come to the conclusion in 2002 that there was no realistic prospect that the application concerning MON810 x GA21 maize could be approved prior to the repeal of Directive 90/220. In our view, Spain's failure to complete its assessment prior to the repeal of Directive 90/220 is therefore consistent with the view that a general moratorium on approvals was in effect at the time.

7.965 We note that Spain was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, in this instance, it is not apparent that the Spanish CA's conduct as of April 2002 reflects a precautionary approach. Indeed, the Spanish CA did not follow up with the applicant to seek more information or additional clarifications after receiving further advice from the National Biosafety Commission in April 2002. We recognize that, by that time, the date of repeal of Directive 90/220 was approaching. However, we note that in another approval procedure, the Spanish CA forwarded questions from the National Biosafety Commission as late as mid-June 2002.[953]

7.966 Furthermore, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application in 2003 is not inconsistent with the United States' assertion that the European Communities was applying a general moratorium on approvals. As was pointed out by the United States, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning MON810 x GA21 maize.

7.967 Regarding Spain's assessment of the application concerning MON810 x GA21 maize under Directive 2001/18, we note that the applicant on 16 January 2003 indicated its intention to submit an updated application in accordance with Directive 2001/18. The European Communities has indicated, however, that the updated application was never received by the lead CA. We have seen no evidence

[951] We recall that the Commission made a proposal for such rules in July 2001.

[952] It is reasonable to assume that as the lead CA in the approval procedure concerning GA21 maize (EC-78), Spain was aware of this situation.

[953] Exhibit EC-75/At. 13.

to the contrary. The only other information regarding this application relates to its withdrawal by the applicant on 15 September 2003. Thus, it appears that the application was never considered by the lead CA under Directive 2001/18. This said, without an updated application, the lead CA could not have done so.

7.968 In the light of the above considerations, we conclude that the failure of Spain to complete its assessment of the application concerning MON810 x GA21 maize prior to the repeal of Directive 90/220 in October 2002 is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

High-oleic soybeans (EC-87)

7.969 The application concerning High-oleic soybeans was submitted to the Netherlands (lead CA) on 19 June 1998. Following several requests for additional information from the lead CA and responses by the applicant, the application was withdrawn by the applicant on 12 December 2002.

7.970 The **United States** argues that the application for High-oleic soybeans was withdrawn because of the European Communities' excessive delay in carrying out the approval process. The United States maintains that this delay was a manifestation of the moratorium on approvals.

7.971 The **European** Communities argues that when the application was withdrawn by the applicant in December 2002, the justification given for the withdrawal pointed to "entirely commercial reasons".

7.972 The **United States** argues that in many cases the withdrawal of applications resulted from the applicant's frustration with the European Communities' suspension of its approval process, although the applicant may not have explicitly so indicated in its reasons for withdrawal. Over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Second, the companies have a strong incentive to maintain cordial relations with EC regulators, and saw no advantage of complaining to EC regulators about the length of the delays resulting from the moratorium.

7.973 The **Panel** notes that in a communication dated 7 December 1998, the Netherlands Institute for Food Safety (RIKILT), one of the advisory scientific bodies considering the application, informed the lead CA that not enough information was available to assess the safety of livestock feed made from High-oleic soybeans.[954] The applicant was formally informed of the request for further data in a letter dated 8 January 1999. However, it appears that the RIKILT's questions had been made available to the applicant by e-mail already on 4 December 1998.[955] On 1 July 1999, the applicant provided responses to the RIKILT's questions "from 4 December 1998". The applicant submitted almost 270 pages of replies and studies.[956] The new information was apparently reviewed by the RIKILT, and on 27 October 1999, the Dutch CA on behalf of the RIKILT requested the applicant to provide further substantiation of the compositional analysis it had submitted.[957] The applicant did not provide the requested substantiation, however. There is no indication of any further communications on this application until it was withdrawn by the applicant more than three years later, on 12 December 2002, *i.e.*, after the repeal of Directive 90/220.

[954] Exhibit EC-87/At. 11.
[955] Exhibit EC-87/Ats. 13 and 14.
[956] Exhibit EC-87/At. 14.
[957] Exhibit EC-87/At. 15.

7.974 It is clear from the foregoing that the progress of this application was adversely affected notably by two elements. *First*, the lead CA's request for additional information of December 1998/January 1999 and the time taken by the lead CA to review the additional information once it had been received. *Secondly*, the applicant's failure, over a period of more than three years, to respond to a follow-up request for additional information.

7.975 Regarding the first element, we have asked the experts advising us whether the information requested in December 1998/January 1999 and October 1999 on the composition of the product and the alteration in the protein profile were necessary to ensure that conclusions of the safety assessment were valid. Dr. Nutti considered that the data requested in December 1998/January 1999 on the lectin content and composition data for at least two seasons was necessary to ensure that conclusions of the safety assessment concerning human use were valid. She also noted, however, that the changes in the fatty acid composition would not be expected to have an impact on livestock feed safety.[958]

7.976 In considering the requests of December 1998/January 1999, it must also be noted, however, that a few months later, in June 1999, the Netherlands formally declared that it would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. In our view, the December 1998/January 1999 requests might reflect a precautionary approach to evaluating applications.

7.977 On 1 July 1999, the applicant provided the information requested in December 1998/January 1999. Almost four months later, on 27 October 1999, the Dutch CA forwarded additional questions from the RIKILT to the applicant. This means that during that period alone, the Netherlands exceeded the 90 days available to it under Directive 90/220 to assess the application. On the one hand, it should be recalled in this context that the applicant's technical response consisted of a 270-page document. In comparison, the original application contained 170 pages.[959] On the other hand, we consider that following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability. It is also reasonable to assume that the Netherlands was aware that after May 1999, in the approval procedures concerning Bt-531 cotton and RR-1445 cotton, the Commission failed to discharge its responsibility inasmuch as it did not submit a draft measure to the Council. Consequently, it is possible, in our view, that the Netherlands considered that the application concerning High-oleic soybeans could not be promptly approved at Community level, and that this affected the speed of its own assessment at the member State level. Hence, we think the Netherlands' conduct is consistent with the view that a general moratorium on approvals was in effect at the time.

7.978 Regarding the second element which contributed to a delay in the completion of this procedure, we note that the reasons for the applicant's failure to provide further substantiation are unclear. In its December 2002 letter of withdrawal, the applicant indicated that there was no safety concern relating to High-oleic soybeans and that the withdrawal was related entirely to commercial reasons.[960] In our view, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application in 2002 is not inconsistent with the United States' assertion that the European Communities was applying a general moratorium on approvals. As was pointed out by the United States, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning High-oleic soybeans.

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[958] Annex H, paras. 673-674.
[959] Exhibit EC-87/At. 1.
[960] Exhibit EC-87/At. 16.

7.979 In the light of the above considerations, we conclude that the failure by the Netherlands to complete its assessment of the application concerning High-oleic soybeans prior to December 2002, when it was withdrawn by the applicant, is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

RR sugar beet (EC-88)

7.980 The application concerning RR sugar beet was submitted for approval in Belgium (lead CA) in December 1998 under Directive 90/220. Following the entry into force of Directive 2001/18, an updated application was submitted by the applicant on 16 January 2003. At the time of establishment of the Panel, the lead CA had not yet submitted its assessment to the Commission. On 16 April 2004, the application was withdrawn by the applicant.

7.981 The **United States** claims that the application for RR sugar beet was delayed at the first stage of the approval process under 90/220 because the member State declined to forward the application to the Commission. Although the applicant provided answers to all of the questions raised by the lead CA, the member States nonetheless delayed and ultimately suspended consideration or failed to approve this product under Directive 90/220. This product was resubmitted under Directive 2001/18.

7.982 **Canada** argues that the lead CA failed to complete its review with regard to the application, and thus exceeded the 90-day limit provided for by Directive 90/220 by several years. Canada argues that during the review process, the lead CA requested three times (April 1999, November 2000 and January 2001) the applicant to "voluntarily" comply with the requirements provided for by Directive 2001/18, even though Directive 2001/18 would not be in force until October 2002.

7.983 The **European Communities** notes that after discussions between the lead CA and the applicant, the application was withdrawn by the companies producing the product on 16 April 2004. As the reason for the withdrawal, the applicant pointed to a decision to stop any further development of the RR sugar beet derived from event T9100152.

7.984 The **United States** argues that in many cases the withdrawal of applications resulted from the applicant's frustration with the European Communities' suspension of its approval process, although the applicant may not have explicitly so indicated in its reasons for withdrawal. Over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Second, the companies have a strong incentive to maintain cordial relations with EC regulators, and saw no advantage of complaining to EC regulators about the length of the delays resulting from the moratorium.

7.985 The **Panel** observes that the application was apparently sent to the lead CA in December 1998, however no record of this application is available to us. Also, the lead CA considered the application to be incomplete. After the applicant submitted further information, the lead CA on 1 March 1999 acknowledged receipt of a complete application.[961] Apparently, the application was considered at a meeting of the Belgian Biosafety Advisory Council held on 26 April 1999. The questions which were generated by this meeting were transmitted to the applicant in June 1999 and included questions on agricultural practices, molecular characterization, toxicology, allergenicity, and

[961] Exhibit EC-88/At. 3.

food/feed equivalence.[962] The applicant provided responses to some of these questions in July 1999.[963] Other questions were answered in December 1999.[964]

7.986 In October 1999 the lead CA requested additional information on gene transfer in digestive tracts.[965] The applicant provided such information in January 2000.[966] We asked the experts advising us whether the information regarding allergenicity, molecular characterization and gene transfer in digestive tracts requested by the lead CA was necessary to ensure that conclusions of the safety assessment were valid. Dr. Nutti stated that the information provided by the applicant prior to October 1999 on these three topics was adequate to ensure that the conclusions of the assessment were valid.[967]

7.987 In February 2000, the lead CA requested missing bibliographical references. The applicant provided the relevant references in February and March 2000.[968] According to the chronology provided to us, in April 2000 the applicant met with the CA to discuss issues relating to identity preservation, Good Agricultural Practices, post-market monitoring, traceability, public information, line-specific detection methods and primers. The record of this meeting was not provided to us, however. In July 2000, the applicant at its own initiative provided additional information on the characterization of a protein and detection protocols. The applicant noted that this data did not change the conclusions of the safety assessment.[969]

7.988 In November 2000, the lead CA requested further clarifications regarding molecular characterization and allergenicity of "event '77'".[970] We asked the experts if the information regarding molecular characterization and allergenicity of "event '77'" requested by the lead CA was necessary to ensure that conclusions of the safety assessment were valid. Dr. Nutti emphasized that the information "for allergenicity was not necessary to ensure that the conclusions of the safety assessment were valid", as the initial application had satisfactorily established the safety of this product in this respect.[971] The applicant apparently did not provide the requested information.

7.989 In January 2001 the lead CA "invited" the applicant to provide a proposal for labelling and traceability as well as a proposal for a monitoring plan and Good Agricultural Practices in accordance with the principles of the Common Position of the Council on the amendment of Directive 90/220. The lead CA indicated that in the absence of voluntary compliance with these principles, it seemed that the Commission and the other member States would oppose the approval of the application even if the lead CA forwarded it with a positive assessment.[972] The applicant apparently did not reply to the lead CA's invitation. In June 2001, the lead CA sent the applicant some comments on its application, asking the applicant to make corresponding corrections.[973] After the June 2001 communication from the lead CA there appear to have been no further exchanges between the lead CA and the applicant until the repeal of Directive 90/220 in October 2002.

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[962] Exhibit EC-88/Ats. 8 and 9.
[963] Exhibit EC-88/At. 10.
[964] Exhibit EC-88/At. 13.
[965] Exhibit EC-88/At. 12.
[966] Exhibit EC-88/At. 15.
[967] Annex H, Dr. Nutti's response to Panel Question 42.
[968] Exhibit EC-88/Ats. 17-21.
[969] Exhibit EC-88/At. 22.
[970] Exhibit EC-88/At. 27.
[971] Annex H, Dr. Nutti's response to Panel Question 43.
[972] Exhibit EC-88/At. 29.
[973] Exhibit EC-88/At. 30.

7.990 In January 2003, the applicant submitted an updated application under Directive 2001/18. There was an acknowledgement by the lead CA in February 2003 that the applicant had provided updates and a request for further information.[974] The applicant apparently did not provide the requested information. Instead, in April 2004 the applicant submitted a letter of withdrawal.

7.991 We begin our examination of the lead CA's assessment of the application concerning RR sugar beet by recalling that the applicant did not respond to the lead CA's November 2000 request for additional information.[975] It would therefore appear that after November 2000 the lack of progress under Directive 90/220 is attributable to the applicant. The question to be examined, then, is why the lead CA did not complete its assessment prior to November 2000. We note in this respect that by the end of March 2000 the applicant had provided all additional information requested by the lead CA. Notwithstanding this, the lead CA did not complete its assessment in the next several weeks. Instead, more than seven months later, in November 2000, the lead CA requested further clarification on molecular characterization and allergenicity issues previously addressed by the applicant. The European Communities did not provide an explanation for why the Belgian CA could not have sought these clarifications much earlier, given that the applicant had provided additional information on these issues before the end of 1999. We note in this connection that by November 2000, Belgium had already far exceeded the 90-day period provided for in Directive 90/220 for the assessment to be made by a lead CA.

7.992 We also recall that in June 1999 Belgium was one of the Group of Seven countries which declared, not that they would take steps to suspend further approvals, but that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, in view of the timing of Belgium's November 2000 request for additional information – it was forwarded more than seven months after the applicant had submitted additional information in March 2000 – we are not convinced that that request was a reflection of the precautionary approach referred to in the June 1999 declaration of the Group of Seven countries.

7.993 We consider that following the June 1999 declaration by the Group of Five countries, Belgium had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability. The Commission made a proposal for such rules in July 2001. In our view, Belgium also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries. Consequently, it is possible, in our view, that Belgium considered that the application concerning RR sugar beet could not be promptly approved at Community level, and that this affected the speed of its own assessment and led it to request information which it might not otherwise have requested.[976] As indicated previously, notably in the case of the clarifications sought concerning allergenicity, Dr. Nutti questioned the need for the information that was requested. The circumstance that the applicant did not respond to the November 2000 request is also consistent with this possibility, for it may indicate that the applicant had lost confidence that its application would be forwarded to the Commission by Belgium while Directive 90/220 was still in force.

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[974] Exhibit EC-88/At. 34.

[975] The lead CA in January 2001 reminded the applicant of its November 2000 request for information. Exhibit EC-88/At. 29.

[976] In fact, as noted earlier, in January 2001 Belgium itself indicated to the applicant that it expected opposition to the approval of the application concerning RR sugar beet if the applicant did not voluntarily comply with certain principles set out in the Common Position on the revision of Directive 90/220.

7.994 Taking account of the aforementioned elements, we consider that Belgium's failure to complete its assessment prior to its November 2000 request for additional information is consistent with the existence of a general moratorium on approvals. This view is not contradicted by the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application in 2004. As was pointed out by the United States, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning RR sugar beet.

7.995 In the light of the above considerations, we conclude that the time taken by Belgium for its assessment of RR sugar beet is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

Transgenic green-hearted chicory (EC-110)

7.996 The application concerning Transgenic green-hearted chicory was submitted for approval in the Netherlands (lead CA) on 11 March 1996 under Directive 90/220. On 15 April 2003, the application was withdrawn.

7.997 The **European Communities** has indicated that, after assessment at both national and European Community level, the notification was withdrawn by the applicant on 15 April 2003. The applicant gave two reasons for the withdrawal: first, the absence of a market for these products; and second, the fact that the company preferred not to be associated with GMOs any longer.

7.998 The **United States** argues that in many cases the withdrawal of applications resulted from the applicant's frustration with the European Communities' suspension of its approval process, although the applicant may not have explicitly so indicated in it reasons for withdrawal. Over time, as the delays mounted and new products were developed, in some cases the commercial incentive for seeking approval changed. Second, the companies have a strong incentive to maintain cordial relations with EC regulators, and saw no advantage of complaining to EC regulators about the length of the delays resulting from the moratorium.

7.999 The **Panel** notes that a draft of a favourable opinion prepared for submission to the European Commission was provided to the applicant for comments on 8 July 1996.[977] Six months later, in January 1997, the applicant submitted a letter requesting that the application not be forwarded to the Commission until there was greater clarity regarding the authorization of Transgenic red-hearted chicory (EC-77).[978]

7.1000 More than two years later, on 25 March 1999, the Dutch advisory body for feed safety, the RIKILT, submitted an assessment report to the Dutch CA. Contrary to the description of this report given by the European Communities, the RIKILT did not request additional information. Rather, the RIKILT stated that given the conclusions of the Provisional Committee For Safety Evaluation of Novel Foods and/or the SCP, there were no indications that occasional use of the modified green-hearted chicory as feed would not be safe. The report did indicate that by current EU standards the data provided on the composition of the modified green-hearted chicory was insufficient to comment on its comparability with non-modified green-hearted chicory. It went on to state, however, that as green-hearted chicory was not a normal ingredient of feed, and in light of the opinion of the Provisional Committee on the Safety of Novel Foods regarding its safety for human consumption,

[977] Exhibit EC-110/At. 4.
[978] Exhibit EC-110/At. 5.

there was no indication that the product would not be safe for both animals and consumers of animal products if occasionally used as feed.[979]

7.1001 On 19 May 1999, the applicant voluntarily provided some supplementary data on food safety aspects "in response to requests by different Member States" in the context of the discussion of the application concerning the same product submitted under Regulation 258/97. The application provided the information, although the application concerning Transgenic green-hearted chicory concerned feed use, not food use.[980] No information was provided to us regarding any further exchanges concerning this application after this date. The application was not re-submitted under Directive 2001/18 and formally withdrawn on 15 April 2003. The withdrawal letters submitted to us are in Dutch and no translation was provided.

7.1002 It is evident from the foregoing that the consideration of this application by the lead CA was not completed within the 90 days foreseen under Directive 90/220. Unfortunately, however, based on the information that was provided to us we are unable to ascertain to what extent any delays which occurred after May 1999, when the applicant voluntarily submitted further information, were attributable to the lead CA. As noted, the evidence seems to suggest that in July 1996, the application was deemed sufficient for the relevant scientific committees within the Netherlands to conclude that the Transgenic green-hearted chicory presented no risk to human or animal health or the environment. But in January 1997, the applicant requested that the application not be forwarded until there was greater clarity about the approval of Transgenic red-hearted chicory. From the evidence before us, it is not clear whether in May 1999, the lead CA was still waiting for the applicant to withdraw its holding request. If that was the case, the failure of the lead CA to complete its assessment after May 1999 and forward the application to the Commission would be the result of the applicant's own request.

7.1003 Even assuming, however, that the lead CA was waiting for the applicant to give it the go-ahead, this would not demonstrate that no moratorium on final approvals was in effect during the relevant time period. As of October 2002, when Directive 90/220 was repealed, the application concerning Transgenic green-hearted chicory had not reached the Community level phase of the approval procedure under Directive 90/220. In other words, it had not yet reached the procedural stage where the Group of Five countries and/or the Commission could have taken action to delay or prevent its final approval.

7.1004 In the light of the above considerations, we conclude that the failure by the Netherlands to complete its assessment of Transgenic green-hearted chicory prior to October 2002, when Directive 90/220 was repealed, is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

Member State failure to give consent to placing on the market

7.1005 In support of their assertion that the European Communities applied a general moratorium on approvals the United States and Canada have pointed to approval procedures in which the member State to which the application was submitted – the lead CA – failed to give its written consent to the placing on the market of a biotech product, after that biotech product had been approved by Commission decision. We consider these approval procedures below, recalling that Article 13(4) provides in relevant part that "[w]here the Commission has taken a favourable decision, the competent authority that received the original notification shall give consent in writing to the notification so that

[979] Exhibit EC-110/At. 7.
[980] Exhibit EC-110/At. 8.

the product may be placed on the market". Article 13(5) further provides that "[o]nce a product has received a written consent, it may be used without further notification throughout the Community in so far as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly adhered to".

MS1/RF1 oilseed rape (EC-89)

MS1/RF2 oilseed rape (EC-90)

7.1006 The applications for both MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape were submitted to France (lead CA) in April 1995 for cultivation, import and marketing. After consideration by the lead CA and subsequently at Community level, these applications were approved by the Commission on 6 June 1997.[981]

7.1007 The **United States** argues that numerous applications that were blocked under Directive 90/220 were not resubmitted under Directive 2001/18, including MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape. These applications languished at the final stage of the process for more than five years because the lead CA withheld its final approval.[982] Both applications were submitted to France in April 1995, which forwarded them with favourable opinions to the European Commission on 27 July 1995. The Commission reviewed the applications and found "no reason to believe that there will be any adverse effect on human health and the environment" from placing MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape on the market.[983] Accordingly, the Commission approved both products on 6 June 1997,[984] consistent with the favourable opinion of the Regulatory Committee.[985] Despite the favourable decision of the Commission, France refused to complete the process by giving its final consent so that MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape could be placed on the market.[986]

7.1008 **Canada** argues that MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape have been affected by the moratorium, as these products have been prevented from receiving the approval necessary for the product to be legally marketed in the European Communities. Canada submits that although these products were approved prior to October 1998, these products are the victims of the moratorium after October 1998 as much as any products.

7.1009 Canada notes that the EC decisions approving the placing on the market of MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape in July 1997 stated that "consent shall be given by the competent authority of France to the placing on the market" of the products in question[987], on the basis, in part, that there was no reason to believe that there would be any adverse effects on human health and the environment. However, the lead CA failed to give its consent for either product contrary to this stipulation and Article 13(4) of Directive 90/220 and despite the fact that the same competent authority originally provided a favourable opinion.

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[981] Commission Decision 97/392/EC of 06/06/1997 in OJ L164 of 21/06/1997, p. 38 (Exhibit EC-89) and Commission Decision 97/393/EC of 06/06/1997 in OJ L164 of 21/06/1997, p. 40 (Exhibit EC-90).

[982] Questions and Answers on the Regulation of GMOs in the EU, at Annex 1 (Exhibit US-107).

[983] Commission Decision 97/392/EC, O.J. 21.6.1997 L164, preamble, fifth recital (Exhibit US-43); Commission Decision 97/393/EC, O.J. 21.6.1997 L164, preamble, fifth recital (Exhibit US-44).

[984] Commission Decision 97/392 (Exhibit US-43); Commission Decision 97/393 (Exhibit US-44).

[985] Commission Decision 97/392, preamble, eighth recital (Exhibit US-43); Commission Decision 97/393, preamble, eighth recital (Exhibit US-44).

[986] Questions and Answers on the Regulation of GMOs in the EU, at Annex 1 (Exhibit US-107).

[987] Canada refers to Article 1(1) of each Commission Decision, respectively.

7.1010 Canada further notes that on 7 July 1999, the Commission sent a "reasoned opinion" to France in relation to the withholding of consent for these products. This procedural step necessarily precedes any legal proceedings by the Commission against a member State for infringement of EC law before the European Court of Justice.[988] However, the Commission did not pursue this matter any further; it did not bring an infringement procedure. Although Canada requested additional information from the European Communities during consultations, the European Communities has yet to provide any additional information on what steps were actually taken. Furthermore, in a judgment dated 4 November 2000, the French Conseil d'Etat, following the decision of an earlier European Court of Justice ruling in relation to Article 13(4) of Directive 90/220, concluded that without new information concerning the risks associated with MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape, the French Ministry could not call into question the decision taken by the Commission.[989]

7.1011 Canada argues that despite the Commission's decisions to place both products on the market over 6 years ago (and the completion of the most recent favourable risk assessment by an EC scientific body on a closely related use of the same product at least 5 years ago), France has continued to withhold consent to the placement of these products on the market. Accordingly, the applicant has been unable to place either plant variety on the EU market.[990]

7.1012 The **European Communities** argues that from a legal point of view, the absence of the final consent does not mean that the applicant is not entitled to place MS1/RF1 oilseed rape (EC-89) and/or MS1/RF2 oilseed rape on the market. These products have obtained marketing approval by virtue of Commission decisions of 6 June 1997. While those decisions were addressed to France and placed an obligation upon France to grant final consent, they could nevertheless develop a direct effect *vis-à-vis* the applicant as well.

7.1013 According to the European Communities, in the case law of the European Court of Justice, EC member States cannot prevail themselves of the fact that they have not implemented (or refuse to implement) Community obligations addressed to them in order to deny an individual a right granted through those same Community provisions.[991] The individual, therefore, can assert this right by directly relying on the Community law in question. These principles form the so-called doctrine of "direct effect." The Court has based this doctrine on a teleological interpretation of Community law, and in particular, on the so-called "effet utile" principle.

7.1014 The European Communities confirms that the Commission initiated infringement proceedings against France in 1998, however it decided not to take the case to the Court. This was because the very legislation on the basis of which the approval had been granted had been identified to be insufficient and was being revised. Furthermore, France had raised the same environmental risk

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[988] European Communities, GMOs: Commission moves against Luxembourg and France, Commission Press Release, IP/99/438, Brussels, 7 July 1999 (Exhibit CDA-52). *See also* European Communities, Commission, Seventeenth Annual Report on Monitoring the Application of Community Law (1999), COM (2000) 92 final, Brussels, 23 June 2000 (Sector on Chemicals and Biotechnology), p. 80 (Exhibit CDA-53).

[989] European Communities, Commission, Eighteenth Annual Report on Monitoring the Application of Community Law (2000), COM (2001) 309 final, Brussels, 16 July 2001 (Sector on Chemicals and Biotechnology), p. 67 (Exhibit CDA-50); *see also*, European Court of Justice, *Association Greenpeace France v. Ministère de l'Agriculture et de la Pêche*, C-6/99, [2000] E.C.R. I-01651 (Exhibit CDA-51).

[990] Canada notes that the processed oil from canola/oilseed rape hybrid MS1/RF1 was approved for placing on the market pursuant to the simplified procedures of Article 5 of Regulation 258/97 as of 24 June 1997 (*see* the summary of Article 5 applications received in 1997, product number 2, contained in Exhibit CDA-25). The application was submitted to the Commission by the United Kingdom following a scientific assessment conducted by its Advisory Committee on Novel Foods and Processes.

[991] *See only* European Court of Justice, Leberpfennig, C-9/70 [1970] ECR 825.

concerns regarding these two products as it had for the products for which it subsequently adopted safeguard measures (*i.e*. the identical product MS1/RF1 oilseed rape which had been approved for breeding activities in 1996).

7.1015 The approvals of MS1/RF1 and MS1/RF2 oilseed rape for import, processing and cultivation in 1996 and 1997 did not provide for any reporting or monitoring of marketing in the European Communities. Accordingly, the European Communities claims it is unable to say whether these products have been sold in the European Communities. According to the European Communities, no oilseed rape varieties derived from MS1/RF1 or MS1/RF2 oilseed rape have been registered in member States' national catalogues or in the Common Catalogue of varieties of agricultural plant species – which is a prerequisite for allowing their commercial cultivation – because there has been no application from companies to do so.

7.1016 The **United States** maintains that under Directive 90/220, the "Community level" approval is not effective unless and until the member State that initially received the application takes the final step of placing the product on the market. In this case, the lead CA never allowed the product to be placed on the market. Thus, these products in fact were never approved for cultivation, import, and marketing in the European Communities. This is an example of how in certain circumstances a single member State can block a product approval, and is furthermore an example of the existence of the general moratorium. Neither of these products is in fact on the market in the European Communities and EC Customs officials would not admit either of these products without the final step (the French consent) in the approval process. The European Communities has failed to explain how a product can be considered approved if additional legal proceedings are required to allow the product to be placed on the market.

7.1017 **Canada** argues that one cannot reasonably conclude that an approval procedure has been brought to an end if an applicant must undergo potentially expensive and time-consuming litigation to enforce its rights.

7.1018 The **Panel** notes that although the two applications concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape were formally approved by the Commission for placing on the market in June 1997, the lead CA subsequently failed to take the final step of the approval procedure provided for in Article 13(4) of Directive 90/220, which is to grant written consent to the placing on the market of a product. The relevant Commission decisions, which are addressed to the member States, also provide in their Article 1(1) that "consent shall be given by the competent authority of France to the placing on the market" of the oilseed rape products in question.[992]

7.1019 Neither Article 13(4) of Directive 90/220 nor the relevant Commission decisions lay down specific time periods within which the lead CA had to give consent. However, it is clear to us that this does not mean that the lead CA could take any amount of time to complete the step required of it. If it were otherwise, the deadlines stipulated in Directive 90/220 for the completion of other steps of the approval procedure, such as the 90-day member State assessment period set out in Article 12, the 60-day objection period set out in Article 13 and the three-month action period set out in Article 21, could easily be nullified and rendered meaningless. We recall that in the case of the two applications at issue, the approval for both applications was given by the Commission on 6 June 1997. As of October 2002, when Directive 90/220 was repealed, France had not granted its consent to the placing

[992] Exhibits US-43 and -44; CDA-48 and -49.

on the market of the products at issue. Thus, France did not grant its consent for more than five years.[993]

7.1020 The European Communities has suggested that France's inaction after June 1997 was due to concerns about environmental risks, and that these same risks led France in November 1998 to adopt a safeguard measure on MS1/RF1 oilseed rape (EC-161). The application concerning MS1/RF1 oilseed rape (EC-161) had been submitted to the United Kingdom and was approved for breeding activities in 1996. In considering this assertion, we note that we have been provided very little information on the approval procedures concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape. In particular, we have seen no evidence which points to the alleged environmental concerns by France. To the contrary, the Commission decisions approving the applications concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape make clear that France forwarded the application to the Commission with a favourable opinion.

7.1021 Furthermore, there is no indication that France after June 1997 sought additional information from the applicant, or proposed to the applicant voluntarily to accept stricter conditions to meet France's alleged environmental concerns. Moreover, the Commission decisions approving the two products specify that Directive 90/220 provides for additional safeguards if new information on risks of the products in question became available. In the light of this, even if France considered that by June 1997 there were justifiable reasons for it to consider that the products in question constituted a risk to the environment, it could have taken a safeguard measure, as it did for MS1/RF1 oilseed rape (EC-161), *after* giving its written consent to the placing on the market of the two products in question.[994] The concerns underlying France's safeguard measure would then have been examined by the SCP, and a decision on the validity of France's concerns would then have had to be taken at Community level.

7.1022 For all these reasons, we are not persuaded that there were outstanding environmental issues which were specific to the products in question, and which France was trying to have the applicant address prior to giving its written consent to the placing on the market of these products.

7.1023 We recall that in June 1999 France was one of the Group of Five countries which declared that they would take steps to suspend further approvals under Directive 90/220 pending the adoption of new EC rules on labelling and traceability. As previously noted, the Complaining Parties argue that one of the steps which the Group of Five countries could take to prevent further approvals was to withhold written consent to the placing on the market of the product to be approved in cases where they were acting as the lead CA. We consider that France's conduct is consistent with the June 1999 declaration by the Group of Five countries. Indeed, despite a clear legal obligation to give written consent to the placing on the market of MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape, France withheld its consent and thus did what was within its power to prevent these products from being approved.

7.1024 Therefore, we consider that at least as from June 1999, France's failure to give its written consent supports the Complaining Parties' assertion that the European Communities was applying a

[993] We note, by way of example, that in the approval procedure concerning the Red-hearted chicory, which was also conducted under Directive 90/220, the lead CA gave its written consent two-and-a-half months after the Commission approved the application for breeding activities. Exhibit EC-77/At. 42.

[994] There is nothing in Directive 90/220 which says that a lead CA forwarding an application with a positive opinion and giving written consent to the placing on the market of a product may not subsequently take a safeguard measure in respect of that product.

general moratorium on final approvals. France's conduct is not inconsistent with the Complaining Parties' assertion that a general EC moratorium was in effect already as from October 1998. However, the fact that France withheld its consent already as from June 1997 could also support the view that although France, for its part, opposed further approvals and used its powers to prevent approvals, no general EC-wide moratorium was in effect in October 1998.

7.1025 We should note that there is uncertainty as to the status of the applications concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape after the repeal of Directive 90/220. Article 35 of Directive 2001/18 provides that applications submitted under Directive 90/220 in respect of which the approval procedures under Directive 90/220 have not been completed by 17 October 2002 are subject to Directive 2001/18. It further provides that by 17 January 2003 applicants had to complement their applications in accordance with Directive 2001/18. There is no indication that the applications concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape were complemented in accordance with Directive 2001/18.

7.1026 The European Communities appears to argue, however, that the approval procedures concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape were completed under Directive 90/220. The European Communities contends that in accordance with the jurisprudence of the European Court of Justice the absence of the final consent from the lead CA does not mean that the applicant is not legally entitled to place MS1/RF1 oilseed rape (EC-89) and/or MS1/RF2 oilseed rape on the market. According to the European Communities, the applicant could invoke before French courts the obligation imposed by the above-noted Commission decisions on France to give its consent to the placing on the market of the products in question. The United States and Canada did not contest that the applicant would have this right under EC law. In these circumstances, and in the absence of evidence to the contrary, we see no grounds for rejecting the European Communities' contention regarding the position under its own law.

7.1027 Accepting the European Communities' contention means that as of the date of establishment of this Panel, the above-noted Commission decisions were still legally binding, and that as of that date the applicant could still invoke the above-noted Commission decisions against France, since France had not given its written consent by then. This does not mean, however, that either before or after the repeal of Directive 90/220 France itself was no longer required to comply with the Commission decisions and was not obliged to grant its written consent. Therefore, the European Communities' contention does not detract from our view that at least as from June 1999 France's continued failure to give its written consent supports the Complaining Parties' assertion that the European Communities was applying a general moratorium on final approvals.

7.1028 In the light of the above considerations, we conclude that at least as from June 1999 the failure of France to give its written consent to the placing on the market of MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape supports the contention of the Complaining Parties that the European Communities applied a general moratorium on approvals.

Delays due to changes in the legislative framework

7.1029 As we have noted at the outset, the European Communities acknowledges that delays occurred in some approval procedures which were pending under Directive 90/220. According to the European Communities, these delays occurred as a result of legislative changes which were being made at the time. Specifically, the European Communities refers to the revision of Directive 90/220 which led to the adoption of Directive 2001/18. The European Communities observes that while Directive 90/220 continued to be the basis for the processing of applications, pending applications presented a problem in that they did not generally contain the data/information necessary to address

the concerns which led to the adoption of Directive 2001/18. The European Communities says that it therefore had to find ways to ensure that the applicant provided the necessary data/information. The European Communities points out that most applicants agreed to do so on a voluntary basis. The European Communities submits that with the adoption and entry into force of the new legislation, all relevant concerns have been addressed. The European Communities asserts that, as a consequence, under Directive 2001/18 all approval procedures have been proceeding normally.

7.1030 Thus, the European Communities essentially argues that to the extent there were delays in the processing of Directive 90/220 applications, they were linked to legislative changes which were completed in October 2002 with the entry into force of Directive 2001/18. They were not linked to legislative changes sought by the Group of Five countries and obtained in September 2003 with the adoption of new EC rules on labelling and traceability. In support of this assertion, the European Communities submits that there were delays before the entry into force of Directive 2001/18, but not after.

7.1031 It is apparent from the above review of individual approval procedures that delays occurred which were linked to the adoption of Directive 2001/18 or to its more or less imminent entry into force. In our view, however, these delays are entirely consistent with the Complaining Parties' contention that a general moratorium on approvals was in effect until at least August 2003. We recall in this respect that in June 1999 the Group of Five countries declared that "pending the adoption of [new EC rules ensuring labelling and traceability of GMOs and GMO-derived products]"[995], they would take steps to have any new authorizations for growing and placing on the market suspended. By October 2002, when Directive 2001/18 entered into force, the new EC rules on labelling and traceability had not been adopted.[996] Thus, it is clear from the June 1999 declaration that the Group of Five countries would oppose approvals until the adoption of the new rules, that is to say, until after the entry into force of Directive 2001/18. We also recall the Complaining Parties' assertion that the Commission was instrumental in the adoption and application of the alleged general moratorium on approvals and that it decided not to discharge its responsibility under Directive 90/220 to complete approval procedures, in view of opposition to final approvals by the Group of Five countries. Accordingly, if a general moratorium on approvals was in effect until at least August 2003, it was to be expected that the Group of Five countries (acting as lead CA or through the Regulatory Committee/Council) and/or the Commission would cause delays prior to the repeal of Directive 90/220 so as to prevent applications from being approved while that Directive was still in force.

7.1032 The European Communities claims that after the entry into force of Directive 2001/18, there were no further delays, except for delays which were the result of a clock-stop while further information was awaited. However, as our preceding analysis has shown, there were in fact delays in the processing of applications under Directive 2001/18 which are consistent with the existence of a moratorium on approvals. Such delays occurred at the member State level in the approval procedures concerning Bt-531 cotton, RR-1445 cotton, BXN cotton and Bt-1507 maize (EC-74). Our analysis also showed that in a number of instances, applications moved to the Community level relatively promptly.[997] However, we have said that, in our view, this does not disprove the Complaining Parties' claim that a moratorium on approvals was in effect during the relevant time period. We observed that the lead CA in the relevant cases could have considered that while Directive 90/220 was still in force, the Group of Five countries and the Commission would prevent the final approval of the application

[995] Exhibits US-76 and -77; CDA-3; ARG-12.
[996] The Commission did not propose such rules until July 2001.
[997] *See, e.g.*, the approval procedures concerning RR oilseed rape (EC-70), Bt-1507 maize (EC-74), Bt-1507 maize (EC-75) and NK603 maize.

in question, whereas after the entry into force of Directive 2001/18, the application might eventually be approved, after the adoption of new EC rules on labelling and traceability. In other words, the lead CAs had reason to believe that under Directive 2001/18 any delays caused by them at member State level might have an impact on when the relevant applications would be approved.

7.1033 The European Communities' contention that there were and should have been no delays after the entry into force of Directive 2001/18 is also inconsistent with the June 1999 declaration by the Group of Five countries. As noted earlier, the Group of Five countries announced that they would take steps to prevent approvals pending the adoption of the new EC rules on labelling and traceability. Such rules were adopted in September 2003, *i.e.*, after the entry into force of Directive 2001/18. The record shows that Group of Five countries continued to oppose the approval of applications even though they had been updated in accordance with the requirements of Directive 2001/18.[998]

7.1034 Furthermore, we note that, as of August 2003, there had been no case where an approval procedure conducted under Directive 2001/18 reached the stage where the Commission had to submit a draft measure to the Regulatory Committee/Council or adopt a draft measure not adopted by the Council. In other words, there was no procedure which reached the stage where the Commission could have taken action to delay or prevent the final approval of an application. Moreover, the first Commission approval of an application under Directive 2001/18 occurred only in July 2004, that is to say, after the establishment of the Panel and after the entry into force of the new EC rules on labelling and traceability. Hence, as far as the Commission's conduct is concerned, the record does not disprove the Complaining Parties' claim that the Commission had decided not to complete approval procedures for as long as the new EC rules had not been adopted.

7.1035 In the light of the above considerations, we are not persuaded by the European Communities' contention that to the extent there were delays in the processing of applications for deliberate release into the environment, they were attributable in part to legislative changes which were completed in October 2002 with the entry into force of Directive 2001/18, but not to legislative changes sought by the Group of Five countries. We consider that the delays which occurred prior to the entry into force of Directive 2001/18 are entirely consistent with the contention of the Complaining Parties that the European Communities was applying a general moratorium on approvals at least until August 2003. We also consider that the record does not support the European Communities' assertion that under Directive 2001/18 there were no delays or at least none which are consistent with the existence of a moratorium on approvals.

(ii) Novel Foods – Applications submitted under Regulation 258/97

7.1036 The Panel now turns to address those of the relevant applications which were submitted and dealt with under the provisions of Regulation 258/97 concerning novel foods and novel food ingredients. From the information provided to us, it appears that all of the biotech products which were the subject of the relevant Regulation 258/97 applications had also been submitted for approval under Directive 90/220.[999] It is also noteworthy that all Regulation 258/97 applications were submitted after the corresponding Directive 90/220 applications.[1000] Furthermore, the two biotech food products which were approved by the Commission in 2004, Bt-11 sweet maize (food) and

[998] *See, e.g.*, the approval procedures concerning RR oilseed rape (EC-70) (Exhibit EC-70/At. 71) and NK603 maize (Exhibit EC-76/At. 46).

[999] In some cases, the Directive 90/220 and Regulation 258/97 applications were submitted to the same lead CA. In most cases, they were submitted to different lead CAs.

[1000] In some cases, the Regulation 258/97 applications were submitted a few days later, in other cases more than a year later.

NK603 maize (food), were approved after having been approved under Directive 90/220 (Bt-11 maize (EC-163)) and Directive 2001/18 (NK603 maize).

7.1037 Some of the approval procedures we address below are for applications covering foods or food ingredients which contain or consist of GMOs.[1001] It should be noted in this respect that according to Regulation 258/97 "risks to the environment may be associated with novel foods or food ingredients which contain or consist of [GMOs]".[1002] Article 9(1) of Regulation 258/97 therefore requires that applications concerning such foods or food ingredients be accompanied by the technical dossier supplying the relevant information required under Article 11 of Directive 90/220 and the environmental risk assessment based on this information or, where appropriate, the decision approving the placing on the market of the relevant product under Directive 90/220. Article 9(2) provides that the decision approving the placing on the market under Regulation 258/97 must "respect the environmental safety requirements laid down by [Directive 90/220] to ensure that all appropriate measures are taken to prevent the adverse effects on human health and the environment which might arise from the deliberate release of [GMOs]". It would seem to follow from Article 9 that if the applicant did not submit an environmental risk assessment, a Regulation 258/97 application could not be approved by the Commission unless the corresponding Directive 90/220 application had previously been approved.

7.1038 The Complaining Parties assert that the facts and histories of the relevant approval procedures support their view that the European Communities applied a general moratorium on final approvals of biotech products, including biotech food products. We recall in this respect that in June 1999 the Group of Five countries declared that "in exercising the powers vested in them regarding the growing and placing on the market of genetically modified organisms (GMOs)", "pending the adoption of [EC rules ensuring labelling and traceability of GMOs and GMO-derived products], in accordance with preventive and precautionary principles, they will take steps to have any new authorizations for growing and placing on the market suspended".[1003] This declaration was made in the context of the revision of Directive 90/220. However, by its terms, the declaration does not exclude from its scope GMOs which are directly used as foods or food ingredients, GMOs contained in foods or food ingredients, or GMOs from which foods or food ingredients are produced, but which do not contain the relevant GMOs.

7.1039 Furthermore, we note that the new EC rules on labelling and traceability of GMOs and GMO-derived products referred to in the June 1999 declaration by the Group of Five countries clearly include those which were adopted in September 2003 as Regulation 1830/2003. That Regulation, as its title makes clear, concerns "the traceability and labelling of [GMOs] and the traceability of *food and feed products produced from [GMOs]*" (emphasis added). The preamble to Regulation 1830/2003 notes that traceability requirements for food and feed produced from GMOs should be established to facilitate accurate labelling of such products in accordance with the requirements of Regulation 1829/2003 on genetically modified food and feed, which was also adopted in September 2003. In the light of this link between the two Regulations, and above all in view of the reference in the Group of Five declaration to new EC rules on "labelling [...] of GMOs and GMO-derived products", it is plausible that the Group of Five declaration was intended to cover also Regulation 1829/2003. That Regulation lays down additional labelling requirements for genetically modified food and feed. In particular, unlike Regulation 258/97, it requires labelling of GMO-derived

[1001] In some cases, from the information provided to us, we could not determine whether an application covered foods or food ingredients containing or consisting of GMOs.
[1002] Fifth preambular paragraph of Regulation 258/97.
[1003] Exhibits US-76 and -77; CDA-3; ARG-12.

food products also in cases where the DNA or protein of GM origin is not detectable in the final food products.

7.1040 In relation to Regulation 1829/2003, we should add that Canada and Argentina submitted to us a Council document which indicates that on the issue of "authorization of new GMO food products" Denmark, supported by France, Italy, Austria, Portugal and Luxembourg, in January 2003 pointed to "the conditions for further approval of [GMOs] since a political agreement had been reached at the Council on 28 November 2002 [...] on the proposal for a Regulation on [GM food and feed]". The document further states that "[s]ome of these delegations" considered that "no new procedure of authorization for placing on the market new GMOs should be granted as long as this Regulation had not yet entered into force".[1004] However, we cannot give much weight to this document as it is not clear what is meant by "the conditions for further approval", nor is it clear how many and which of these delegations were against further approvals pending the entry into force of the new Regulation 1829/2003 on GM food and feed.

7.1041 Finally, we note that if the Group of Five countries considered it appropriate, pending the adoption of new EC rules on labelling and traceability, to take steps to prevent the approval under Directives 90/220 or 2001/18 of biotech products which are for cultivation and/or feed use, it would be surprising if they did not oppose on the same grounds the approval under Regulation 258/97 of the identical products for food use, at least where those products contain or consist of GMOs. To recall, Regulation 258/97 indicates that environmental risks may also be associated with the food use of biotech products and requires that food products containing or consisting of GMOs satisfy the environmental safety requirements of Directives 90/220 and 2001/18. In fact, the record shows that Denmark and France have invoked the June 1999 declaration by the Group of Five countries in the context of approval procedures conducted under Regulation 258/97, when raising objections to favourable lead CA assessments of specific applications.[1005]

7.1042 With these observations in mind, we now turn to review the approval procedures conducted for the relevant Regulation 258/97 applications. As with our review of the procedures conducted for the Directive 90/220 applications, we will first focus on the Commission's conduct. Then, we consider the conduct of the SCF. Finally, we examine the conduct of individual member States acting as lead CAs.

Failure by the Commission to submit a draft measure to the Regulatory Committee

7.1043 In support of their assertion that the European Communities applied a general moratorium on approvals the Complaining Parties have pointed to a number of approval procedures in which the Commission failed to submit to the Regulatory Committee[1006] a draft measure on the relevant applications. We consider these approval procedures below, recalling that Article 13(3) of Regulation 258/97 provides in relevant part that "[t]he representative of the Commission shall submit to the Committee a draft of the measures to be taken".

[1004] Press Office of the Council, 2481st Council meeting – Agriculture and Fisheries, Brussels, 27 and 28 January 2003, p. 23 (Exhibit ARG-52). *See also* Exhibit CDA-118.

[1005] Exhibits EC-91/At. 32 (food containing or consisting of GMOs and food produced from, but not containing GMOs); EC-92/Ats. 23 and 27 (food containing or consisting of GMOs); EC-96/At. 27 (food containing or consisting of GMOs and food produced from, but not containing GMOs).

[1006] We recall that the Regulatory Committee established under Article 13 of Regulation 258/97 was the Standing Committee on Foodstuffs.

GA21 maize (food) (EC-91)

7.1044 The application for GA21 maize (food) was submitted to the Dutch CA (lead CA) on 24 July 1998. The initial assessment of the lead CA was provided to the Commission on 21 January 2000, and circulated by the Commission to member States on 18 February 2000. On 18 May 2000, the Commission requested the SCF to evaluate the application; the opinion of the SCF was issued on 27 February 2002. At the time the Panel was established, the Commission had not submitted a draft measure on the application to the Regulatory Committee.

7.1045 The **United States** argues that the Commission asked the SCF for an opinion on 18 May 2000. However, it was eleven months later that the SCF contacted the applicant for the first time, asking for additional information.[1007] Within less than one month, the applicant provided answers to all questions.[1008] It took a further 11 months for the SCF to issue an opinion on 27 February 2002.[1009] Hence the application was delayed for 17 months at the Community level before the SCF rendered its positive opinion on 27 February 2002. In its opinion, the SCF concluded that the data submitted, including the two whole food studies, were "sufficient for evaluation"[1010] and cited these studies in support of its ultimate conclusion that "from the point of view of consumer health, maize grain from maize line GA21 and derived products […] are as safe as grain and derived products from conventional maize lines."[1011]

7.1046 According to the United States, almost two months passed after the positive SCF opinion with no activity on this application. On 23 April 2002, the applicant offered to reduce the scope of the application to include only processed grain and derived ingredients, but not unprocessed grains, in order to enable the authorization procedure under Regulation 258/97 to proceed immediately.[1012] The applicant explained that the reason for this proposal was because the food use of unprocessed grains is also subject to Directive 90/220 and that "progress under this Directive has been suspended for some time, with the result that GA21 maize grain has not yet been considered for consent."[1013]

7.1047 The United States argues that despite the efforts of the applicant to remove any possible impediments, the Commission still failed to forward the application to the Regulatory Committee after the positive SCF opinion. Instead, as reflected in the minutes of a meeting on 5 June 2002 between the Commission and the applicant, the Commission noted that although the next step was to take a Community Decision, "[i]t is desirable that such a Decision would take into account in an appropriate manner the legislative developments with respect to the authorization of GM food and feed as well as the labelling of GM products".[1014] The United States maintains that the European Communities simply halted the processing of this application in anticipation of possible upcoming changes to its regulations, an action entirely consistent with the moratorium which the European Communities and member State officials had announced. Although both the new food and feed and traceability and labelling legislations would not enter into force until 2004, and although the applicant stated its preference to apply the labelling requirements currently in effect under Regulation 258/97, the Commission noted that "it is clear that it would be more difficult to obtain a favourable opinion by

[1007] Exhibit EC-91/At. 39.
[1008] Exhibit EC-91/At. 40.
[1009] The United States observes that the current revised regulatory framework recognizes that a period of six months is an achievable timeframe for the European Communities' scientific authority (EFSA GMO Panel) to come to an opinion. Regulation (EC) No. 1829/2003, Article 6.1.
[1010] Exhibit EC-91/At. 43, pp. 11-12.
[1011] Exhibit EC-91/At. 43.
[1012] Exhibit EC-91/At. 44.
[1013] Exhibit EC-91/At. 44.
[1014] Exhibit EC-91/At. 45, p. 1.

a majority of Member States in the Comitology procedure" if the applicant were not required to anticipate the new labelling requirements before the new legislation was adopted.[1015] In other words, the applicant was required to wait until the requirements for labelling under pending legislation were finalized. Thus the Commission failed to forward a draft measure to the Regulatory Committee as is required to complete the approval process, resulting in further delay that lasted until the new Food and Feed regulation was passed in September 2003.

7.1048 **Canada** notes that after GA21 maize received a favourable assessment by the lead CA, other member States raised objections. The SCF was then requested to conduct its own independent risk assessment and specifically "to focus its deliberations on the issues raised in the comments made by member States' authorities."[1016] The risk assessment, taking into consideration the objections raised by member States, concluded that the product in question was as safe as conventional maize. Specifically, the SCF concluded in February 2002:

> "Having reviewed all the information provided by the petitioner and in the light of current published scientific information it is concluded that from the point of view of consumer health maize grain from maize line GA21 and derived products that are the subject of this application are as safe as grain and derived products from conventional maize lines."[1017]

7.1049 Canada notes, however, that GA-21 maize is among those products where no decision has been taken despite having received a favourable opinion from the relevant scientific committee. Since 1998, the Regulatory Committee has not delivered a single favourable opinion in relation to the authorization of biotech products under Regulation 258/97. Canada rejects the European Communities' attempt to rationalize the "delay" in approving this product on the basis that legislative change was required to enable regulators to adopt "risk management". The risk assessment of GA21 maize under Regulation 258/97 did not identify any risks for which risk management measures would be justified. Therefore there is no justification for imposing "risk management" measures, be they labelling, post market monitoring or tools to facilitate the implementation and enforcement of such risk management measures (*e.g.* product tracing or detection). Canada maintains, rather, that the "delays" in approving GA21 maize under Regulation 258/97 are a result of the moratorium on the approval of biotech products.

7.1050 **Argentina** argues that for GA21 maize (food), the risk assessment required by Regulation 258/97 has been completed. However, since 27 February 2002, the date on which the SCF expressed its favourable opinion, there has been no further progress in the approval process. Argentina indicates that the application was withdrawn in September 2003 because no progress had been made since 27 February 2002. This means that the process dragged on for a total of 5 years and 2 months since the initial submission of the application without a definitive response.

7.1051 The **European Communities** recalls that in May 2000, the Commission requested the opinion of the SCF. The SCF issued its opinion in February 2002, finding that the application did not contain sufficient information concerning substantial equivalence and toxicity testing, and requested additional information from the applicant.[1018]

[1015] Exhibit EC-91/At. 45, p. 2.
[1016] Exhibit CDA-35-J, p. 2; Exhibit CDA-35-K, p. 2; Exhibit CDA-35-M, p. 11.
[1017] Exhibit CDA-35-K, pp. 11-12; Exhibit EC-91/at.43.
[1018] Exhibit EC-91/At. 17.

7.1052 The European Communities notes the difference between risk assessment and risk management and argues that the former is the task of the scientific committees, while the latter is the function of the Regulatory Committee. Since the Regulatory Committee fulfils risk management functions, it has to take into account all relevant factors, including risk assessment *stricto sensu*. The European Communities argues that the draft measures forwarded by the Commission to the Regulatory Committee are therefore supported by scientific assessments, but also address other legitimate issues, including risk management issues, which are not addressed by a scientific committee.

7.1053 Specifically in relation to the application concerning GA21 maize (food), the European Communities submits that the SCF's opinion did not address sufficiently all relevant elements. The elements which determined the insufficiency of the SCF's opinion related to the issues of detection and validation methods, which were requirements to be included in the new legislation on "Food and Feed" and on whose importance the applicant agreed. More particularly, the European Communities notes that in view of the pending legislative proposal for "Food and Feed", in June 2002 the applicant committed on a voluntary basis to providing detection and validation methods for its product in collaboration with the Joint Research Centre of the Commission (hereafter the "JRC").

7.1054 The European Communities notes that agreement on the amount of data and material and the circumstances of their submission to the JRC took a considerable amount of time. All the necessary data were received in proper condition in mid-September 2003. The pre-validation study was initiated in October and was concluded after the applicant delivered the full data set at the end of November 2003. Some additional testing on the method and materials was carried out in early 2004. The collaborative study of method validation was launched in April 2004 and was expected to be finished by the end of June 2004.

7.1055 The **Panel** notes that the lead CA forwarded the application with its positive assessment to the Commission on 21 January 2000. After the circulation of this assessment report to all member States three weeks later, a number of member States submitted comments, requested further data, or raised objections within the 60-day period provided under Regulation 258/97. On 18 May 2000, the Commission requested the SCF to give an opinion regarding potential health concerns related to GA21 maize (food), and to focus specifically on the issues raised in the comments by member States.

7.1056 Shortly after the application was submitted to the SCF, the applicant provided responses to questions from two member States and submitted a revised labelling proposal; all of this possibly new information was, however, available by the end of August 2000. In April 2001, the SCF requested further information from the applicant. The applicant apparently provided the data requested by the SCF within two months. However, another eight months elapsed before the SCF issued its favourable opinion on 27 February 2002.

7.1057 On 23 April 2002, the applicant informed the Commission that it was no longer seeking to obtain approval to place on the market unprocessed GA21 maize grain for food use. The applicant explained that this food use would be subject to Directive 90/220[1019], and noted that the progress of the application concerning GA21 maize (EC-78) under Directive 90/220 had been suspended for some

[1019] Pursuant to Article 9 of Regulation 258/97, in the case of foods or food ingredients containing or consisting of GMOs, the approval decision to be taken must "respect the environmental safety requirements laid down by Directive 90/220 to ensure that all appropriate measures are taken to prevent the adverse effects on human health and the environment which might arise from the deliberate release of [GMOs]".

time. The applicant was hoping that this move would enable the application under Regulation 258/97 to proceed immediately.[1020]

7.1058 More than a month later, on 5 June 2002, the Commission services met with the applicant. The Commission in its report of the meeting states that "it would be desirable that a [draft measure on the application] would take into account in an appropriate manner the legislative developments with respect to the authorization of GM food and feed as well as the labelling of GM products".[1021]

7.1059 The report first addresses the issue of the labelling of foods and food ingredients derived from GA21 maize. It states that the applicant preferred to comply only with the labelling requirements set out in Article 8 of Regulation 258/97, which requires labelling only of foodstuffs where detectable traces of modified DNA or the resulting protein are present (*i.e.*, GM-maize oil was not required to be labelled). According to the report, the applicant believed that this was the scheme which would be in force at the time a decision would be made on this application, and would also avoid that GA21 maize would be treated differently from foods derived from other varieties of GM maize already on the EC market. The report notes that the applicant considered that if and when the labelling scheme was changed, those changes would automatically become obligatory for all authorized foodstuffs derived from any GM-maize variety. However, the Commission observed that it was clear that it would be more difficult to obtain a favourable opinion by a majority of member States if not all foods and food ingredients derived from GA21 maize had to be labelled, recognizing that anticipating the new labelling requirements (before the new legislation was adopted) would require re-consideration of the labelling of foods derived from GM maize already on the market. It was agreed that the Commission and the applicant would meet again to discuss the labelling issue once the European Parliament had debated the proposal for the new legislation in July 2002. There is nothing in the record to indicate that such a meeting took place in July 2002, or that the labelling issue was otherwise pursued further.

7.1060 The report of the meeting then goes on to address the issue of "[d]etection methods, traceability, reference materials [and] identification". The report indicates that the applicant "agreed to provide" the necessary information and materials to the JRC in a timely manner. There is nothing in the record which indicates that this "agreement" from the applicant was not voluntary. The report of the meeting indicates that there should be "no particular problem with respect to the validation. However, the availability of reference material has not been discussed."[1022] The report notes that a draft measure might be presented to the Regulatory Committee in November 2002, provided that a validated detection method was available by then.

7.1061 In September 2002, another meeting took place between the Commission and the applicant. The report of the meeting indicates that little progress had been made with regard to the validation of a detection method. This was because of a deadlock resulting from a request by the applicant that the method be kept confidential until the date of approval of the application. The report further notes that once a material transfer agreement was reached and a detection method and the necessary materials were available, the validation would take three months.[1023] Apparently, a material transfer agreement was finally signed in late February 2003, but a detection method was not provided until the end of March 2003.[1024] At the time of establishment of the Panel, the question of the validation of the detection method had not yet been resolved by the JRC, and so by August 2003 no draft measure had been forwarded to the Regulatory Committee.

[1020] Exhibit EC-91/At. 44.
[1021] Exhibit EC-91/At. 45.
[1022] Exhibit EC-91/At. 45.
[1023] Exhibit EC-91/At. 46.
[1024] Exhibit EC-91/At. 50.

7.1062 It is clear from the foregoing that after the SCF opinion was issued, the progress of the application was adversely affected by the fact that the Commission waited for more than three months before seeking voluntary commitments from the applicant. As well, the applicant agreed to provide additional information and materials so as to provide a basis for traceability, as envisaged in the new EC rules proposed by the Commission. This in turn resulted in further delays, due to the need for validation of a detection method.

7.1063 The Complaining Parties consider that the Commission's failure promptly to submit a draft measure to the Regulatory Committee, without seeking additional commitments from the applicant, reflects the adoption by the European Communities of a general moratorium, that is, a decision not to allow any application to proceed to final approval. We recall in this regard the June 1999 declaration by the Group of Five countries in which these countries stated that they would take steps to suspend approvals pending the adoption of new EC rules ensuring the labelling and traceability of GMOs and GMO-derived products. Thus, in April 2002, following the issuance of the SCF opinion, the Commission had reason to believe that the Group of Five countries would act as a "blocking minority" in the Regulatory Committee and the Council, and that the Commission would then have to adopt the draft measure submitted to the Regulatory Committee and Council, as required under Regulation 258/97. It is the Complaining Parties' contention, however, that the Commission decided not to discharge its responsibility under Regulation 258/97 to complete approval procedures, in view of opposition to final approvals by the Group of Five countries and that the Commission was therefore instrumental in the adoption and application of the alleged general moratorium.

7.1064 In considering the Complaining Parties' contention, we note, first of all, that the Commission could have forwarded a draft measure based on the requirements of Regulation 258/97 only. It did not do so. Instead, the Commission sought voluntary commitments from the applicant with regard to labelling and traceability. The commitments sought were based on legislative proposals for new EC rules on labelling and traceability. In relation to labelling, the Commission specifically pointed out that it would be difficult to obtain a majority without additional commitments. These elements suggest that the Commission wanted to prepare and forward a draft measure which could obtain qualified majority support in the Regulatory Committee or the Council. As pointed out earlier, however, in view of the June 1999 declaration by the Group of Five countries, the Commission had reason to believe that no qualified majority could be achieved before the new EC rules on labelling and traceability of GMOs and GMO-derived products were adopted.[1025] It should also be noted in this connection that the record contains no example of an approval procedure, whether it be one conducted under Directives 90/220 and 2001/18 or one conducted under Regulation 258/97, where the Commission adopted its own draft measure prior to the adoption of the new EC rules on labelling and traceability. For these reasons, we consider that the Commission's conduct in the approval procedure concerning GA21 maize (food) is consistent with the Complaining Parties' contention that at least until August 2003 the Commission followed a decision not to discharge its responsibility under Regulation 258/97 to prevent the Group of Five countries from blocking the approval of applications.

7.1065 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning GA21 maize (food) to the Regulatory Committee prior to August 2003 is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

[1025] This view is supported by the fact that Denmark invoked the June 1999 declaration by the Group of Five countries in the approval procedures concerning GA21 maize (food), when raising objections to the lead CA's favourable assessment of the application. Exhibit EC-91/At. 32.

Bt-11 sweet maize (food) (EC-92)

7.1066 A request for the approval of products processed from Bt-11 sweet maize (food) was initially submitted to the Netherlands (lead CA) on 6 April 1998. An amendment submitted on 24 November 1998 extended the scope of the request to cover also the consumption of fresh Bt-11 sweet maize. The documentation for these two requests was joined in a single document, which was submitted to the Commission on 11 February 1999 in accordance with Regulation 258/97. On 12 May 2000, the lead CA forwarded its initial assessment report to the Commission who circulated it to all member States on 15 June 2000. The Commission requested the opinion of the SCF in December 2000; the SCF issued its opinion in April 2002. At the time the Panel was established, the Commission had not submitted a draft measure on the application to the Regulatory Committee.

7.1067 Subsequent to the establishment of the Panel, on 10 November 2003, the Regulatory Committee failed to vote on the draft measure submitted by the Commission. On 8 December 2003, the Regulatory Committee voted on the draft measure but failed to reach a qualified majority. On 24 April 2004, the Council failed to reach a qualified majority on the draft measure submitted by the Commission. On 19 May 2004, the Commission adopted its draft measure concerning Bt-11 sweet maize (food).

7.1068 The **United States** notes that Bt-11 sweet maize (food) application was for marketing the maize as a fresh vegetable or after processing, not for cultivation. Moreover, the maize line was derived from an already reviewed and approved version of Bt-11 field maize.[1026] On 10 February 1998, the SCF published an opinion in which it concluded that the use of seed carrying the Bt-11 event was as safe as the use of seed from conventional maize varieties.[1027]

7.1069 The United States argues that following the positive assessment of the SCF in April 2002, there were delays in the processing of this application. The United States notes that the European Communities attempts to justify delays in the processing of the Bt-11 sweet maize (food) application by claiming that "[b]etween October and early December 2003 [after the SCF positive opinion], three new risk assessment were issued by the Member States, all of which conflicted with the SCF opinion".[1028] These risk assessments were supposedly provided by Austria, Belgium and France. The United States maintains that the EC contention is unsupported by the record. No risk assessments were in its view submitted during that time period. According to the European Communities' own chronology, the only events that occurred between October to December 2003 were: the finalization of a method validation by the JRC on 2 October 2003;[1029] the applicant's agreement to making public the validation method on 20 October 2003[1030]; a meeting of the Standing Committee on the Food Chain and Animal Health on 10 November 2003;[1031] a comment from France on 27 November 2003;[1032] the vote at the Regulatory Committee on 8 December 2003 (which did not reach a qualified majority);[1033] and a 20 November 2003 letter from the applicant to the Commission releasing technical data.[1034] None of these documents contain any purported risk assessments conducted by

[1026] According to the United States, the key difference between sweet and field maize is that, irrespective of whether it is genetically modified or not, sweet maize has a higher amount of natural sugars.

[1027] Exhibit EC-92/At. 17, p. 1 (referring back to the February 1998 SCP Opinion).

[1028] Responses by the European Communities to the questions posed by the Panel on the 3rd of June, 2004, Response to Question 1.

[1029] Exhibit EC-92/At. 66.

[1030] No document available per the European Communities' chronology.

[1031] Exhibit EC-92/At. 67 (misdated in the EC chronology as November 8).

[1032] Exhibit EC-92/At. 69.

[1033] Exhibit EC-92/At. 70.

[1034] Exhibit EC-92/At. 68.

France, Austria, or Belgium. At the 10 November 2003 meeting of the Standing Committee on the Food Chain and Animal Health,[1035] only a comment was provided by France, not a risk assessment.[1036] At the Regulatory Committee meeting on 8 December 2003, Austria[1037], Belgium[1038] and France[1039] submitted written declarations to their votes. But none of these was a risk assessment. Rather, when the Regulatory Committee failed to obtain a qualified majority in December 2003 it was because certain member States objected due to the proposed new traceability and labelling regulations (which did not become effective until April 2004).[1040]

7.1070 In May 2004, the novel food application for Bt-11 sweet maize was finally approved. The United States contends that the history of this application confirms the delays resulting from the moratorium, and its ultimate approval does not indicate that the moratorium has finally ended. Rather, in the view of the United States, the Bt-11 approval in May 2004 is entirely consistent with, and in fact supports, the existence of a general moratorium during the period covered within the Panel's terms of reference. Both the Commission and the Council have stated that the entry into force of the new traceability and labelling rules for biotech products might finally allow for the lifting of the moratorium. Those new rules went into effect on 19 April 2004. The United States considers that the fact that the Commission then approved the application concerning Bt-11 sweet maize (food) just one month later is not mere coincidence. To the contrary, this timing indicates that the EC approval system was held up not by any problems with particular applications, but by events outside the scope of its approval legislation. Moreover, the United States emphasizes that the Council itself acknowledged the existence of the "moratorium" – using this very word – in a statement concerning the scheduled approval of the application concerning Bt-11 sweet maize (food).[1041]

7.1071 **Canada** argues that Bt-11 sweet maize is one of six products whose approval was delayed for as long as five years, despite having received a favourable assessment from the lead CA, and, in the case of this product, having also received a positive assessment from the SCF. Canada notes that the Regulatory Committee held a vote on the application concerning Bt-11 sweet maize (food) on 8 December 2003, after the establishment of the Panel. However, the Regulatory Committee failed to obtain the qualified majority necessary for approval, despite having received a favourable opinion from the SCF.

7.1072 Canada further argues that it is unjustifiable to fail to approve products under Regulation 258/97 on the basis that the existing legislation does not provide for risk management

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[1035] Exhibit EC-92/At. 67.

[1036] The French comment does not "evaluate the potential for adverse effects on human or animal health" posed by the sweet corn's different sugar metabolism from field corn. The comment is concerned with unintended effects, theoretical risks not identified by any of the existing protein toxicity or animal studies conducted. As the Commission stated in its Proposal for a Council Decision of 28 January 2004, "[t]he concerns raised in the opinion of the 'Agence française de sécurité sanitaire des aliments' (AFSSA) of 26 November 2003 do not bring any new scientific elements in addition to the initial assessment of sweet maize Bt-11 carried out by the competent authorities of the Netherlands". In fact, these concerns were also expressed in two AFSSA opinions of 21 July 2000 and 20 March 2001 and were duly considered by the SCF in its opinion of 17 April 2002, which confirmed the findings of the initial assessment that Bt-11 sweet maize is as safe for human food use as conventional maize. Exhibit EC-92/At. 77.

[1037] Exhibit EC-92/At. 71.

[1038] Exhibit EC-92/At. 73.

[1039] Exhibit EC-92/At. 72.

[1040] Exhibit EC-92/Ats. 67 (noting that "[f]inally, several Member States questioned the opportunity to proceed with the authorization of this product in anticipation of the coming into application of Regulation (EC) 1829/2003 and 1830/2003."), 71, 74, 75 and 76.

[1041] EC first written submission, para. 157.

measures, where the risk assessments for those products have not identified any risks that need to be managed. The SCF concluded in April 2002 that Bt-11 sweet maize (food) is as safe for human food use as its conventional counterparts.[1042]

7.1073 In relation to the Commission's decision of May 2004 to approve the placing on the market of Bt-11 sweet maize (food), Canada observes that the Commission has been forced to adopt a decision authorizing Bt-11 sweet maize (food) only after resort to the exceptional Regulatory Committee procedure. Despite favourable opinions of EFSA and despite the entry into force of the new legislative regime,[1043] member States voted against the Commission's proposal for the approval of the product in question at the Regulatory Committee stage. Moreover, the Council failed to act. Far from demonstrating that the moratorium has been lifted, the fact that approval is granted only at the last possible step is another indication of the existence of the moratorium.

7.1074 **Argentina** argues that although some products, including Bt-11 sweet maize (food), received positive scientific opinions under Regulation 258/97, approval of these products was nonetheless stalled, both before reaching the Regulatory Committee stage and within that stage.

7.1075 The **European Communities** notes that following the submission of this application to the Netherlands in 1999, the lead CA requested additional information relating mainly to the antibiotic resistance marker used (PAT protein) and to the toxicity studies done in relation to this protein. After the lead CA sent its initial assessment report to the Commission in May 2000, four member States raised objections and several more requested additional information, relating mainly to the above issues as well as to molecular characterization. The Commission requested an opinion of the SCF in December 2000. The SCF requested further data which the applicant only supplied in February 2002. The SCF issued its opinion in April 2002, stating that on the basis of the information supplied in the application and further material supplied by the applicant in response to queries raised by member States and in the light of the published literature, it was to be concluded that Bt-11 sweet maize (food) was as safe for human food use as its conventional counterparts.

7.1076 According to the European Communities, in view of the pending legislative proposal on "Food and Feed", the applicant, on a voluntary basis agreed to provide detection and validation methods for its product in collaboration with the JRC. The amount of data and material and the circumstances of their submission to the JRC were agreed upon in a planning meeting in October 2002. The first set of material sent at the beginning of 2003 was inadequate in terms of necessary amounts of information, and the method provided by the applicant performed very poorly in a pre-validation study. The applicant delivered a proper method and all the necessary materials only by July 2003. The JRC finalized the validation method in October 2003. Following the finalization of the validation method, the Commission prepared a proposal for a decision on a market authorization. The proposal did not obtain a qualified majority in the Regulatory Committee or in the Council and was adopted by the Commission on 19 May 2004.

7.1077 The European Communities argues that the history of the application concerning Bt-11 sweet maize (food) is an illustration of the fact that the approval process has been steadily proceeding over the past years. The marketing authorization of Bt-11 sweet maize (food) did not occur because of a sudden change in the European Communities' policy on GMOs, but as the result of a normal process of assessment, which has known no suspension and has been conducted taking into account the

[1042] Exhibit CDA-35-J, pp. 9-10.

[1043] Regulation 1829/2003 (GM food and feed) (Exhibit CDA-20) and Regulation 1830/2003 (traceability and labelling) (Exhibit CDA-30) entered into force on 18 April 2004.

reactions of the applicants, the constant evolution of the scientific and regulatory debate concerning GMOs and the entry into force of new legislation resulting from this debate.

7.1078 The **Panel** notes that the lead CA forwarded the application with its positive assessment to the Commission on 12 May 2000. After the circulation of this assessment report to all member States, a number of member States submitted comments, requested further data, or raised objections within the 60-day period provided under Regulation 258/97. On 13 December 2000, the Commission requested the SCF to give an opinion regarding potential health concerns related to Bt-11 sweet maize (food), and to focus specifically on the issues raised in the comments by member States. The SCF apparently considered the application for four months before requesting further information from the applicant on 15 April 2001. It appears that no response was forthcoming from the applicant, and on 12 November 2001 the SCF reminded the applicant that it was awaiting information requested in April. The applicant apparently replied that it expected to provide the requested data in January 2002. On 17 April 2002, the SCF issued its report with the conclusion that Bt-11 sweet maize (food) is as safe for human food use as its conventional counterparts.

7.1079 More than a month and a half later, on 5 June 2002, the Commission services met with the applicant. The Commission in its report of the meeting states that "it would be desirable that a [draft measure on the application] would take into account in an appropriate manner the legislative developments with respect to the authorization of GM food and feed as well as the labelling of GM products".[1044]

7.1080 The report of the meeting addresses the issue of "[d]etection methods, traceability, reference materials [and] identification". The report indicates that the applicant "agree[d] to provide" the necessary information and materials to the JRC in a timely manner.[1045] There is nothing in the record which indicates that this "agreement" from the applicant was not voluntary. The report notes that a draft measure might be presented to the Regulatory Committee in November 2002, provided that a validated detection method was available by then.

7.1081 Apparently, the applicant did not transfer any material until late January 2003. Following unsatisfactory results of the detection methods validation, and further provision of materials for the validation, in January 2003 the JRC indicated that it would provide a template protocol for the validation for use by the applicant.[1046] The JRC continued to find the results unacceptable, and in July 2003 the applicant accepted to use the method proposed by the JRC and submitted materials.[1047] The JRC finalized its method validation in October 2003.[1048] Thus, at the time of establishment of the Panel, the question of the validation of the detection method had not yet been resolved by the JRC, and so by August 2003 no draft measure had been forwarded to the Regulatory Committee.

7.1082 It is clear from the foregoing that after the SCF opinion was issued the progress of the application was adversely affected by the fact that the Commission waited for more than a month and a half before seeking voluntary commitments from the applicant. As well, the applicant agreed to provide additional information and materials so as to provide a basis for traceability, as envisaged in the new EC rules proposed by the Commission. This in turn resulted in further delays, due to the need for validation of a detection method.

[1044] Exhibit EC-92/At. 54.
[1045] *Ibid*.
[1046] Exhibit EC-92/Ats. 56 and 57.
[1047] Exhibit EC-92/Ats. 59 and 63.
[1048] Exhibit EC-92/At. 66.

7.1083 In its responses to questions by the Panel, the European Communities submits that another reason for the delay in the forwarding of a draft measure to the Regulatory Committee was the circumstance that between October and early December 2003 new risk assessments were issued by Austria, Belgium and France, all of which, according to the European Communities, conflicted with the SCF opinion. We note that this explanation concerns a period of time that post-dates the date of establishment of this Panel, and we will therefore not consider this explanation.

7.1084 The Complaining Parties consider that the fact that the Commission did not promptly submit a draft measure to the Regulatory Committee, without seeking additional commitments from the applicant, reflects the adoption by the European Communities of a general moratorium, that is, a decision not to allow any application to proceed to final approval. We recall in this regard the June 1999 declaration by the Group of Five countries in which these countries stated that they would take steps to suspend approvals pending the adoption of new EC rules ensuring the labelling and traceability of GMOs and GMO-derived products. Thus, in April 2002, following the issuance of the SCF opinion, the Commission had reason to believe that the Group of Five countries would act as a "blocking minority" in the Regulatory Committee and the Council, and that the Commission would then have to adopt the draft measure submitted to the Regulatory Committee and Council, as required under Regulation 258/97. It is the Complaining Parties' contention, however, that the Commission decided not to discharge its responsibility under Regulation 258/97 to complete approval procedures, in view of opposition to final approvals by the Group of Five countries and that the Commission was therefore instrumental in the adoption and application of the alleged general moratorium.

7.1085 In considering the Complaining Parties' contention, we note, first of all, that the Commission could have forwarded a draft measure based on the requirements of Regulation 258/97 only. It did not do so. Instead, the Commission sought voluntary commitments from the applicant. The commitments sought were based on legislative proposals for new EC rules on labelling and traceability of GMOs and GMO-derived products. These elements suggest that the Commission wanted to prepare and forward a draft measure which could obtain qualified majority support in the Regulatory Committee or in the Council. As pointed out earlier, however, in view of the June 1999 declaration by the Group of Five countries, the Commission had reason to believe that no qualified majority could be achieved before the new EC rules on labelling and traceability of GMOs and GMO-derived products were adopted.[1049] It should also be noted in this connection that the record contains no example of an approval procedure, whether it be one conducted under Directives 90/220 and 2001/18 or one conducted under Regulation 258/97, where the Commission adopted its own draft measure prior to the adoption of the new EC rules on labelling and traceability. We recall that in the case of the application concerning Bt-11 sweet maize (food), the Commission adopted its own draft measure only after the entry into force of the new EC rules. For these reasons, we consider that the Commission's conduct in the approval procedure concerning Bt-11 sweet maize (food) is consistent with the Complaining Parties' contention that at least until August 2003 the Commission followed a decision not to discharge its responsibility under Regulation 258/97 to prevent the Group of Five countries from blocking the approval of applications.

7.1086 We note the European Communities' argument that the approval of the application concerning Bt-11 sweet maize (food) did not occur because of a sudden change in the European Communities'

[1049] This view is supported by the fact that Denmark and France invoked the June 1999 declaration by the Group of Five countries in the approval procedures concerning Bt-11 sweet maize (food), when raising objections to the lead CA's favourable assessment of the application. Exhibit EC-92/Ats. 23 and 27. We also note that even after the adoption of the new EC rules in September 2003, neither the Regulatory Committee in its December 2003 vote nor the Council in its April 2004 vote achieved a qualified majority in favour of the application concerning Bt-11 sweet maize (food).

policy on GMOs, but as the result of a normal process of assessment, which steadily proceeded and knew no suspension. We recall that the Complaining Parties' contention is that the European Communities was applying a general moratorium on final approvals. Thus, "steady progress" of an application short of final approval is not inconsistent with the Complaining Parties' contention. As of August 2003, the application concerning Bt-11 sweet maize (food) had not yet been approved by the Commission. The application was only approved after the entry into force of the new EC rules on labelling and traceability in April 2004, and then only after every procedural step had been exhausted. Neither the Regulatory Committee nor the Council achieved a qualified majority in favour of the application.

7.1087 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning Bt-11 sweet maize (food) to the Regulatory Committee prior to August 2003 is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

Transgenic tomato (food) (EC-100)

7.1088 The application concerning the Transgenic tomato (food) was initially submitted to the United Kingdom (lead CA) and to the Commission on 2 March 1998. The lead CA forwarded its initial assessment to the Commission on 4 June 1998, and this was circulated to all member States on 22 June 1998. On 23 December 1998, the SCF was requested to evaluate the application; the opinion of the SCF was given on 7 September 2000. The application was withdrawn by the applicant on 24 September 2001.

7.1089 The **United States** argues that after this application received a positive assessment from the SCF, the application was withdrawn because of the excessive delay in carrying out the approval process.

7.1090 The **European Communities** contends that after assessment at the national level, the request was withdrawn by the applicant. As the reason for its withdrawal, the applicant pointed to "commercial re-positioning" following a merger.

7.1091 The **United States** argues that in many cases the withdrawal of applications resulted from the applicant's frustration with the European Communities' suspension of its approval process, although the applicant may not have explicitly so indicated in it reasons for withdrawal. Over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Second, the companies have a strong incentive to maintain cordial relations with EC regulators, and saw no advantage of complaining to EC regulators about the length of the delays resulting from the moratorium.

7.1092 The **Panel** notes that the initial assessment by the lead CA was completed well within the 90-day time period established in Regulation 258/97. Following the circulation of the initial positive assessment to member States, a number of member States submitted comments and objections. On 23 December 1998, after further comments from other member States had been submitted, and responses provided by the applicant, the Commission requested an opinion of the SCF.

7.1093 On 23 September 1999, the SCF gave its opinion and concluded that from the human health point of view, processed tomato products derived from these tomatoes were as safe as products from conventional fruit.[1050] The next step in the procedure was for the Commission to prepare and submit a

[1050] Exhibit EC-100/At. 48.

draft measure on the application to the Regulatory Committee. However, there is no evidence of this step being completed during the eleven months following the SCF opinion.

7.1094 On 7 September 2000, the SCF issued another opinion on the application concerning the Transgenic tomato (food).[1051] Apparently, the Commission had requested this further opinion to obtain the SCF's comments on the relevance of particular studies undertaken in the United States on transgenic tomatoes for fresh consumption. This request was apparently prompted by a question to the Commission from a member of the European Parliament. The SCF concludes that these results have no relevance for the assessment of the safety of the processed tomato products which were to be approved in accordance with the application concerning the Transgenic tomato (food).

7.1095 Even after this second positive assessment by the SCF, the Commission did not forward a draft measure to the Regulatory Committee before the application was withdrawn by the applicant more than one year after the second positive opinion by the SCF. As noted by the European Communities, in the letter of withdrawal the applicant made reference to recent mergers and to its commercial re-positioning.[1052]

7.1096 It is clear from the foregoing that the application concerning the Transgenic tomato (food) did not progress because the Commission did not forward a draft measure to the Regulatory Committee. The SCF gave a favourable opinion of the application on two separate occasions, and no reasons for the lack of progress were provided to us.

7.1097 The United States considers that the Commission's failure, over a period of more than two years, to submit a draft measure to the Regulatory Committee reflects the adoption by the European Communities of a general moratorium on approvals, that is to say, of a decision not to allow any application to proceed to final approval. We recall in this regard the June 1999 declaration by the Group of Five countries in which these countries stated that they would take steps to prevent approvals pending the adoption of new EC rules ensuring the labelling and traceability of GMOs and GMO-derived products. Thus, in September 1999, following the issuance of the first SCF opinion, the Commission had reason to believe that the Group of Five countries would act as a "blocking minority" in the Regulatory Committee and the Council, and that the Commission would then have to adopt the draft measure submitted to the Regulatory Committee and Council, as required under Regulation 258/97. It is the United States' contention, however, that the Commission decided not to discharge its responsibility under Regulation 258/97 to complete approval procedures, in view of opposition to final approvals by the Group of Five countries and that the Commission was therefore instrumental in the adoption and application of the alleged general moratorium.

7.1098 We consider that the Commission's conduct in the approval procedure concerning the Transgenic tomato (food) is consistent with the contention that the Commission followed a decision not to discharge its responsibility under Regulation 258/97 to prevent the Group of Five countries from blocking the approval of applications. In our view, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application is not inconsistent with the United States' assertion that the European Communities was applying a general moratorium on approvals at the time. As was pointed out by the United States, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning the Transgenic tomato (food).

[1051] Exhibit EC-100/At. 49.
[1052] Exhibit EC-100/At. 50.

7.1099 In the light of the above considerations, we conclude that the Commission's failure to submit a draft measure concerning the Transgenic tomato (food) to the Regulatory Committee prior to the withdrawal of the application in September 2001 is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

Failure by the Scientific Committee on Food to complete its review

7.1100 In support of its assertion that the European Communities applied a general moratorium on approvals, the United States has pointed to two approval procedures in which it says the Scientific Committee for Food (SCF) which the Commission consulted with regard to these applications did not complete its review. We consider these approval procedures below, recalling that Article 11 of Regulation 258/97 provides that "[t]he Scientific Committee for Food shall be consulted on any matter failing within the scope of this Regulation likely to have an effect on public health".

Transgenic red-hearted chicory (food) (EC-97)

Transgenic green-hearted chicory (food) (EC-98)

7.1101 The applications concerning Transgenic red-hearted chicory (food) and Transgenic green-hearted chicory (food) for human consumption were initially submitted to the Netherlands (lead CA) in April 1998. The lead CA provided initial positive assessments for both products to the Commission on 23 April 1998, which was circulated to member States as drafts on 13 May 1998. On 27 October 1998, the Commission informed member States that the initial assessments were not draft texts, and that the lead CA was not undertaking any further assessment. A large number of member States submitted comments or objections on these applications, and on 29 April 1999 the Commission requested the SCF to give an opinion. The SCF considered both products at the same time in its evaluation. No opinion had been issued by the SCF at the time these applications were withdrawn on 27 May 2003.

7.1102 The **United States** argues that although these products received favourable initial assessments by the lead CA, as of May 2003, when the application for both was withdrawn, the products had been "under assessment" by the SCF for more than five years. The United States contends that these withdrawn applications are direct evidence of the existence of a general moratorium, and that the withdrawal evinces the applicant's frustration with the suspension of the EC approval process.

7.1103 The **European Communities** notes that after assessment of these products by the lead CA, the request was withdrawn by the applicant with the indication that the applicant preferred to no longer be associated with genetically modified products because of the negative response from the market.

7.1104 The **Panel** notes that the initial assessments by the lead CA were made within the 90-day period foreseen for this purpose under Regulation 258/97. Delays in the consideration of the applications for these two products occurred primarily in the course of the evaluation by the SCF. For example, more than four months went by after the SCF received the request by the Commission to evaluate these products before the SCF requested better quality images of certain analytical results from the applicant. The information provided does not indicate when or if the applicant provided the requested data, but only that, two months later, the SCF requested additional information, and after a 7-month delay, the SCF requested that the applicant provide studies covering two growing seasons and at least six locations. The applicant apparently instead offered to provide data from previous growing seasons, which the SCF indicated might be acceptable.

7.1105 In a communication to the SCF of 14 November 2000, the applicant expressed very apparent frustration with the progress of evaluation of these two products.[1053] The applicant noted that much information had been provided to permit the determination of substantial equivalence between the transgenic chicory and conventional chicory, and expressed the view that "it does not make sense to continue year after year with experiments without having any indication that there is no substantial equivalence".[1054] The applicant also expressed concern that since the SCF had not indicated whether it would accept the new experiments as proposed by the applicant, "this might be a new reason for the SCF to ask the company to do new experiments after the proposed experiments have been finished".[1055] The alternative suggested by the SCF would require the applicant to apply for additional field trials in several countries, and the applicant indicated that it would take at least one year to get permission from all competent authorities. The total process would thus take at least three additional years, and the applicant indicated that this would have negative financial implications. The applicant indicated that it had reached the conclusion that the applications for the Transgenic red-hearted chicory (food) and the Transgenic green-hearted chicory (food) were a kind of "never ending story", and that "the procedure, time energy and costs are disproportionate compared to conventional breeding programs. This may lead to the conclusion that development and marketing of transgenic vegetable crops in the European Union do not have any opportunity."[1056] The applicant nevertheless provided additional information from various years of field introductions to substantiate its claims of substantial equivalence, and requested that the SCF extract its conclusions and take decisions based on the information now available to it.

7.1106 Five months after the November 2000 communication from the applicant, the SCF informed the applicant that it would accept the data provided regarding field studies, and requested additional information regarding nutritional composition.[1057] The applicant indicated, in response, that it had not yet decided whether to execute additional experiments. It expressed concern that the question regarding antibiotic resistance markers would need to be resolved before new experiments were started, and requested clarification regarding whether products containing antibiotic resistance markers would be permitted to enter the EC market after the entry into force of Directive 2001/18.[1058] In a response dated 24 July 2001, the Commission indicated that the provisions of Directive 2001/18 did not include a general legal ban on antibiotic resistance marker genes as such but linked their phasing out to certain qualifiers. The Commission also indicated that consideration of the applications for the Transgenic red-hearted chicory (food) and the Transgenic green-hearted chicory (food) was suspended until the requested information on nutritional composition had been provided.[1059] The record does not include any further response from the applicant until the formal withdrawal of the applications on 27 May 2003.[1060] However, the European Communities asserts that the SCF was requested as early as 24 September 2001 to suspend its consideration of the applications concerned.

7.1107 We sought the views of the experts advising us regarding the necessity of the information requested by the SCF on substantial equivalence, molecular characterization and antibiotic resistance marker genes to ensure that the safety assessment was valid.[1061] The only expert who provided a

[1053] Exhibits EC-97/At. 25 and EC-98/At. 35.
[1054] *Ibid*.
[1055] *Ibid*.
[1056] *Ibid*.
[1057] Exhibits EC-97/At. 28 and EC-98/At. 38.
[1058] Exhibits EC-97/At. 29 and EC-98/At. 39.
[1059] Exhibits EC-97/At. 31 and EC-98/At. 41.
[1060] Exhibits EC-97/At. 32 and EC-98/At. 42.
[1061] Annex H, Question 55 and 56.

response to this question, Dr. Nutti, considered that the information requested regarding the establishment of substantial equivalence was necessary, and that the information requested on nutritional composition was also required.[1062]

7.1108 The United States considers that the SCF's failure, for more than two years, to complete its assessment of the applications in question reflects the adoption by the European Communities of a general moratorium, that is, a decision not to allow any application to proceed to final approval. We note that the United States does not assert that the SCF was an active participant in the alleged moratorium on approvals and that the time taken by the SCF for its assessment is a reflection of the SCF's support for the moratorium. We understand the United States to argue instead that the alleged general moratorium on approvals affected the manner in which, and the speed with which, the SCF conducted its assessments of the applications in question.

7.1109 It is reasonable to assume that the SCF was aware of the June 1999 declaration by the Group of Five countries, and thus of their declared intention to act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability.[1063] In our view, it can further be assumed that the SCF was aware of the failure by the Commission in the approval procedure concerning the Transgenic tomato (food) to submit a draft measure to the Regulatory Committee following the two positive SCF opinions. Against this background, it is conceivable that the SCF could have been requesting more information than it would otherwise have requested, notwithstanding the fact that such requests could be expected to result in delays.

7.1110 The November 2000 communication from the applicant, referring to a "never ending story", clearly documents the applicant's frustration with the long delays and repeated requests for information. This communication is therefore consistent with the possibility that the progress of the SCF's assessment was affected by the alleged general moratorium on approvals. In our view, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application is not inconsistent with the United States' assertion that the European Communities was applying a general moratorium on approvals at the time. As was pointed out by the United States, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the applications concerning the Transgenic red-hearted chicory (food) and the Transgenic green-hearted chicory (food).

7.1111 On the other hand, the record shows that in other approval procedures, and during the relevant time period, the SCF completed its assessment of applications within a shorter timeframe.[1064] Furthermore, we recall the advice of Dr. Nutti that the information requested by the SCF may be considered necessary to ensure that the conclusions of the safety assessment of the Transgenic red-hearted chicory (food) and the Transgenic green-hearted chicory (food) were valid. However, even if it is accepted that the time taken by the SCF may be explained by the need for valid conclusions, this would not contradict the United States' assertion that the European Communities applied a general moratorium on approvals. In June 1999, the Group of Five countries indicated that they would act as a "blocking minority" in the Regulatory Committee and in the Council, and we recall that in the approval procedure concerning the Transgenic tomato (food), the Commission failed to discharge its

[1062] Annex H, paras. 759-760.
[1063] We recall that the Commission made a proposal for such rules in July 2001.
[1064] *See*, *e.g*, the approval procedure concerning Bt-11 sweet maize (food), where an SCF opinion was requested in December 2000 and provided in April 2002. During that period, the clock was stopped for several months. Exhibit EC-92/Ats. 47-53.

responsibility inasmuch as it did not submit a draft measure to the Regulatory Committee. These acts and omissions affect and concern stages of the approval procedure subsequent to the SCF's involvement. The applications concerning the Transgenic red-hearted chicory (food) and the Transgenic green-hearted chicory (food) had not reached these stages as of September 2001, when the SCF was apparently requested to suspend its work.

7.1112 In the light of the above considerations, we conclude that the failure of the SCF to complete its assessment of the applications concerning the Transgenic red-hearted chicory (food) and the Transgenic green-hearted chicory (food) prior to September 2001, when the SCF was apparently requested by the applicant to suspend its work, is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

Delays at member State level

7.1113 In support of their assertion that the European Communities applied a general moratorium on approvals the Complaining Parties have pointed to a number of approval procedures in which they say the member State to which the application was submitted – the lead CA – either did not complete its assessment of the relevant application or completed it with considerable delay. We consider these approval procedures below, recalling that Article 6(3) of Regulation 258/97 provides that "[t]he initial assessment report [by the lead CA] shall be drawn up within a period of three months from receipt of [the application]". Article 6(4) further provides that the lead CA "shall without delay forward the [initial assessment report] to the Commission, which shall forward it to the other Member States."

GA21 maize (food) (EC-91)

7.1114 The application for GA21 maize (food) was submitted to the Netherlands CA (lead CA) on 24 July 1998. The initial assessment of the lead CA was provided to the Commission on 21 January 2000, and circulated to member States on 18 February 2000. At the time the Panel was established, the Commission had not submitted a draft measure on the application to the Regulatory Committee.

7.1115 The **United States** argues that the application for GA21 maize (food) under Regulation 257/98 was delayed at the member State level for 18 months while the lead CA completed its risk assessment. The lead CA requested the applicant to perform a further study on compositional analysis. The request was made on 24 February 1999, and the applicant provided its response by 26 October 1999.[1065] Thus, the total time between the first submission, 24 July 1998, and the lead CA's opinion, 17 January 2000, was 18 months. Of those 18 months, 8 were used by the applicant to answer questions.

7.1116 **Canada** argues that the total time taken by the lead CA for its review was 18 months, and that only 8 of the 18 months were taken by the applicant to respond to questions. The difference of 10 months exceeds the 3-month period provided for in Regulation 258/97.

7.1117 The **European Communities** argues that this application was pending at the member State level for about a year and a half due to requests by the lead CA for completion of the dossier and for additional scientific data. The United States ignores the fact that the 18 months spent at member State level were due to the incompleteness of the dossier initially submitted by the applicant and to the need for additional scientific data.[1066]

[1065] Exhibit EC-91/Ats. 11 and 14.
[1066] The European Communities refers to Exhibit EC-91/Ats. 1-6.

7.1118 The **Panel** notes from the record that this application was submitted to the Netherlands in July 1998. A month and a half later, the applicant was apparently requested to complete the dossier. The applicant seems to have provided the missing information in December 1998, although some references were provided only in January 1999. In February 1999, the Dutch Health Council put forward its first substantive request for information. The applicant provided the requested information in March 1999. In June 1999, the Health Council informed the applicant that it needed more data than that provided by the applicant in March. The applicant provided the data in October 1999. The Health Council completed its assessment in December 1999, and the Dutch CA forwarded its initial assessment report in January 2000.

7.1119 We note that the record for this approval procedure is incomplete, but it appears that the Dutch CA did not have a reasonably complete file until December 1998. We also note, however, that the Dutch CA then waited for almost three months before forwarding an initial request for information. After receiving the requested information, the Dutch CA again waited for almost three months before making a follow-up request for more data. Finally, after obtaining the necessary data, the lead CA spent another period of almost three months finalizing its assessment. It is clear, therefore, that the lead CA exceeded the three-month period foreseen in Regulation 258/97 for an initial assessment.

7.1120 The United States and Canada do not assert that the time taken by the Netherlands to complete its assessment is a reflection of Dutch support for the moratorium. Rather, their assertion is that the time taken by the Netherlands reflects the impact of the alleged moratorium. According to the United States and Canada, the Netherlands was placed in a position of having to recognize the moratorium as a reality and that this affected the speed with which it conducted its assessment.

7.1121 We consider that following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability. In our view, the Netherlands also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission might not complete the approval procedure in the face of systematic opposition by the Group of Five countries. We note, however, that the lead CA's initial request for additional information and its follow-up request for more data were made in February and early June 1999, respectively, and thus pre-date the June 1999 declaration of the Group of Five countries. On the other hand, it was after the June 1999 declaration that the lead CA spent an additional three months finalizing its initial assessment report.

7.1122 We also note, however, that the Netherlands was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, in this instance, we are not convinced that the Dutch CA's conduct reflects a precautionary approach. In particular, we are not convinced that the Dutch CA could not forward its June 1999 follow-up request for more data sooner than it did even while following a precautionary approach, or that after receiving the applicant's response it could not finalize its initial assessment earlier than in January 2000.

7.1123 It is pertinent to note in this regard that the applicant had submitted two other applications concerning the same product under Directive 90/220, one to the United Kingdom (GA21 maize (EC-85)) and one to Spain (GA21 maize (EC-78)). By the time the Dutch CA was finalizing its assessment report, the two Directive 90/220 applications were under assessment at Community level. As we have noted, following the June 1999 declaration by the Group of Five countries, the Dutch CA in our view had reason to believe that at Community level the Group of Five countries and/or the Commission could take action to delay or prevent the final approval of these applications. Since a

special environmental safety assessment was necessary for the application concerning GA21 maize (food) to be approved under Regulation 258/97[1067], we think it could also be that the time taken by the Dutch CA before forwarding its initial assessment report in January 2000 reflects a view on the part of the Dutch CA that the Directive 90/220 applications concerning GA21 maize would be delayed at Community level.

7.1124 In the light of the above considerations, we conclude that the time taken by the Netherlands for its initial assessment of the application concerning GA21 maize (food), and in particular the time taken by the lead CA as from October 1999 to finalize its initial assessment report, is consistent with the contention of the Complaining Parties that during the relevant time period the European Communities applied a general moratorium on final approvals.

LL soybeans (food) (EC-93)

7.1125 The application concerning LL soybeans (food) was submitted to Belgium on 30 November 1998. The application was sent to the Commission on 2 February 1999. At the time of establishment of the Panel, the lead CA had not completed its assessment of the application. In July 2004, the applicant withdrew the application.

7.1126 The **United States** submits that Belgium refused to forward the application for LL soybeans (food) for consideration at the Community level.

7.1127 **Argentina** argues that there was an overall delay of 5 years and 8 months since the application was submitted.

7.1128 The **European Communities** notes that the application for LL soybean (food) was with the Belgian CA only as of February 1999. The Commission gave notice of the Belgian application to all other member States in March 1999. In April 1999, the Belgium Biosafety Council requested additional information from the applicant in order to proceed with the initial assessment. The request touched upon the issues of substantial equivalence and presence of transgenic PAT DNA and PAT protein.[1068] The applicant did not fully respond to this request for additional information. Greece (June 1999) and Italy (July 1999) also asked for additional information on various points such as nutritional and biochemical characterization and toxicity of the transgenic plant, but did not receive any answer.[1069] In April 2004, the lead CA reminded the applicant to respond to the requests for additional information so that it would be able to finalize the pending assessment report.

7.1129 The European Communities submits that the Complaining Parties choose to ignore the fact that the applicant failed to provide the additional information that was requested by the lead CA in April 1999, and by Greece and Italy in June and July 1999. According to the European Communities, all three requests for additional information remained mostly unanswered. The European Communities points out that on 6 July 2004, the applicant withdrew its application.

7.1130 The **Panel** notes that contrary to what the European Communities asserts, the application concerning LL soybeans (food) was with the Belgian CA as of early December 1998, and not only as

[1067] We note that the application concerning GA21 maize (food) as submitted to the Dutch CA *inter alia* concerned foods or food ingredients containing or consisting of GMOs and as such would appear to be subject to the provisions of Article 9 of Regulation 258/97. To recall, Article 9 requires that approval decisions concerning foods or food ingredients containing or consisting of GMOs must respect the environmental safety requirements laid down in Directive 90/220.

[1068] Exhibit EC-93/At. 11.

[1069] Exhibit EC-93/Ats. 16 and 17.

of February 1999.[1070] On 8 December 1998, the Belgian General Food Inspectorate requested the Belgian Biosafety Council to prepare a first evaluation report within 90 days of referral of the file.

7.1131 The record indicates that the Biosafety Council met on the application on 17 December 1998. At that meeting, concerns were raised that while the application focused on animal nutrition, a number of tests concerning possible human consumption impacts were absent. The applicant apparently gave a written undertaking to address these concerns relating to substantial equivalence following instructions from a Belgian expert.[1071]

7.1132 In March 1999, the Commission circulated the application for information to all member States. The chronology provided by the European Communities indicates that Denmark requested further information from the applicant at that time, however this correspondence was not provided to us.

7.1133 Towards the end of April 1999, the Belgian Biosafety Council responded to a query from the Belgian General Food Inspectorate. The letter notes that the applicant had still not addressed the Biosafety Council's concerns relating to substantial equivalence. The letter further states that the applicant needed to provide additional information regarding the implementation of labelling and, more specifically, the presence of PAT DNA and PAT protein in derived soya products.[1072] The letter of the Biosafety Council concludes by saying that due to the absence of data and information on substantial equivalence and the presence of transgenic PAT DNA and PAT protein it was not possible for the Biosafety Council to issue a final evaluation report with regard to the application concerning LL soybeans (food). We asked the experts advising us whether information regarding substantial equivalence and the presence of transgenic PAT DNA and PAT protein was necessary to ensure that conclusions of the safety assessment were valid. Dr. Nutti responded that these requests were valid.[1073]

7.1134 In May 1999, the lead CA sent a reminder to the applicant informing it that it had yet to reply to the two requests for additional information from April 1999.[1074] The lead CA also informed the Commission that the deadline for evaluation of this application would not be met due to the lack of response from the applicant to the aforementioned two requests for additional information.[1075] The record indicates that as of August 2003, the applicant had still not fully replied to the first request relating to substantial equivalence.[1076] It appears that the applicant responded to the first request concerning the presence of PAT DNA and PAT protein in derived soya products, but it is not clear when.[1077]

7.1135 Greece (June 1999) and Italy (July 1999) also requested additional information regarding nutritional and biochemical characterization and toxicity of the transgenic plants. We again asked the experts advising us whether the additional information requested by Greece and Italy was necessary to ensure that conclusions of the safety assessment were valid. Dr. Nutti responded that the application did not provide all the information which would be expected in order to comply with the recommended Codex evaluation procedure, and therefore the requests for some of this information

[1070] Exhibit EC-93/Ats. 1 and 3.
[1071] Exhibit EC-93/At. 11.
[1072] *Ibid*.
[1073] Annex H, Dr. Nutti's response to Panel Question 48.
[1074] Exhibit EC-93/At. 14.
[1075] Exhibit EC-93/At. 13.
[1076] Exhibit EC-93/At. 25.
[1077] *Ibid*.

were justified.[1078] In December 2000 and again in July 2001, the applicant apparently provided additional information to the lead CA regarding insert characterization, however this information was not provided to us. In the same correspondence, the applicant indicated that information on compositional analyses would be forthcoming at a later date.[1079] Seven months later, in correspondence dated July 2001, the applicant apparently provided information to satisfy these requests, although this information was not included in the evidence provided to us.[1080]

7.1136 In August 2001, the lead CA requested clarification regarding nutritional composition, stating that the data provided by the applicant in July 2001 had not adequately addressed the lead CA's request of April 1999. We again asked the experts whether this clarification was necessary to ensure that conclusions of the safety assessment were valid. Dr. Nutti noted that the information requested would normally be necessary to judge the safety of the product, however given the incompleteness of the record, it was impossible for her to determine whether or not this information had previously been provided to the lead CA.[1081] The lead CA also inquired about a broiler chicken growth performance study which the applicant had said was already included in the dossier, but which the lead CA could not find. Finally, the lead CA indicated that in accordance with new recommendations by the Biosafety Council on molecular characterization, the lead CA would be requesting some additional information on molecular characterization.

7.1137 The record suggests that the applicant never replied to the August 2001 request for clarification. Indeed, in June 2003, in internal e-mail correspondence concerning a request from the Commission for an update on this dossier, the lead CA highlighted the fact that the applicant had not provided the requested broiler chicken growth study. The lead CA also indicated that it had requested, but not received, additional information on molecular characterization. However, the record does not indicate that such a request was forwarded to the applicant.[1082]

7.1138 It is unfortunate that the evidence provided on this application is incomplete. While the experts indicated that much of the information requested by the lead CA and by other member States was necessary to ensure a valid safety assessment, it was not possible to determine to what extent such information may already have been provided by the applicant. It is also very difficult to determine from the information before us whether particular requests for information were met by the applicant.

7.1139 This said, as noted earlier, it appears that the applicant never fully replied to the lead CA's April 1999 request for additional information. It also seems that the responses which were given were not provided in a timely manner. Furthermore, the record suggests that the applicant never responded to the August 2001 request for clarification. In fact, there does not appear to have been any further communication from the applicant until it withdrew its application in July 2004.

7.1140 In considering the applicant's conduct, and in particular its failure to respond to the August 2001 request for clarification, it is important to recall that the applicant had submitted an application concerning the same product under Directive 90/220. That application was also being evaluated by Belgium. As we have noted earlier, however, the consideration of that application – the application concerning LL soybeans (EC-71) – appears to have been suspended as from September 2001 as a result of the applicant's refusal to discontinue another Directive 90/220 application concerning the

[1078] Annex H, Dr. Nutti's response to Panel Question 49.
[1079] Exhibit EC-93/At. 21.
[1080] Exhibit EC-93/At. 22.
[1081] Annex H, Dr Nutti's responses to Panel Question 50.
[1082] Exhibit EC-93/At. 25.

same product, which had been submitted to Portugal. Directive 90/220 was repealed in October 2002. The applicant withdrew its application from Portugal and submitted an updated application to Belgium. Belgium then continued its consideration of the application under Directive 2001/18 as of February 2003.

7.1141 We further recall that Article 9(2) of Regulation 258/97 provides that decisions approving the placing on the market of foods or food ingredients containing or consisting of GMOs must "respect the environmental safety requirements laid down by [Directive 90/220] to ensure that all appropriate measures are taken to prevent the adverse effects on human health and the environment which might arise from the deliberate release of [GMOs]". As noted, the environmental safety assessment under Directive 90/220 was suspended as of September 2001. Since a specific environmental safety assessment was necessary for the application concerning LL soybeans (food) to be approved under Regulation 258/97, it seems plausible that the applicant did not see much use in seeking progress in the Regulation 258/97 procedure as long as the Directive 90/220 procedure was suspended. In relation to the application concerning LL soybeans (EC-71), we said earlier that the fact that Belgium suspended consideration of that application – in response to the applicant's refusal to discontinue one of the two Directive 90/220 applications – does not directly confirm that a general moratorium was in effect in the European Communities.

7.1142 Nevertheless, we consider that the history of the approval procedure concerning LL soybeans (food) at the member State level is consistent with the Complaining Parties' assertion that the European Communities applied a general moratorium on approvals. We recall in this regard that in June 1999, the Group of Five countries indicated that they would act as a "blocking minority" in the Regulatory Committee and in the Council, and that in the approval procedure concerning the Transgenic tomato (food), the Commission after October 1999 failed to discharge its responsibility inasmuch as it did not submit a draft measure to the Regulatory Committee following the first SCF opinion of September 1999. These acts and omissions affect and concern the Community level phase of the approval procedure under Regulation 258/97. However, the application concerning LL soybeans (food) as of August 2003 had not reached the Community level.

7.1143 In the light of the above considerations, we conclude that the record of the progress of the application concerning LL soybeans (food) at the member State level is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

MON810 x GA21 maize (food) (EC-94)

7.1144 The application concerning MON810 x GA21 maize (food) was submitted to the Netherlands (lead CA) on 29 February 2000. A summary of the file was circulated by the Commission to all member States on 29 March 2000. At the time of establishment of the Panel, the lead CA had not completed its initial assessment.

7.1145 The **United States** argues that approval for MON810 x GA21 maize (food), which is produced by conventionally hybridizing two "parental" biotech products, MON810 maize and GA21 maize, has been delayed by the failure of the lead CA to complete its initial assessment. More specifically, the United States argues that at the time of establishment of the Panel, the application had already been under consideration by the lead CA for three and a half years. The United States contends that this lag had two distinct causes.

7.1146 According to the United States, one cause for the lag was the undue delay in the EC approval of GA21 maize under Regulation 258/97. The application for approval of MON810 x GA21 maize

(food) submitted under Regulation 258/97 referenced the detailed risk assessments undertaken on the parental biotech products, complemented with confirmatory safety and characterization data on the MON810 x GA21 hybrid. One parent, MON810 maize, was approved under Directive 90/220 in 1998[1083] and was notified in 1998 on the basis of an opinion of substantial equivalence as required under Regulation 258/97 in 1998.[1084] However, the application for the single trait parent GA21 maize (food) under Regulation 258/97 stalled at the Commission level after the Commission requested an opinion from the SCF in May 2000 and then again after the final SCF opinion in February 2002. Therefore, progress on GA21 maize (food) was a limiting step on the progress of the application concerning MON810 x GA21 maize (food) in the regulatory process. In fact, in its comments on the application for MON810 x GA21 maize (food), Italy stated that "examination of the documentation relating to authorization [of MON810 x GA21 maize] should only be carried out after the marketing of GA21 has been authorized [under Regulation 258/97]."[1085] At the time of establishment of the Panel, the approval of GA21 maize (food) under Regulation 258/97 had not yet been granted.

7.1147 The United States contends that the other cause of the lag reflected, in part, the need for the applicant to respond to requests for information that were scientifically unjustified. The United States points out that the lead CA insisted on molecular characterization of the MON810 x GA21 line without regard to the previous data that had been submitted on the parental lines. In particular, the lead CA requested an additional whole food study in mice.[1086] The rationale offered for this request was the need to address hypothetical concerns that unknown pieces of DNA could be scattered over the genome. The impact of any such insertions can be determined by evaluating the compositional analyses of the plant as well as its agronomic performance. If both analyses indicate no unexpected changes, the United States argues, there is no basis on which to hypothesize a food safety concern for food from the plant. In this case, such assessments had been performed on each of the parental lines and no unexpected changes were observed. At no time did the lead CA provide any explanation of the reason it believed that the compositional analyses or feeding studies previously submitted on both the parent lines, as well as the compositional analyses submitted on the hybrid, did not adequately address this issue.

7.1148 The United States notes that, nonetheless, the applicant analysed the composition of the MON810 x GA21 maize, which was found to be comparable to that of the parental lines and other commercial maize varieties.[1087] The applicant also had previously submitted several whole food feeding studies, including a 90-day feeding study in rats using MON810 maize or GA21 maize, and a broiler chicken feeding study using grain from MON810 x GA21 maize. None of these studies revealed any adverse effects.

7.1149 Furthermore, the United States notes, the lead CA requested further information on the levels of EPSPS protein expressed in the hybrid lines, although such information is not relevant to assessing the risks given the known safety information about the EPSPS protein.[1088] The lead CA also

[1083] Commission Decision concerning the placing on the market of genetically modified maize (zea mays L. line MON810) pursuant to Council Directive 90/220/EEC, (98/294/EC), April 22, 1998, Official Journal of the European Communities, L 131/32, May 5, 1998 (Exhibit US-131).

[1084] Exhibit US-132.

[1085] Exhibit EC-94/At. 11.

[1086] Exhibit EC-94/At. 12.

[1087] Exhibit EC-82/At. 9.

[1088] The United States refers to LA Harrison, MR Bailey, MR Naylor, JE Ream, BG Hammond, DL Nida, BL Burnette, TE Nickson, TA Mitsky, ML Taylor, RL Fuchs, and SR Padgette, "The Expressed Protein in Glyphosate-Tolerant Soybean, 5-Enolypyruvylshikimate-3-Phosphate Synthase from Agrobacterium sp. Strain CP4, Is Rapidly Digested in Vitro and Is Not Toxic to Acutely Gavaged Mice", *Journal of Nutrition* 126:728-740 (1996) (Exhibit US-143).

requested unnecessary comparisons of compositional data between the new hybrid and non-transgenic control lines. The data submitted in the application analysed the new hybrid in comparison to the transgenic parental lines.[1089] The transgenic parental lines had already been shown to be substantially equivalent to non-genetically modified maize except for the introduced traits. Given all of the data that had been submitted on both parental lines, the United States argues that the requests for yet further studies lacked any scientific basis.

7.1150 According to the United States, the United Kingdom also insisted that the applicant provide extensive characterization of the new hybrid, rather than rely on the analyses previously carried out on the transgenic parental lines.[1090] As part of this request, the United Kingdom requested molecular characterization to "confirm[] the absence of antibiotic resistance markers and have details regarding the homology between the two constructs introduced as a result of the crosses."[1091] Given that neither parent contained an antibiotic marker gene, there is absolutely no scientific basis, in the United States' view, for theorizing that cross-breeding between the two products would somehow introduce such a gene.

7.1151 Under these circumstances, the United States argues that it was pointless for the applicant to devote resources to pursue the application for MON810 x GA21 maize (food) as long as consideration of the applications for the single trait parent GA21 maize remained suspended under the moratorium. The United States contends that the delay in the application for MON810 x GA21 maize (food) and GA21 maize (food) is thus a direct consequence of the delays in the application for GA21 maize under the moratorium. The United States further points out that because of the delay in the approval procedure concerning GA21 maize (food), that product, as well as MON810 x GA21 maize, have been superseded by a second generation Roundup Ready maize product (NK603 maize and NK603 × MON810 maize, respectively). Nonetheless, the applicant has continued to pursue the necessary regulatory clearance for MON810 x GA21 maize (food).

7.1152 **Canada** argues that the application is still pending with the lead CA.

7.1153 The **European Communities** argues that the lead CA requested additional information from the applicant in July 2000, however the request was only partly answered in February 2002. Contrary to the United States, the European Communities maintains that the lead CA request for a whole food study in mice was necessary to assess unintended effects caused by possible additional DNA fragments. Since the request was made on valid grounds, the delay caused by it cannot be considered "undue." Furthermore, issues such as molecular characterization of inserted DNA from transgenic parent lines, the determination of flanking DNA or compositional analysis still remain unanswered. Finally, the European Communities considers that it is obvious that the assessment of a hybrid cannot be concluded as long as the assessment of one of its parental lines is still open.

7.1154 The **Panel** notes that under Regulation 258/97 the initial assessment report is to be drawn up by the lead CA within a period of three months from receipt of an application meeting the applicable conditions. When the Commission circulated notice of this application to all member States on 29 March 2000, it indicated that the initial assessment was to be completed by 16 June 2000 at the latest.[1092] However, the lead CA's assessment had not been completed by the time of the establishment of the Panel, that is, three and a half years after submission of the application.

[1089] Exhibit EC-94/At. 2.
[1090] Exhibit EC-94/At. 10.
[1091] *Ibid*.
[1092] Exhibit EC-94/At. 5.

7.1155 The first indication of any contact from the lead CA was a request for additional data sent to the applicant on 17 July 2000.[1093] No specific explanation has been provided as to why this information was not requested much sooner, rather than one month after the normal deadline for completion of the assessment. The response to the July 2000 request was provided by the applicant only on 15 February 2002. Subsequently, there was a five-month delay before the lead CA followed up with the applicant to request additional information on 2 July 2002. No specific explanation has been provided for this further delay. Furthermore, no information has been provided regarding any action on this application between July 2002 and August 2003. It appears that during that period the applicant did not respond to the lead CA's July 2002 request for information.

7.1156 We sought the views of the experts advising us regarding the necessity of the information requested by the lead CA in July 2000 to ensure that the conclusions of the safety assessment were valid.[1094] Dr. Nutti addressed the lead CA's requests regarding the EPSPS protein, the effect of glyphosate treatment on the composition of maize plants, the additional information on the composition of the hybrid, and the additional toxicological feeding study. Dr. Nutti did not consider that any of this requested information was necessary to ensure the validity of the safety assessment, in light of the information already provided in the application and already known about the parental lines. In her view, the responses provided by the applicant in February 2002 confirmed the data previously submitted.[1095] Dr. Andow addressed the requests regarding the effect of glyphosate treatment and toxicology. In his view, the request regarding the glyphfosate treatment was necessary, as he believes the applicant had provided an incorrect statistical analysis. With regard to the toxicology request, Dr. Andow considered that the underlying concern was valid, but he considered that the applicant should have been able to address this concern through other means, and the request for toxicity testing was not necessary to ensure that the conclusions of the safety assessment were valid for MON810 x GA21 maize.[1096]

7.1157 We are cognizant of the fact that the European Communities disagrees with some of the responses by the experts. The European Communities notes that the results of the additional studies were required to confirm the information provided in the application, and that there are different regulatory approaches regarding the comparisons of a GM hybrid and the data requirements needed to assess the safety of these hybrids. In particular, the European Communities argues that the fact that the approach of the lead CA differs from the one preferred by the Panel's experts does not mean it is not valid. Furthermore, the European Communities submits that the lead CA requested information on additional substances in light of the information that had just become available regarding the presence of unintended DNA fragments in a genetically modified glyphosate-resistant soybean.

7.1158 We accept that different regulatory practices may result in differences in perceptions as to what information is necessary to a safety assessment. However, even accepting that contrary to the views of the experts the information requested by the lead CA in July 2000 was necessary to ensure the validity of the safety assessment, this still would not explain the long delays in responses by the lead CA both before and after the July 2000 request.

7.1159 The United States argues that these delays reflect the alleged general moratorium on final approvals. More particularly, the United States contends that the delay in the application for MON810 x GA21 maize (food) was a direct consequence of the delays in the applications for GA21 maize (EC-78) and GA21 maize (food) under the moratorium. We recall that the United States does

[1093] Exhibit EC-94/At. 12.
[1094] Annex H, question 44.
[1095] Annex H, paras. 682-687.
[1096] Annex H, para. 700.

not assert that the time taken by the Netherlands in its assessment of the application concerning MON810 x GA21 maize (food) is a reflection of its support for the alleged moratorium. Rather, the United States asserts that the Netherlands was placed in a position of having to recognize the moratorium as a reality, and that this affected the speed with which it conducted its assessment.

7.1160 We consider that following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability. In our view, the Netherlands also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries. We note in this regard that in 2000, when the application concerning MON810 x GA21 maize (food) was submitted, the single trait parent applications concerning GA21 maize (EC-78) and GA21 maize (food) were both under assessment at Community level. In relation to these single trait parent applications, we have previously noted that the Commission in both procedures failed to submit a draft measure concerning these applications to the Regulatory Committee prior to August 2003, and that this is consistent with the assertion that the European Communities applied a general moratorium on final approvals.

7.1161 Against this background, and in particular in view of the situation with regard to the single trait parent applications concerning GA21 maize (EC-78) and GA21 maize (food)[1097], we consider that the Netherlands could have come to the conclusion that there was no realistic prospect that the single trait parent applications concerning GA21 maize would be approved prior to the date of repeal of Directive 90/220, and that as long as they were not approved the hybrid application concerning MON810 x GA21 maize (food) would likewise not be approved.[1098] In our view, the time taken by the Netherlands both before and after its July 2000 request for information is therefore consistent with the existence of a general moratorium on approvals.

7.1162 We note that the Netherlands was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, in this instance, we are not convinced that the Dutch CA's conduct reflects a precautionary approach. Indeed, we are not convinced that the Dutch CA could not forward its July 2000 and July 2002 requests to the applicant sooner than it did even while following a precautionary approach.

7.1163 Regarding the fact that the applicant took more than a year and a half to provide its response to the lead CA's July 2000 request, and that it did not respond to the July 2002 request for information, we consider this is consistent with the United States' suggestion that the applicant thought that the single trait parent applications concerning GA21 maize (EC-78) and GA21 maize (food) were being delayed at Community level as a result of the alleged moratorium and that the applicant therefore saw little value in actively pursuing the hybrid application for MON810 x GA21 maize (food).

7.1164 In the light of the above considerations, we conclude that the time taken by the Netherlands for its assessment of the application concerning MON810 x GA21 maize (food) is consistent with the

[1097] Since these applications were at Community level, it is reasonable to assume that the Dutch CA was aware of the relevant situation.

[1098] We note that the application concerning MON810 x GA21 maize (food) referenced Article 9 of Regulation 258/97 which applies to foods or food ingredients containing or consisting of GMOs and which requires that the approval decision respect the environmental safety requirements laid down in Directive 90/220.

Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

Bt-1507 maize (food) (EC-95)

7.1165 The application concerning Bt-1507 maize (food) was submitted to the Netherlands (lead CA) on 15 February 2001. At the time of establishment of the Panel, the lead CA had not completed its initial assessment. This assessment was completed on 4 November 2003, and the report circulated to all member States by the Commission on 10 December 2003.

7.1166 The **United States** argues that the lead CA refused to forward this application to the Commission.

7.1167 The **European Communities** observes that after receiving the application in February 2001, the lead CA asked for additional information in June 2001. This information was finally provided in February 2003. Between February 2003 and July 2003, there was ongoing correspondence between the applicant and the lead CA on additional information to be submitted by the applicant, in particular on labelling, monitoring, molecular characterisation, and event-specific detection methods. The lead CA finalized the initial assessment report in November 2003, and concluded that the consumption of Bt-1507 maize as well as foods and food ingredients derived from it were as safe for humans as the consumption of the non-genetically modified counterparts.

7.1168 The European Communities further notes that the Commission forwarded the initial assessment report to member States for comments in December 2003, and received comments and reasoned objections against the initial assessment. On 26 March 2004, the complete dossier (including responses to the objections and comments raised by member States) was forwarded to EFSA for consideration under Regulation 1829/2003. In parallel, the applicant undertook the steps to ensure the production of certified reference material and for the validation of a detection method by the JRC.

7.1169 The **Panel** recalls that according to Regulation 258/97, an initial assessment report is to be drawn up by the lead CA within a period of three months from receipt of an application meeting the applicable conditions. In this case, this initial assessment was not completed until 4 November 2003, that is, almost three years after receipt of the application. We note, however, that an initial request for additional data was made by the lead CA on 28 June 2001, that is four months following receipt of the application.[1099] The applicant apparently provided some information in November 2001, although this was not given to us, but did not provide all of the information requested until 12 February 2003.[1100] In March 2003, the lead CA requested further clarifications, which were provided in May 2003.[1101] In June 2003, the lead CA posed questions in relation to the applicant's May 2003 reply.[1102] The applicant provided answers by 9 July 2003.[1103] The information as provided by 9 July 2003 was apparently deemed sufficient by the lead CA to conclude its assessment. As noted, a positive assessment was reported on 4 November 2003.

7.1170 It is clear from the foregoing that the major delay in the assessment of this application is attributable to the time taken by the applicant to provide the information requested in June 2001. We

[1099] Exhibit EC-95/At. 8.
[1100] Exhibit EC-95/At. 12.
[1101] Exhibit EC-95/Ats. 13 and 14.
[1102] Exhibit EC-95/At. 15.
[1103] Exhibit EC-95/At. 16.

asked the experts advising us for their views on the necessity of the information requested by the lead CA in June 2001 to ensure that the conclusions of the safety assessment were valid.[1104] Dr. Nutti responded to this question and commented specifically on the lead CA's requests related to compositional and toxicological analyses. She considers that some of the information requested, such as three seasons of field tests (as opposed to two seasons as provided in the application), was not necessary to ensure the safety assessment. On the other hand, the request for compositional data regarding certain substances and the oral toxicity study to rule out unintended change in Bt-1507 maize were necessary in her view.[1105] All of this information was provided by the applicant in February 2002, except for the results of the oral toxicity study which was submitted only in February 2003.

7.1171 Even accepting that the information requested by the lead CA in June 2001 was necessary to ensure the validity of the safety assessment, it should be noted that the application concerning Bt-1507 maize (food) had been under review in the Netherlands for almost four and a half months before the Dutch CA forwarded its June 2001 request for information. Similarly, the lead CA on two occasions took a month to analyse responses provided by the applicant and forward follow-up requests for information. And once the applicant had provided information in response to the Dutch CA's last request for information, the lead CA still took several months to complete its initial assessment report.

7.1172 The United States does not assert that the time taken by the Netherlands to complete its assessment is a reflection of Dutch support for the moratorium. Rather, its assertion is that the time taken by the Netherlands reflects the impact of the moratorium. The United States contends that the Netherlands was placed in a position of having to recognize the moratorium as a reality and that this affected the speed with which it conducted its assessment.

7.1173 We consider that following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability. In our view, the Netherlands also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries.

7.1174 We also note, however, that the Netherlands was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, in this instance, we are not convinced that the Dutch CA's conduct reflects a precautionary approach. In particular, we are not convinced that the Dutch CA could not forward its June 2001 request for information to the applicant sooner than it did even while following a precautionary approach, or that it could not complete its assessment report earlier than in November 2003.

7.1175 It is pertinent to note in this regard that the applicant had submitted an application concerning the same product under Directive 90/220. That application was also under assessment by the Dutch CA. The Dutch CA did not complete its assessment of the application concerning Bt-1507 maize (EC-74) until August 2003. We have previously concluded in this respect that the failure of the Netherlands to complete its assessment of the application concerning Bt-1507 maize (EC-74) earlier than in August 2003 is not inconsistent with the contention that the European Communities applied a general moratorium during the relevant time period. Since a special environmental safety assessment

[1104] Annex H, Question 51.
[1105] Annex H, Dr. Nutti's responses to Question 51.

was necessary for the application concerning Bt-1507 maize (food) to be approved under Regulation 258/97[1106], we think it could also be that the time taken by the Dutch CA before forwarding its June 2001 request or before completing its initial assessment report in November 2003 reflects the delays in the approval procedure concerning Bt-1507 maize (EC-74).

7.1176 Taking account of the aforementioned elements, we consider that the Dutch CA's conduct in the approval procedure concerning Bt-1507 maize (food) is consistent with the United States' view that a general moratorium on final approvals was in effect in the European Communities at the time. It should be recalled, in addition, that the application concerning Bt-1507 maize (food) as of August 2003 had not reached the Community level. In other words, it had not yet reached the procedural stage where the Group of Five countries and/or the Commission could have taken actions to delay or prevent its final approval.

7.1177 In the light of the above, we conclude that the failure of the Netherlands to complete the initial assessment of the application concerning Bt-1507 maize (food) by August 2003 is consistent with the contention of the Complaining Parties that during the relevant time period the European Communities applied a general moratorium on final approvals.

NK603 maize (food) (EC-96)

7.1178 The application for NK603 maize (food) was submitted to the Netherlands (lead CA) in April 2001. The lead CA forwarded its initial assessment report to the Commission in November 2002. In January 2003, the Commission forwarded the initial assessment report by the lead CA to member States for comments and objections.

7.1179 The **United States** argues that although the application concerning NK603 maize (food) eventually received a positive assessment from the lead CA, this product was at the member State level for almost 19 months, instead of the 90 days foreseen by Regulation 258/97. Of this period of time, only 3½ months were used by the applicant to provide additional information; the lead CA used the remaining 14½ months.

7.1180 The United States questions certain requests for additional information from the lead CA, arguing they were scientifically unnecessary. For example, the lead CA requested an additional whole food feeding study in mice or rats, to address concerns about the presence of unintended DNA fragments that the applicant had identified as part of their molecular characterization data.[1107] The lead CA stated that "the presence of additional unintended modifications cannot be excluded with sufficient certainty". The United States argues that the mere fact that an additional insert is present does not necessarily mean that the product presents an additional risk. Rather, the determination turns on the results of all of the other data and information provided by the applicant, which the lead CA failed to take into consideration in making this request. If the results of those tests raise questions, then further examination would be warranted. But in this case, the applicant had conducted compositional analysis and a broiler chicken whole food study with the product containing the additional insert, and in these circumstances would have detected any resulting changes relevant to

[1106] We note that the application concerning Bt-1507 maize (food) applies to foods or food ingredients containing or consisting of GMOs and as such would appear to be subject to the provisions of Article 9 of Regulation 258/97. To recall, Article 9 requires that approval decisions concerning foods or food ingredients containing or consisting of GMOs must respect the environmental safety requirements laid down in Directive 90/220.

[1107] Exhibit EC-96/At. 7.

food safety. The United States observes that the applicant nevertheless conducted the requested test, which identified no adverse effects.

7.1181 **Canada** argues that the total time taken by the lead CA for its review was 18 months, and that only 3.5 of the 18 months were taken by the applicant to respond to questions. The difference of 14.5 months exceeds the 3-month period provided for in Regulation 258/97.

7.1182 **Argentina** argues that the assessments performed by the lead CA and subsequently the EFSA concluded that there was no evidence of risk to human health or life. Therefore, the delays by the lead CA to complete its initial assessment and forward this application to the Commission were not justified.

7.1183 The **European Communities** notes that the application for food use of the NK603 maize was submitted to the Netherlands in 2001. After the applicant submitted additional information requested by the lead CA, the lead CA completed its evaluation in November 2002 and sent its initial assessment report to the Commission. The 18 months spent at member State level were due to the incompleteness of the dossier initially submitted by the applicant and the need for further data on molecular characterization and compositional analysis.

7.1184 The **Panel** understands from the record that the applicant first submitted the application to the lead CA in April 2001. Two months later the lead CA requested copies of cited literature and data in order to facilitate the lead CA's work. The applicant provided these documents in July 2001.

7.1185 There were two separate requests for additional information before the lead CA forwarded its initial assessment report to the Commission in November 2002. First, the lead CA requested further information in December 2001 on the sequence of the inserted DNA fragment as well as further information on the flanking sequences, semi-chronic toxicity study, and further information on compositional data from the field trials.[1108] A cover letter indicates that the applicant provided this information three months later, however the record does not include the details from the applicant's response.

7.1186 We asked the experts advising us whether the information regarding molecular characterization, toxicity effects of unintended changes and compositional data requested by the lead CA was necessary to ensure that conclusions of the safety assessment were valid. Dr. Nutti noted that the applicant had provided all the information usually requested for the food safety assessment, and had also confirmed that the GM maize in question was equivalent in composition and nutrition to the conventional counterpart. She emphasized that "there was no need for requesting a semi chronic toxicity study in mice or rats, using maize grain or meal, in order to rule out possible undesired effects of additional, unidentified changes".[1109] The European Communities contests Dr. Nutti's conclusion that the additional 90-day toxicity study was not necessary. The European Communities indicates that the lead CA provided as rationale for its request for the 90-day study that it would provide additional reassurance of no unintended undesired effects.[1110] The European Communities argues that Dr. Nutti's conclusion should be dismissed on the basis of the available scientific evidence on the relevance of such studies.

7.1187 The second request for information came from Italy in January 2002 in a letter to the Commission. This request asked for further information on the evaluation of substantial equivalence,

[1108] Exhibit EC-96/At. 7.
[1109] Annex H, Dr. Nutti's responses to question 53.
[1110] Exhibit EC-96/At. 7.

molecular characterization, and detection analysis. Italy noted that the request was particularly important as "in the Community context, it has been shown that the simplified procedure needs to be suspended for GMOs".[1111]

7.1188 We again asked the experts whether the information requested by Italy was necessary to ensure that the conclusions of the safety assessment were valid. Dr. Nutti noted that "additional animal feeding studies may be warranted for GM foods if changes in the bioavailability of the nutrients are expected or if the composition of the GM food is not comparable to conventional food".[1112] She considered that the applicant had adequately established the substantial equivalence of the NK603 maize with its conventional counterpart, and that the request from Italy for more animal feeding studies was therefore not necessary to ensure that conclusions of the safety assessment were valid. In any event, there is no evidence on the record that the applicant was ever requested by the lead CA to provide the information sought by Italy. Nor is there any evidence that the applicant submitted information to address the requests made by Italy.

7.1189 In August 2002, five months after the applicant supplied the information requested by the lead CA, the lead CA's advisory body, the Dutch Health Council's Committee on the Safety Assessment of Novel Foods, finished its assessment report. The Committee concluded that "the consumption of NK603 maize and food and food ingredients derived from this is just as safe for humans as the consumption of non-genetically modified maize and maize products".[1113] It was not until November 2002 that the lead CA forwarded its assessment report to the Commission.[1114]

7.1190 In considering the foregoing, we note that this application was under assessment at the member State level for eighteen months. The lead CA's December 2001 request for information led to a delay, inasmuch as the applicant took three months and a half to respond to the request. We recall the view expressed by one of the experts that the request in question was not necessary to ensure the validity of the safety assessment. However, even accepting that the information requested by the lead CA in December 2001 was appropriate to ensure the validity of the safety assessment, it should be noted that the Netherlands took considerably more time for its assessment than the three months foreseen under Regulation 258/97. Notably, the application concerning NK603 maize (food) had been under review in the Netherlands for more than seven months before the Dutch CA forwarded its December 2001 request for information.[1115] Moreover, once the applicant had provided information in response to the Dutch CA's December 2001 request for information, the Health Council's Committee on the Safety Assessment of Novel Foods still took more than four months to complete its initial assessment report. While this report needed to be adopted by the Dutch CA, the report was not forwarded to the Commission for another two and a half months.

7.1191 The United States does not assert that the time taken by the Netherlands to complete its assessment is a reflection of Dutch support for the moratorium. Rather, its assertion is that the time taken by the Netherlands reflects the impact of the moratorium. The United States contends that the Netherlands was placed in a position of having to recognize the moratorium as a reality and that this affected the speed with which it conducted its assessment.

[1111] Exhibit EC-96/At. 9.
[1112] Annex H, Dr. Nutti's responses to question 54.
[1113] Exhibit EC-96/At. 7.
[1114] Exhibit EC-96/At. 12.
[1115] The application had been under review for more than four and a half months after receipt of copies of the cited literature and data. These copies were requested by the lead CA two months after receipt of the application.

7.1192 We consider that following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability. In our view, the Netherlands also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries.

7.1193 We also note, however, that the Netherlands was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, in this instance, we are not convinced that the Dutch CA's conduct reflects a precautionary approach. In particular, we are not convinced that the Dutch CA could not forward its December 2001 request for information to the applicant sooner than it did even while following a precautionary approach, or that it could not forward its completed assessment report earlier than in November 2002.

7.1194 It is pertinent to note in this regard that the applicant had submitted an application concerning the same product under Directive 90/220. That application was under assessment by the Spanish CA during the same time period. The Spanish CA did not complete its assessment while Directive 90/220 was still in force. Under Directive 2001/18, the Spanish CA forwarded its positive assessment report concerning NK603 maize to the Commission on 14 January 2003. We have previously concluded in this respect that Spain's failure to complete its assessment of NK603 maize earlier than in January 2003 is not inconsistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period. Since a special environmental safety assessment was necessary for the application concerning NK603 maize (food) to be approved under Regulation 258/97[1116], we think it could also be that the time taken by the Dutch CA before forwarding its December 2001 request or before forwarding its initial assessment report in November 2003 reflects a view on the part of the Dutch CA that the Spanish CA would not forward the application concerning NK603 maize to the Commission and the other member States until after the entry into force of Directive 2001/18.

7.1195 Taking account of the aforementioned elements, we consider that the Dutch CA's conduct in the approval procedure concerning NK603 maize (food) is consistent with the Complaining Parties' view that a general moratorium on final approvals was in effect in the European Communities at the time. It should also be recalled in this regard that the application concerning NK603 maize (food) as of August 2003 had not reached the Community level. In other words, it had not yet reached the procedural stage where the Group of Five countries and/or the Commission could have taken action to delay or prevent its final approval.

7.1196 In the light of the above considerations, we conclude that the time taken by the Netherlands to complete its initial assessment of the application concerning NK603 maize (food) is consistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

[1116] We note that the application concerning NK603 maize (food) concerns foods or food ingredients containing or consisting of GMOs and as such would appear to be subject to the provisions of Article 9 of Regulation 258/97. To recall, Article 9 requires that approval decisions concerning foods or food ingredients containing or consisting of GMOs must respect the environmental safety requirements laid down in Directive 90/220.

High-oleic soybeans (food) (EC-99)

7.1197 The application concerning High-oleic soybeans (food) was submitted to the Netherlands (lead CA) on 24 July 1998. The application was withdrawn by the applicant on 12 December 2002. At that time, the lead CA had not yet issued its initial assessment of the application.

7.1198 The **United States** argues that the application for High-oleic soybeans (food) was withdrawn because of the European Communities' excessive delay in carrying out the approval process.

7.1199 The **European Communities** argues that after discussions between the lead CA and the applicant, the applicant in December 2002 withdrew its application. The applicant gave as the reason for its withdrawal "entirely commercial reasons."

7.1200 The **United States** argues that in many cases the withdrawal of applications resulted from the applicant's frustration with the European Communities' suspension of its approval process, although the applicant may not have explicitly so indicated in it reasons for withdrawal. Over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Second, the companies have a strong incentive to maintain cordial relations with EC regulators, and saw no advantage of complaining to EC regulators about the length of the delays resulting from the moratorium.

7.1201 The **Panel** observes that in circulating notice of this application to all member States, the Commission indicated that the initial assessment by the lead CA would be available by 5 November 1999 at the latest. In contrast, at the time this application was withdrawn in December 2002, this initial assessment had not yet been completed.

7.1202 It appears that the lead CA requested further references from the applicant sometime before mid-October 1998, which was when these were provided. The information provided is incomplete and does not permit identification of when these references had been requested. Furthermore, in March 1999, the lead CA contacted the applicant to request explanations regarding certain results reported in the initial application.[1117] This was more than seven months after its receipt of the application. No explanation has been provided for this delay. The applicant provided the explanations and information requested in May 1999.[1118] More than three months later, in September 1999, the lead CA requested further clarification of the information provided.[1119] The applicant responded within three weeks, on 22 September 1999.[1120] It appears that the applicant's response addressed all questions asked by the lead CA. There is no indication that subsequent to September 1999 the lead CA sought further information or took any further action on this application until the application was withdrawn more than three years later on 12 December 2002.

7.1203 We note that no explanation has been provided to us for why the lead CA did not complete its assessment during the three years following the applicant's September 1999 response to a request for clarification. The United States argues that this delay was due to the alleged general moratorium on approvals. The United States does not assert that the time taken by the Netherlands to complete its assessment is a reflection of Dutch support for the moratorium. Rather, its assertion is that the time taken by the Netherlands reflects the impact of the moratorium. The United States contends that the

[1117] Exhibit EC-99/At. 11.
[1118] Exhibit EC-99/At. 14.
[1119] Exhibit EC-99/At. 15.
[1120] Exhibit EC-99/At. 16.

Netherlands was placed in a position of having to recognize the moratorium as a reality and that this affected the speed with which it conducted its assessment.

7.1204 We consider that following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability. In our view, the Netherlands at the time also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries.

7.1205 We also note, however, that the Netherlands was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, in this instance, we are not convinced that the Dutch CA's conduct reflects a precautionary approach. In particular, we are not convinced that it was not possible for the Dutch CA to complete its assessment before December 2002 even while following a precautionary approach.

7.1206 It is pertinent to note in this context that the applicant had submitted an application concerning the same product under Directive 90/220. That application was also under assessment by the Dutch CA. In the procedure conducted under Directive 90/220, the Dutch CA requested additional information in October 1999.[1121] However, the applicant did not provide a response to that request until it withdrew its application in December 2002. Since a special environmental safety assessment was necessary for the application concerning High-oleic soybeans (food) to be approved under Regulation 258/97[1122], we think it could be that the time taken by the Dutch CA after the September 1999 response by the applicant reflects the delays in the approval procedure concerning High-oleic soybeans. We have previously concluded that the record of the member State level assessment of that application is not inconsistent with the contention of the Complaining Parties that the European Communities applied a general moratorium during the relevant time period.

7.1207 Taking account of the aforementioned elements, we consider that the unexplained failure by the lead CA to complete its assessment of the application concerning High-oleic soybeans (food) after September 1999 is consistent with the United States' view that a general moratorium on final approvals was in effect in the European Communities at that time. It should also be recalled in this regard that the application concerning High-oleic soybeans (food) as of August 2003 had not reached the Community level. In other words, it had not yet reached the procedural stage where the Group of Five countries and/or the Commission could have taken action to delay or prevent its final approval.

7.1208 In our view, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application in December 2002 is not inconsistent with the United States' assertion that the European Communities was applying a general moratorium on approvals at the time. As was pointed out by the United States, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning High-oleic soybeans (food).

[1121] Exhibit EC-87/At. 15.

[1122] We note that the application concerning High-oleic soybeans (food) concerns foods or food ingredients containing or consisting of GMOs and as such would appear to be subject to the provisions of Article 9 of Regulation 258/97. To recall, Article 9 requires that approval decisions concerning foods or food ingredients containing or consisting of GMOs must respect the environmental safety requirements laid down in Directive 90/220.

7.1209 In the light of the above considerations, we conclude that the failure by the Netherlands to complete its assessment of the application concerning High-oleic soybeans (food) prior to December 2002, when it was withdrawn by the applicant, is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

T25 x MON810 maize (food) (EC-101)

7.1210 The application concerning T25 x MON810 maize (food) was submitted to the Netherlands (lead CA) on 20 April 2000. The application was withdrawn on 12 December 2002. At that time, the lead CA had not completed its initial assessment. (An application for approval of this product under Regulation 90/220 was also submitted; see EC-86 above.)

7.1211 The **United States** argues that the application for T25 x MON810 maize (food) was withdrawn because of the European Communities' excessive delay in carrying out the approval process.

7.1212 The **European Communities** maintains that after discussions between the lead CA and the applicant, in its letter withdrawing the application the applicant pointed to "entirely commercial reasons."

7.1213 The **United States** argues that in many cases the withdrawal of applications resulted from the applicant's frustration with the European Communities' suspension of its approval process, although the applicant may not have explicitly so indicated in it reasons for withdrawal. Over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Second, the companies have a strong incentive to maintain cordial relations with EC regulators, and saw no advantage of complaining to EC regulators about the length of the delays resulting from the moratorium.

7.1214 The **Panel** notes that in bringing the application to the attention of all member States on 3 May 2000, the Commission stated that the initial assessment was to be concluded by 28 July 2000 at the latest.[1123] However, it was apparently only on 17 July 2000 that the lead CA first contacted the applicant to request additional information.[1124] After the applicant responded on 22 November 2000, another five months lapsed before the lead CA requested further information on 23 April 2001.[1125]

7.1215 In responding to the April 2001 request from the lead CA, on 21 November 2001 the applicant noted that not only had both parental lines been previously approved, but the same hybrid T25 x MON810 maize product had been reviewed under Directive 90/220 and had received a favourable assessment from the Dutch CA and from the SCP in June 2000. Given these circumstances, the applicant questioned the need for providing additional information on molecular characterization. It also noted that the request for a semi-chronic toxicity study was "an unexpected requirement".[1126] Nonetheless, the applicant indicated its intention to provide the information requested by mid-2002, and asked that the Dutch Health Council allow the applicant the opportunity to provide the additional information before completing its safety assessment. It appears from the applicant's November 2001 response that the Health Council had previously indicated its intention to finalize its safety assessment before the end of 2001.

[1123] Exhibit EC-101/At. 4.
[1124] Exhibit EC-101/At. 11.
[1125] Exhibit EC-101/Ats. 13 and 14.
[1126] Exhibit EC-101/At. 15.

7.1216 No evidence has been provided of further correspondence on this application until the letter of 12 December 2002 from the applicant withdrawing the application. We can only presume that the applicant did not provide the information as indicated in its letter of 21 November 2001, and that the lead CA did not explain to the applicant the reasons for its "unexpected requirement" nor otherwise further seek information requested from the applicant.

7.1217 We sought the advice of the experts assisting us as to whether the additional information regarding molecular characterization, field trials, secondary plant metabolites, and toxicological tests requested by the lead CA in April 2001 were necessary to ensure that conclusions of the safety assessment were valid.[1127] Dr. Nutti did not consider that the requests regarding compositional and toxicological analysis were necessary, in light of the information available on the parental lines. She characterized the likelihood of fortuitous changes in the plant metabolism as a result of the conventional cross-breeding of two GMO maizes as being "vanishingly small".[1128]

7.1218 Dr. Andow considered that there is a scientific justification for requiring comparison of T25 maize with and without the pesticide treatment with conventional and untreated maize, although he indicates that there is a scientific debate as to whether all three comparisons are necessary to ensure the safety assessment. With respect to the secondary plant metabolites, Dr. Andow also considers that the likelihood of a change in the plant metabolism may be very small, but that it is difficult to argue how small, and since a potential human health risk could arise from such changes, he considered the requested information to be necessary to ensure a valid safety assessment. Dr. Andow, however, agreed that the requested toxicology study was not necessary for the safety assessment.[1129]

7.1219 Dr. Squire considered that the requests by the lead CA were arguably consistent with the type of information required in the Codex Guideline for the conduct of food safety assessment of food derived from recombinant-DNA plants.[1130]

7.1220 We are cognizant of the European Communities' disagreement with the views of Drs. Andow and Nutti regarding the need for the toxicology study, and with Dr. Nutti regarding the data on herbicide treatment and on secondary compounds. Even accepting that the information requested by the Health Council in April 2001 was necessary to ensure the validity of the safety assessment, this would not explain the time taken by the lead CA before initially requesting additional information in July 2000 (three months), and the time taken to review the information received in November 2000 (five months).

7.1221 The United States does not assert that the time taken by the Netherlands to complete its assessment is a reflection of Dutch support for the moratorium. Rather, its assertion is that the time taken by the Netherlands reflects the impact of the alleged moratorium. The United States contends that the Netherlands was placed in a position of having to recognize the moratorium as a reality and that this affected the speed with which it conducted its assessment.

7.1222 We consider that following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability. In our view, the Netherlands also had reason to believe that, as in the case

[1127] Annex H, Question 57.
[1128] Annex H, para.766.
[1129] Annex H, para. 772.
[1130] Annex H, para. 774.

of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries.

7.1223 We also note, however, that the Netherlands was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, in this instance, we are not convinced that the Dutch CA's conduct reflects a precautionary approach. In particular, we are not convinced that the Dutch CA could not forward its July 2000 request for information to the applicant sooner than it did even while following a precautionary approach, or that after receiving the applicant's response it could not identify the need for more detailed information earlier than in April 2001.

7.1224 It is pertinent to note, furthermore, that the applicant had submitted an application concerning the same product under Directive 90/220. That application had also been assessed by the Dutch CA. At the time the application concerning T25 x MON810 maize (food) was submitted to the Dutch CA, the application concerning T25 x MON810 maize was being assessed at Community level. In June 2000, the SCP issued a favourable opinion, but the Commission subsequently did not forward a draft measure to the Regulatory Committee prior to the withdrawal of the application in December 2002. We have previously concluded in this respect that the Commission's failure to submit a draft measure concerning T25 x MON810 maize to the Regulatory Committee is consistent with the Complaining Parties' assertion that the European Communities applied a general moratorium on final approvals.

7.1225 Taking account of the aforementioned elements, we consider that the time taken by the lead CA before initially requesting additional information in July 2000, and the time taken to review the information received in November 2000, is consistent with the United States' view that a general moratorium on final approvals was in effect in the European Communities at that time. It should also be recalled in this regard that the application concerning T25 x MON810 maize (food) as of the date of its withdrawal had not reached the Community level. In other words, it had not yet reached the procedural stage where the Group of Five countries and/or the Commission could have taken action to delay or prevent its final approval.

7.1226 Furthermore, in our view, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application in December 2002 is not inconsistent with the assertion that the European Communities was applying a general moratorium on approvals at the time. As was pointed out by the United States, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning T25 x MON810 maize (food).

7.1227 In the light of the above, we conclude that the time taken by the Netherlands for its initial assessment of the application for T25 x MON810 maize (food) is consistent with the contention of the Complaining Parties that during the relevant time period the European Communities applied a general moratorium on final approvals.

RR sugar beet (food) (EC-102)

7.1228 The application concerning RR sugar beet (food) was submitted to the Netherlands (lead CA) in November 1999. At the time of establishment of the Panel, the lead CA had not yet completed its initial assessment. The application was withdrawn by the applicant on 16 April 2004.

7.1229 The **United States** argues that the lead CA refused to forward this application to the Commission.

7.1230 The **European Communities** argues that after discussions between the Dutch CA and the applicant, the request was withdrawn on 16 April 2004. As the reason for its withdrawal the applicant pointed to a decision to stop any further development of the RR sugar beet.

7.1231 The **United States** argues that in many cases the withdrawal of applications resulted from the applicant's frustration with the European Communities' suspension of its approval process, although the applicant may not have explicitly indicated so in it reasons for withdrawal. Over time, as the delays mounted, in some cases the commercial incentive for seeking approval changed. Second, the companies have a strong incentive to maintain cordial relations with EC regulators, and saw no advantage of complaining to EC regulators about the length of the delays resulting from the moratorium.

7.1232 The **Panel** notes from the record that this application was submitted to the Netherlands in November 1999. Four months later, in March 2000, the Health Council of the Netherlands requested information from the applicant regarding missing and illegible references and a request for information on the nutritional value of glyphosate-treated RR sugar beet.[1131] The applicant responded one month later and indicated that further studies on DNA and protein detection from sugar produced from RR sugar beet were in process.[1132] In May 2000, the lead CA requested further information on protein toxicity.[1133] The applicant provided a response in December 2000, which included new scientific reports and data.[1134]

7.1233 In January 2001, Denmark requested further information regarding compositional analysis of RR sugar beet treated with herbicide, as well as non-treated, and field management for RR and conventional sugar beet. The Danish CA also requested information on the level of amino acid in treated sugar beet as well as a series of technical reports which were cited in the application, but not provided, by the applicant.[1135] There is no indication on record that the applicant responded to the request from Denmark.

7.1234 In May 2001, after reviewing the additional information provided by the applicant in December 2000, the lead CA requested further information on protein analysis. The lead CA indicated that it was not yet fully satisfied with the information provided by the applicant concerning the likelihood of specific protein formation. In addition, mentioning recent studies which had shown that "unintended effects on GMOs" were possibly caused by transformation of plant cells, the lead CA also requested a semi-chronic oral toxicity study on rats in order to "to rule out possible undesirable effects [...] with sufficient certainty".[1136] No specific study was cited in this regard.

7.1235 There is no indication in the evidence before us that the applicant responded to the requests from the lead CA for further information. Although the European Communities indicates in the chronology it provided on this application that the applicant sent a message regarding the status of the application in November 2001, there is no such document in the record. The next item in the chronology is the withdrawal of the application by the applicant in April 2004.

7.1236 We sought the advice of the experts assisting us as to whether the additional information requested by the lead CA in May 2001 was necessary to ensure that the conclusions of the safety

[1131] Exhibit EC-102/At. 21.
[1132] Exhibit EC-102/At. 22.
[1133] Exhibit EC-102/At. 23.
[1134] Exhibit EC-102/At. 26.
[1135] Exhibit EC-102/At. 31.
[1136] Exhibit EC-102/At. 32.

assessment were valid. Dr. Nutti expressed the view that "the information requested by the lead CA regarding the derived proteins and the request for a semi-chronic oral toxicity test on mice or rats with edible parts of sugar beet was not necessary to ensure that the conclusions of the safety assessment were valid". She emphasized that the applicant had already completed an acute toxicity test on rats and conducted studies which confirmed that RR sugar beet "was equivalent in composition and nutrition to the conventional counterpart".[1137]

7.1237 Even accepting that contrary to the views of Dr. Nutti the information requested by the Health Council in May 2001 was necessary to ensure the validity of the safety assessment, this would not explain the time taken by the lead CA before initially requesting additional information in March 2000 (almost five months), and the time taken to review the information received in December 2000 (five months).

7.1238 The United States does not assert that the time taken by the Netherlands to complete its assessment is a reflection of Dutch support for the moratorium. Rather, its assertion is that the time taken by the Netherlands reflects the impact of the alleged moratorium. The United States contends that the Netherlands was placed in a position of having to recognize the moratorium as a reality and that this affected the speed with which it conducted its assessment.

7.1239 We consider that following the June 1999 declaration by the Group of Five countries, the Netherlands had reason to believe that the Group of Five countries would act as a "blocking minority" both in the Regulatory Committee and in the Council pending the adoption of new EC rules on labelling and traceability. In our view, the Netherlands also had reason to believe that, as in the case of some of the previously discussed approval procedures, the Commission would not complete the approval procedure in the face of systematic opposition by the Group of Five countries.

7.1240 We also note, however, that the Netherlands was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, in this instance, we are not convinced that the Dutch CA's conduct reflects a precautionary approach. In particular, we are not convinced that the Dutch CA could not forward its March 2000 request for information to the applicant sooner than it did even while following a precautionary approach, or that after receiving the applicant's response it could not identify the need for more detailed information earlier than in May 2001.

7.1241 It is pertinent to note, furthermore, that the applicant drew the Dutch CA's attention to an application concerning the same product which the applicant had previously submitted to Belgium under Directive 90/220.[1138] Belgium did not complete its assessment of that application, and the applicant withdrew it in April 2004. We have previously concluded in relation to that application that the time taken by Belgium for its assessment of RR sugar beet is consistent with the Complaining Parties' assertion that during the relevant time period the European Communities applied a general moratorium on final approvals.

7.1242 Taking account of the aforementioned elements, we consider that the time taken by the lead CA before initially requesting additional information in March 2000, and the time taken to review the information received in December 2000, is consistent with the United States' view that a general moratorium on final approvals was in effect in the European Communities at that time. It should also be recalled in this regard that the application concerning RR sugar beet (food) as of the date of its

[1137] Annex H, para. 775.
[1138] Exhibit EC-102/At. 20.

withdrawal had not reached the Community level. In other words, it had not yet reached the procedural stage where the Group of Five countries and/or the Commission could have taken action to delay or prevent its final approval.

7.1243 Furthermore, in our view, the fact that the applicant did not specifically cite a general EC moratorium on approvals as a reason for the withdrawal of the application in April 2004 is not inconsistent with the assertion that the European Communities was applying a general moratorium on approvals at the time. As was pointed out by the United States, if a moratorium was in effect, there are plausible explanations for why the applicant did not specifically cite the alleged moratorium or resulting delays as a reason for withdrawing the application concerning RR sugar beet (food).

7.1244 In the light of the above, we conclude that the time taken by the Netherlands for its initial assessment of the application concerning RR sugar beet (food) is consistent with the contention of the Complaining Parties that during the relevant time period the European Communities applied a general moratorium on final approvals.

(iii) Conduct of Group of Five countries generally

7.1245 In the preceding analysis, the Panel has addressed certain conduct of one particular Group of Five country, France, in its capacity as lead CA in individual approval procedures.[1139] In what follows, the Panel focuses on the conduct of Group of Five countries in approval procedures in which they were not acting as the lead CA. In particular, the Panel considers how Group of Five countries voted in the Regulatory Committee or Council and whether they raised objections to favourable assessments circulated by the lead CA.

Voting behaviour by Group of Five countries in the Regulatory Committee or Council

7.1246 We begin by considering the voting behaviour by Group of Five countries in the Regulatory Committee or Council. The record makes clear that there was no vote on any application in the Regulatory Committee or the Council between June 1999, when the Group of Five countries made their joint declaration, and August 2003. It is therefore not possible to establish whether, consistent with their June 1999 declaration, the Group of Five countries cast their votes in the Regulatory Committee or the Council in such a way as to prevent the necessary qualified majority from being reached.

7.1247 In response to a question from the Panel, the European Communities pointed out that between October 1998 and June 1999 four votes took place in the Regulatory Committee and that during that time period two Group of Five countries voted in favour of applications.[1140] Specifically, the European Communities mentions that Italy cast a favourable vote in the Regulatory Committee on four applications submitted under Directive 90/220[1141] and that Denmark did the same in relation to one application submitted under Directive 90/220[1142].

[1139] *See* the approval procedures concerning RR oilseed rape (EC-79) and MS1/RF1 oilseed rape (EC-89) as well as MS1/RF2 oilseed rape.

[1140] EC reply to Panel question No. 87.

[1141] The applications in question are those concerning Bt-531 cotton, RR-1445 cotton, MON809 maize and the Transgenic tomato.

[1142] The application in question is that concerning the Transgenic tomato. It should be noted that Denmark voted against the applications concerning Bt-531 cotton and RR-1445 cotton. Exhibits EC-65/At. 59 and EC-66/At. 57. Regarding the application concerning MON809 maize, Denmark abstained. Exhibit EC-83/At. 65.

7.1248 In the Panel's view, the fact that Italy and Denmark voted in favour of a number of applications between October 1998 and June 1999 does not support the inference that if there had been votes between June 1999 and August 2003, these two member States would have voted in favour of additional applications. To begin with, in June 1999 Italy and Denmark declared that they would take steps to prevent new applications from being approved. In addition, between June 1999 and August 2003, Italy and Denmark repeatedly objected to the placing on the market of biotech products which had received a favourable initial assessment from the lead CA.[1143]

7.1249 The European Communities also points out that in February 2004, Italy and France in the Regulatory Committee voted in favour of a Commission draft measure approving the application concerning NK603 maize.[1144] The Panel notes that the vote referred to by the European Communities occurred well after 29 August 2003, the date of establishment of this Panel. As these votes may have been influenced by the establishment of this Panel, it would be inappropriate to infer from these votes that if votes had been held prior to August 2003, Italy and France would have voted in favour of applications.[1145] Also, the voting behaviour by Italy and France in the procedure concerning NK603 maize is consistent with the June 1999 declaration of the Group of Five, in that the new EC rules on labelling and traceability were adopted in September 2003.

Objections by Group of Five countries to favourable assessments by lead CAs

7.1250 We now turn to consider whether the Group of Five countries raised any objections to favourable assessments by lead CAs in the period between June 1999, when the Group of Five countries made their joint declaration, and August 2003. In considering this issue, we first of all recall that under the approval procedures set out in Directives 90/220 and 2001/18 as well as Regulation 258/97, when the lead CA circulates a favourable assessment report, the other member States have 60 days within which to raise objections to the placing on the market of the biotech product in question. If such objections are maintained, the decision on whether to approve the relevant biotech product must be made at Community level.

7.1251 The record indicates that there were relatively few individual approval procedures in which the 60-day period for objections ended between June 1999 and August 2003. More specifically, it is possible to identify a total of nine applications which fall within this category. They include six applications which were being assessed under Directives 90/220 and/or 2001/18[1146] and three applications which were being assessed under Regulation 258/97[1147].

7.1252 We note that in the case of each of the nine applications in question, there was at least one Group of Five country which raised and maintained an objection to the placing on the market of the biotech product in question. The nine applications include three in which Group of Five country

[1143] *E.g.*, in the approval procedures concerning Bt-11 maize (EC-69) (Denmark and Italy), RR oilseed rape (Denmark and Italy), GA21 maize (EC-85) (Denmark and Italy), T25 x MON810 maize (Denmark and Italy), GA21 maize (food) (Italy) and Bt-11 sweet maize (food) (Denmark and Italy.

[1144] EC first written submission, para. 565; EC reply to Panel question No. 87. It should be noted that other Group of Five countries – Greece, Luxembourg and Denmark – voted against approving the application. Exhibit EC-114.

[1145] For completeness, it should be noted that in February 1999, France in the Regulatory Committee voted against approving Bt-531 cotton and RR-1445 cotton. Exhibits EC-65/At. 59 and EC-66/At. 57.

[1146] The six approval procedures are the approval procedures concerning (i) Bt-11 maize (EC-69), (ii) RR oilseed rape (EC-70), (iii) NK603 maize, (iv) GA21 maize (EC-78), (v) GA21 maize (EC-85) and (vi) T25 x MON810 maize.

[1147] The three approval procedures are the approval procedures concerning (i) GA21 maize (food), (ii) Bt-11 sweet maize (food) and (iii) NK603 maize (food).

objections were raised and maintained under the provisions of Directive 2001/18. We further note that in none of the nine cases did all Group of Five countries raise objections.[1148] It should, however, be recalled in this connection that under Directives 90/220 and 2001/18 as well as Regulation 258/97 an objection from a single Group of Five country was sufficient to force a decision at Community level and hence for the Group of Five countries to obtain the opportunity to use their "blocking minority" in the Regulatory Committee and Council.

7.1253 The fact that at least one Group of Five country raised and maintained an objection in the case of each of the nine relevant applications does not necessarily mean that all of these objections were maintained for the reasons underlying the June 1999 declaration by the Group of Five countries.[1149] Nonetheless, the existence of an objection from at least one Group of Five country in each of the nine cases is consistent with the Complaining Parties' assertion that certain member States intentionally delayed or prevented the final approval of applications. Even if the reason presented by a Group of Five country for its objection differed from the reasons underlying the June 1999 declaration, this fact alone would not contradict the Complaining Parties' assertion. Since this particular Group of Five country raised an objection, it cannot simply be assumed that if the reason offered for the objection had not existed, the country in question would have refrained from objecting on the basis of the June 1999 declaration.[1150]

(iv) Commission conduct prior to the June 1999 declaration by the Group of Five countries

7.1254 We note that Argentina has commented on the conduct of the Commission prior to the issuance of the June 1999 declaration by the Group of Five countries. The conduct in question affected the progress in the approval process of a number of applications which had been submitted under Directive 90/220. In Argentina's view, the Commission's conduct in respect of these applications confirms the existence of a general moratorium on approvals as from October 1998.

7.1255 **Argentina** argues that all applications which had received positive opinions from EC scientific committees in 1998 were prevented by the Commission from progressing in the approval process. The Commission did so by holding lengthy inter-service consultations in September 1998 and May 1999. According to Argentina, a first group of these applications – those concerning Falcon oilseed rape, MS8/RF3 oilseed rape and RR fodder beet – was delayed by inter-service consultations which began in September 1998. The relevant applications did not reach the Regulatory Committee stage until June or October 1999. A second group of applications – those concerning Bt-531 cotton and RR-1445 cotton – reached the Regulatory Committee stage, but failed to achieve a qualified majority vote in the Regulatory Committee in February 1999. The Commission launched inter-service consultations in May 1999 on draft measures to be submitted to the Council, but the Commission did not submit any draft measures, and so the applications in question made no progress

[1148] In three approval procedures there were three Group of Five countries which raised and maintained objections, and in another three approval procedures there were two Group of Five countries which did so.

[1149] In relation to DS291 and DS292, we note that the United States and Canada have demonstrated that in some of the nine relevant approval procedures objections by Group of Five countries were based on reasons which explicitly included those underlying the June 1999 declaration.

[1150] Indeed, if a Group of Five country opposed the placing on the market of a biotech product and it considered there existed, in its view, clear product- or application-specific reasons for doing so, then there was no need for it to fall back on the more general reasons underlying the June 1999 declaration. In other cases, however, the relevant Group of Five country might well have wished to base its opposition to the product in question on the June 1999 declaration. Cases in point are Denmark's first objection concerning Bt-11 maize (EC-69), which was based on product- and application-specific reasons (Exhibit EC-69/At. 66), and Denmark's objection concerning Bt-11 sweet maize (food), which was based on the June 1999 declaration (Exhibit EC-92/At. 27).

until they had to be updated under Directive 2001/18 in January 2003. For Argentina, the September 1998 and May 1999 inter-service consultations undertaken by the Commission are evidence of the existence of a general *de facto* moratorium. Argentina finds further support for this view in the circumstance that the "inter-service consultation" phase was not provided for in Directive 90/220.

7.1256 The **Panel** has already addressed the delays that occurred as from May 1999 as a result of the Commission's inter-service consultations on the applications concerning Bt-531 cotton and RR-1445 cotton. Accordingly, the Panel need only address the inter-service consultations on the applications concerning Falcon oilseed rape, MS8/RF3 oilseed rape and RR fodder beet. These consultations were all launched in September 1998. The Panel considers that in addition to these three approval procedures mentioned by Argentina, the approval procedures concerning MON809 maize, the Transgenic tomato, Bt-531 cotton and RR-1445 cotton are also relevant. These additional applications also received favourable opinions from EC scientific committees in 1998[1151], and the Commission launched inter-service consultations on them in or before September 1998[1152]. The following table summarizes the factual situation.

Application	**Commission inter-service consultations on draft measure to be submitted to Regulatory Committee**	**Launch by Commission of vote in Regulatory Committee**	**Vote in Regulatory Committee**	**Commission inter-service consultations on draft measure to be submitted to Council**
MON809 maize	12/06/1998	04/09/1998	23/10/1998 (absence of qualified majority)	01/02/1999
Transgenic tomato	05/10/1998	26/11/1998	18/12/1998 (absence of qualified majority)	16/02/1999
Bt-531 cotton	04/09/1998	26/11/1998	22/02/1999 (absence of qualified majority)	07/05/1999
RR-1445 cotton	04/09/1998	26/11/1998	22/02/1999 (absence of qualified majority)	07/05/1999
Falcon oilseed rape	04/09/1998	29/06/1999	29/10/1999 (no vote) 09/03/2000 (no vote)	
MS8/RF3 oilseed rape	04/09/1998	30/06/1999	29/10/1999 (no vote) 09/03/2000 (no vote)	
RR fodder beet	04/09/1998		29/10/1999 (no vote)	

7.1257 The above table shows that the Commission on 4 September 1998 began inter-service consultations on five different applications. While in the approval procedures concerning Falcon oilseed rape, MS8/RF3 oilseed rape and RR fodder beet, these consultations apparently went on for almost ten months (or more in the case of RR fodder beet), in the approval procedures concerning Bt-531 and RR-1445 cotton, the consultations were completed much sooner, in less than three months. In considering this discrepancy, account should be taken of the four votes which took place in the Regulatory Committee after 4 September 1998. As is clear from the table, the application concerning MON809 maize was voted on in October 1998, the application concerning the Transgenic tomato in December 1998, and the applications concerning Bt-531 cotton and RR-1445 cotton in February 1999. In each case, the Commission's draft measure approving the relevant application failed to obtain the necessary qualified majority. It may well be that in view of these four successive "defeats" in the Regulatory Committee, the Commission did not find it opportune quickly to launch

[1151] Exhibits EC-83/At. 54; EC-84/At. 42; EC-65/At. 47; EC-66/At. 43.
[1152] Exhibits EC-83/At. 55; EC-84/At. 43; EC-65/At. 48; EC-66/At. 44.

further votes on other applications submitted under Directive 90/220. The timing of the launch of the next votes – 29 June 1999 for Falcon oilseed rape and 30 June 1999 for MS8/RF3 oilseed rape – tends to suggest that the Commission preferred to wait until after the Environment Council meeting of 24/25 June 1999 at which a Common Position was adopted on the proposal to amend Directive 90/220.[1153]

7.1258 The Panel is not convinced that the Commission's conduct in respect of the applications concerning Falcon oilseed rape, MS8/RF3 oilseed rape and RR fodder beet supports Argentina's and the other Complaining Parties' assertion that a general moratorium on approvals was in effect already as from October 1998. It was not until June 1999 that the Group of Five countries announced that they would take steps to suspend new approvals. Moreover, the record of the above-mentioned four votes shows that only some of the five member States which later issued the June 1999 joint declaration voted against the Commission's draft measures.[1154] In the absence of evidence of systematic member State opposition to final approvals, comparable to the kind of opposition announced in June 1999 by the Group of Five countries, there is no apparent reason to believe that the Commission's conduct reflects a decision to prevent the final approval of applications.

7.1259 It might be argued that the Commission's four successive "defeats" in the Regulatory Committee could be evidence of reluctance on the part of certain member States to approve applications under Directive 90/220 which was considered to require amendment. Even accepting this argument, the circumstance that the Commission could have found it increasingly difficult to get member States to vote in favour of applications submitted under Directive 90/220 might provide a rationale for not precipitating further votes. But it does not provide a plausible rationale for the Commission deciding not to make full use of its powers under Directive 90/220 and not to complete approval procedures on its own, if necessary. It is noteworthy in this respect that the Commission eventually did call votes on the applications concerning Falcon oilseed rape, MS8/RF3 oilseed rape and RR fodder beet. The Commission did not do so in the case of applications which had obtained favourable opinions from EC scientific committees after the June 1999 declaration by the Group of Five countries. The view that a moratorium on approvals was not already in effect as from October 1998 draws further support from the explanation offered by Greece for abstaining from voting on the Transgenic tomato in December 1998. Greece stated that "we support the *idea* of a 'moratorium' for G.M.O., as presented by some Member-States".[1155] This statement suggests that a moratorium was an idea entertained by some member States at the time, but not that it was a reality.

7.1260 The Panel does not agree with Argentina that the very fact that the Commission launched inter-service consultations is evidence of a *de facto* moratorium on approvals.[1156] It is correct that Commission inter-service consultations were not provided for in Directive 90/220 as a distinct stage in the approval process.[1157] However, as the European Communities explained in response to a question from the Panel, inter-service consultation is a process internal to the Commission, designed

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[1153] Particularly in relation to MS8/RF3 oilseed rape and RR fodder beet, some of the delay may also be attributable to additional information supplied by the applicant.

[1154] Regarding MON809 maize, only Greece voted against, with Denmark, France and Luxembourg abstaining. Exhibit EC-83/At. 65. Regarding the Transgenic tomato, no Group of Five country voted against. Greece and Luxembourg abstained. Exhibit EC-84/At. 45. Regarding Bt-531 cotton, Denmark, France and Greece voted against, with Luxembourg abstaining. Exhibit EC-65/At. 59. Regarding RR-1445 cotton, Denmark, France and Greece voted against, with Luxembourg abstaining. Exhibit EC-66/At. 57.

[1155] Exhibit EC-84/At. 45 (emphasis added).

[1156] The United States makes a similar argument about the inter-service consultations launched in May 1999 on the applications concerning Bt-531 cotton and RR-1445 cotton. US second written submission, paras. 56-57; US first oral statement, para. 30.

[1157] *En passant*, the Panel notes that the same is true for Directive 2001/18 and Regulation 258/97.

to ensure that the Commission services with a legitimate interest in the matter on which a Commission decision is being prepared, work in close co-operation and in co-ordinated fashion.[1158] As the European Communities also pointed out, inter-service consultation is mandated by the Commission's rules of procedure for the preparation and implementation of each Commission decision.[1159] It is clear to the Panel, therefore, that the inter-service consultations of September 1998 were not an additional procedural stage devised by the Commission to prevent the approval of biotech products.

7.1261 In the light of the above considerations, the Panel concludes that the time taken by the Commission to submit to the Regulatory Committee draft measures on the applications concerning Falcon oilseed rape, MS8/RF3 oilseed rape and RR fodder beet does not support Argentina's and the other Complaining Parties' assertion that the European Communities applied a general moratorium on final approvals already as from October 1998.

(v) Concluding observations

7.1262 The Panel notes that the Complaining Parties did not present detailed arguments in respect of each of the individual approval procedures discussed above. In fact, Canada and Argentina did not present any arguments in respect of some of these approval procedures. The European Communities argues in this regard that addressing only a limited selection of individual approval procedures is not sufficient to prove the existence of an across-the-board moratorium, *i.e.*, of a moratorium which applies to any and all applications which were pending during the relevant time period.[1160] In other words, according to the European Communities, the Complaining Parties cannot sustain their burden of establishing a prima facie case of the existence of a general moratorium on approvals unless they provide detailed evidence and arguments in respect of each and every of the above-mentioned individual approval procedures. In response to a question from the Panel, the Complaining Parties dispute this EC argument.[1161]

7.1263 The Panel agrees with the European Communities that the Complaining Parties could have sought to establish a prima facie case of the existence of a general, or across-the-board, moratorium by offering evidence and argumentation in respect of each and every of the individual approval procedures which were pending between October 1998 and August 2003. But the Panel cannot accept the European Communities' suggestion that this was the only way in which the Complaining Parties could discharge their burden of demonstrating prima facie that the alleged moratorium applied to all pending applications.

7.1264 As is clear from the Panel's preceding analysis, the Complaining Parties have provided other relevant evidence and argumentation to demonstrate the generality of the alleged moratorium. First and foremost, the Complaining Parties demonstrated that not a single biotech application under consideration between October 1998 and August 2003 was approved on or before the date of establishment of this Panel. Moreover, the Complaining Parties relied on the June 1999 declaration by the Group of Five countries, which states that the Group of Five countries "will take steps to have *any* new authorizations for growing and placing on the market suspended" (emphasis added). Finally, the Complaining Parties submitted numerous EC documents and statements by EC or member State

[1158] EC reply to Panel question No. 94. In response to a question from Argentina, the European Communities defined "inter-service consultation" as the process by which the lead service(s) consults with other interested services. EC reply to Argentina's question Nos. 9 and 10.

[1159] *Ibid*.

[1160] EC second written submission, footnote 212.

[1161] Complaining Parties' replies to Panel question No. 179.

officials. The Panel found that these documents and statements support the Complaining Parties' assertion that the European Communities applied a general moratorium during the relevant time period. In the specific circumstances of this case, these elements of proof taken together are sufficient, in the Panel's view, to establish a prima facie case of the generality of the alleged moratorium.

7.1265 Having regard to the individual approval procedures which the Complaining Parties did address, the Panel notes that, according to the Complaining Parties, these approval procedures confirm that certain member States and/or the Commission did cause delays or prevent the final approval of applications in the manner alleged by the Complaining Parties. The relevant approval procedures support this contention. To illustrate this, the Panel recalls below its findings on member States' and the Commission's ability to delay or prevent the final approval of applications and indicates whether it has been established that member States and/or the Commission actually did delay or prevent the approval of applications in this manner. The Panel begins with the relevant member State actions and/or omissions:

(a) The Panel found that the lead CA could delay the completion and circulation of its initial assessment. The United States and Canada have established that a Group of Five country delayed the completion and circulation of its initial assessment, so much so that the applicant withdrew the application.[1162] The European Communities has correctly pointed out, however, that the same Group of Five country in another approval procedure[1163] in April 1999 transmitted to the Commission a favourable initial assessment and that it confirmed that assessment in June 2003, after the application had been updated in accordance with the requirements of Directive 2001/18.[1164] To the extent this is viewed as inconsistent behaviour[1165], it suggests that in situations where the relevant Group of Five country acted as the lead CA, it was not in all cases prepared to assume the possible consequences of delaying or blocking action[1166].

[1162] The approval procedure in question is that concerning RR oilseed rape (EC-79).
[1163] The approval procedure in question is that concerning Bt-11 maize (EC-69).
[1164] EC reply to Panel question No. 87.
[1165] A special circumstance which should be pointed out is the previously mentioned fact that the biotech product at issue – Bt-11 maize – had already been approved for marketing in the European Communities in April 1998, although not for cultivation (Bt-11 maize (EC-163)), which was the use at issue in the approval procedure concerning Bt-11 maize (EC-69).
[1166] By failing to complete its initial assessment, a lead CA exposes itself to the risk of legal action being instituted against it under its own domestic law. EC first written submission, para. 186. There is no such risk, or less of a risk, where a Group of Five country avails itself of its right to object to an initial assessment prepared by a lead CA, or exercises its right to vote against a draft measure submitted by the Commission to the Regulatory Committee or to the Council. For this reason, the Panel does not consider that the fact that France in April 1999 and June 2003 transmitted a favourable initial assessment of Bt-11 maize (EC-69) to the Commission is necessarily inconsistent with the June 1999 declaration by the Group of Five countries. France may have considered that other Group of Five countries, and even the Commission, would take the necessary steps to delay or prevent Bt-11 maize (EC-69) from being approved at member State level or at Community level.

With reference to DS291, the Panel notes that the United States submitted a July 1999 news report which is consistent with the view that Group of Five countries which acted as lead CAs might not always have been willing to face the possible legal consequences of delaying or blocking action. The news report states that "the Commission pointed out on 15 July 1999 that France and Denmark have GMO applications pending, even though they were the leading proponents of GMO moratorium in June". The news report then reports the spokesman for then-Environment Commissioner Ritt Bjerregard to have said that "[w]e cannot understand why

(b) The Panel found that member States other than the lead CA could object to the placing on the market of a biotech product following a favourable assessment by the lead CA. The record establishes that one or more Group of Five countries raised and maintained an objection in each of the approval procedures in which the deadline for raising objections expired in the period between June 1999, when the Group of Five countries made their joint declaration, and August 2003.

(c) The Panel found that a group of member States that constituted a blocking minority could prevent the appropriate Regulatory Committee or the Council from reaching the qualified majority necessary to adopt a draft measure proposing approval of an application. The Panel also found that the Group of Five countries constitute such a group of member States and that the formation of that group was announced in June 1999 in a joint declaration. In this respect, the record makes clear that there was no vote on any application in the Regulatory Committee or the Council between June 1999 and August 2003. It is therefore not possible to establish that consistent with their June 1999 joint declaration, the Group of Five countries cast their votes in the Regulatory Committee or the Council in such a way as to prevent the necessary qualified majority from being reached.

(d) The Panel found that the lead CA could refuse to give its consent to the placement on the market of a biotech product after the Commission has approved an application. The United States and Canada have established that one Group of Five country refused to give its consent to the placement of a biotech product after the Commission had approved the application.[1167]

7.1266 The Panel now turns to relevant Commission actions and/or omissions:

(a) The Panel found that the Commission could delay the submission of a draft measure to the appropriate Regulatory Committee, or it could fail to convene the Regulatory Committee for a vote on a draft measure which has been submitted. The United States, Canada and Argentina have established that the Commission failed to submit draft measures to the appropriate Regulatory Committee.[1168] The United States and Canada have further established that the Commission failed to re-convene the Regulatory Committee for a vote on a draft measure which had been previously submitted, but on which no vote was held.[1169]

(b) The Panel found that the Commission could delay the submission of a draft measure to the Council where the Regulatory Committee was unable to reach the qualified

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these countries do not withdraw their applications after all the statements they made at the Council of Ministers. [...] It is one thing to make all these grand declarations and go before the press and assert their desire for a moratorium. But it seems to be another to take the step of withdrawing their applications. Until these applications are withdrawn, the Commission has a clear legal obligation to pursue the procedures set out in the EEC/90/220 directive". The news report also quotes the spokesman as saying that "[w]e are basically asking the member states to put their money where their mouth is". "EU Official Calls on Members to Pull GMO Applications in Light of 'Moratorium'", International Trade Reporter, 21 July 1999, p. 1214 (Exhibit US-96).

[1167] *See* the Panel's earlier analysis of the approval procedures concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape.

[1168] *See* the Panel's earlier analysis of various approval procedures under the sub-headings "Failure by the Commission to submit a draft measure to the Regulatory Committee".

[1169] *See* the Panel's earlier analysis of various approval procedures under the sub-heading "Failure by the Commission to re-convene the Regulatory Committee for a vote on a draft".

> majority necessary to deliver an opinion. The United States, Canada and Argentina have established that the Commission failed to submit draft measures to the Council in a situation where the Regulatory Committee was unable to reach the qualified majority necessary to deliver an opinion.[1170]

7.1267 As a final matter, the Panel recalls the European Communities' assertion that the Complaining Parties' claims in respect of the general moratorium would collapse when the facts and history of each approval procedure are considered. The European Communities contended that an analysis of the relevant facts would show that during the relevant time period there were no acts and/or omissions which stalled applications at key decision-making stages in the approval process. In the alternative, the European Communities argued that even if the delays that occurred could be viewed as the result of a moratorium, that moratorium ended with the entry into force in January 2003 of Directive 2001/18.

7.1268 The Panel has undertaken an extensive analysis of each individual application discussed by the European Communities as well as of those applications which were withdrawn during the time period in question. As is clear from the above analysis, the facts and histories of the relevant approval procedures do not demonstrate that there were no acts and/or omissions which stalled applications at key decision-making stages in the approval process. To the contrary, for the time period from June 1999 to August 2003, the facts and histories of all approval procedures which have been examined are consistent with the Complaining Parties' assertion that during that time period Group of Five countries and/or the Commission were delaying or preventing the final approval of applications.

7.1269 Moreover, the Panel's analysis does not bear out the European Communities' alternative contention that any acts and/or omissions which might have served to prevent the final approval of applications prior to the entry into force of Directive 2001/18 ended when that Directive entered into force in January 2003. The Panel found in this regard (i) that at the member State level there were delays in the processing of applications under Directive 2001/18 which are consistent with the existence of a moratorium on final approvals, (ii) that Group of Five countries continued to oppose the approval of applications even though they had been updated in accordance with the requirements of Directive 2001/18; and (iii) that, as of August 2003, no procedure had reached the stage where the Commission could have taken action to delay or prevent the final approval of an application.[1171]

7.1270 It follows from the foregoing that the Panel's analysis of individual approval procedures does not lead to the "collapse" of the Complaining Parties' claim that the European Communities applied a general *de facto* moratorium on approvals. Nevertheless, while the Panel considers that the facts and histories of individual approval procedures are consistent with the Complaining Parties' contention that a general moratorium was in effect in August 2003, the Panel was not persuaded that the facts and histories of these procedures support the Complaining Parties' claim that a general moratorium was in effect already before June 1999, and, more specifically, as from October 1998.

(f) Overall conclusions

7.1271 The Panel has now completed its consideration of the various elements it said it would address. To determine to what conclusion these elements lead, it is useful to recall the Panel's main findings:

[1170] *See* the Panel's earlier analysis of various approval procedures under the sub-heading "Failure by the Commission to submit a draft measure to the Council".

[1171] *See supra*, paras. 7.1032-7.1034.

(a) The Panel found that during the relevant time period (October 1998 to August 2003) member States and the Commission had the ability and opportunity to prevent or delay the approval of applications in the manner identified by the Complaining Parties.

(b) The Panel found that the June 1999 joint declaration by the Group of Five countries constitutes direct evidence of an intention on the part of the relevant five member States (Denmark, Italy, France, Greece and Luxembourg) to do what was within their power to prevent the approval of further applications, pending the adoption of EC rules concerning labelling and traceability of biotech products. The Panel also found that because of the June 1999 declaration by the Group of Five countries, the Commission had reason to believe that it could no longer approve applications with the (qualified majority) support of the member States. The Panel found it plausible that the systematic opposition by the Group of Five countries was an issue for the Commission, and that this situation, while it continued, could have affected the Commission's readiness to make full use of the relevant procedures to complete the approval process.

(c) The Panel found that no applications were approved between October 1998 and August 2003. This is despite the fact that a large number of applications were pending and that many of these had received one or more favourable scientific assessments. The Panel also noted that before October 1998 ten agricultural biotech products had been approved and that after August 2003 three applications were approved. The Panel highlighted the fact that the post-August 2003 approvals were granted when the present panel proceedings were already under way.

(d) The Panel found that each of the Complaining Parties had submitted numerous official and internal EC documents and statements by high-ranking officials which explicitly state that the reason for the absence of approvals was a general *de facto* moratorium on approvals. The Panel also found that the documents and statements submitted by each Complaining Party permit the inference that a general moratorium was in effect between June 1999 and August 2003. The Panel was not convinced that they warrant the inference that a general moratorium was in effect already as from October 1998, or that it ended in January 2003, when Directive 2001/18 entered into force.

(e) The Panel found that the facts and histories of individual approval procedures confirm that Group of Five countries and/or the Commission did cause delays or prevent final approvals in the manner alleged by the Complaining Parties.

(f) The Panel found that for the time period from June 1999 to August 2003 the facts and histories of all approval procedures examined by the Panel are consistent with the Complaining Parties' assertion that the final approval of applications was intentionally being prevented by Group of Five countries and/or the Commission. The Panel was not persuaded that it can be inferred from the facts and histories of the relevant approval procedures that a general *de facto* moratorium was in effect already as from October 1998, or that it ended in January 2003, when Directive 2001/18 entered into force.

7.1272 The Panel considers that all of these findings taken together lead logically to the following conclusion:

(i) that a moratorium on approvals was in effect in the European Communities between June 1999 and August 2003, when this Panel was established;

(ii) that this moratorium was generally applicable, *i.e.*, to all applications for approval which were pending between June 1999 and August 2003 under Directives 90/220 and/or 2001/18 or under Regulation 258/97; and

(iii) that this moratorium was applied *de facto*, *i.e.*, without having been adopted through a formal EC rule- or decision-making process, and, more particularly, that the final approval of applications was prevented by the Group of Five countries[1172] and/or the Commission through their actions and/or omissions.

7.1273 The Panel also considers that the record supports the inference that the Group of Five countries and the Commission prevented the final approval of applications pursuant to decisions which were intended to be generally applicable. In the case of the Group of Five countries, it can be inferred from their June 1999 joint declaration that they decided to use their powers in the approval process so as to prevent any and all new applications from being approved, until new EC rules on labelling and traceability were adopted. The actual conduct of these countries in the context of individual approval procedures is consistent with the existence of such decisions. During the relevant time period (June 1999 to August 2003), numerous applications received favourable initial assessments from the lead CA. But in each case, one or more Group of Five countries objected to the placing on the market of the relevant biotech product, sometimes explicitly invoking the Group of Five declaration as a reason for their objection. This meant that no application was approved at member State level. At Community level, the Regulatory Committee or the Council did not proceed to a vote on any application between June 1999 and August 2003. There thus exists no information about the voting behaviour of the Group of Five countries during that time period.

7.1274 Regarding the Commission, the Panel made the point that the Commission was faced with highly exceptional circumstances when in June 1999 the Group of Five countries formally signalled its systematic opposition to final approvals. In the Panel's view, it is plausible that the Commission in those circumstances effectively decided not to make full use of the relevant procedures to complete the approval process. In fact, during the relevant time period there was no case where the Commission completed the approval process. Moreover, the Panel's analysis of the facts and histories of individual approval procedures reveals a clear and repeated pattern of inaction, or delayed action, by the Commission at certain stages of the EC approval processes. It shows that the Commission repeatedly failed to forward draft measures to the Council in situations where the Regulatory Committee did not reach the required qualified majority. It also shows that the Commission repeatedly failed to submit a draft measure to the Regulatory Committee, or failed to call a vote in the Regulatory Committee. In the Panel's assessment, the aforementioned elements – the exceptional circumstances presented by the formation of the Group of Five, the fact that the Commission did not approve a single application during the relevant time period, and the fact that during the same time period there was an observable pattern of inaction by the Commission – warrant the inference that the

[1172] The Panel's reference to the Group of Five countries is not intended to suggest that there were no member States other than the Group of Five countries which took steps, during part of the relevant time period (June 1999 to August 2003), with a view to delaying or preventing the final approval of any and all applications. It should be recalled in this respect that Canada submitted evidence which shows that in February 2001 Austria formally expressed its support for the June 1999 declaration by the Group of Five countries, and that the United States submitted a document which suggests that Belgium as of December 2001 also supported the June 1999 declaration by the Group of Five countries.

Commission's conduct was the result of an effective decision not to make full use of the relevant procedures to complete the approval process.[1173]

7.1275 The European Communities appears to argue that the described pattern of inaction by the Commission should rather be considered as a practice in the sense of a pattern of similar responses to a similar set of circumstances.[1174] The European Communities' concept of practice implies that the Commission was engaged in case-by-case decision-making to formulate and develop policy, and that the Commission's conduct in specific cases was subsequently repeated in similar cases, with the consequence that this conduct crystallized into a practice.

7.1276 The Panel is not persuaded that the Commission's conduct reflects nothing more than a practice as that term is understood by the European Communities. True enough, a pattern of inaction could point to the existence of a Commission practice. But it may equally be the consequence of a generally applicable decision by the Commission. Furthermore, the mere fact that the record contains no document embodying such a Commission decision does not imply that no such decision existed and that the described pattern of inaction amounted to a practice. It is important to bear in mind in this regard that the Commission had to respond to decisions of the Group of Five countries which were applicable to all pending and new applications. In these circumstances, the most logical course of action was for the Commission to define and establish a policy which was likewise applicable to all pending and new applications. This was not a situation where the Commission lacked the necessary information to make a general decision and where it was therefore advisable to proceed on a case-by-case basis. The June 1999 declaration by the Group of Five countries provided the Commission with a clear and predictable scenario of how the Group of Five countries would exercise their powers in the context of the EC approval process.

7.1277 Without prejudice to the preceding remarks, the Panel would accept that, in one sense, the Commission's conduct might be considered to reflect a practice. The practice the Panel is referring to relates to the implementation of the Commission's effective decision not to make full use of the relevant procedures to complete the approval process. It is reasonable to assume that there was no predetermined general policy with regard to implementation, as implementation necessarily had to take account of attendant circumstances, including, most notably, the stage in the relevant EC approval procedure to which particular applications had progressed. Indeed, the record shows that the Commission's conduct varied according to the procedural stage reached by a given application.[1175] Another indicator that there was no predetermined general policy with regard to implementation is the circumstance that at one point the Commission changed its conduct in relation to applications which

[1173] For present purposes, it matters little whether the Commission's effective decision was intended to establish Commission policy for several years or whether the decision was tacitly renewed from time to time. Regarding the 2004 approvals of Bt-11 maize (food), NK603 maize and NK603 maize (food), it should be noted that there is no evidence on record which would demonstrate that the Commission decided before 29 August 2003 to complete the approval process in respect of the aforementioned applications. In the case of Bt-11 sweet maize (food), a draft measure was on the agenda of the relevant Regulatory Committee on 8 November 2003. The record does not indicate when the Commission forwarded the draft measure. Exhibit EC-92/At. 67. In the case of NK603 maize, the Commission launched inter-service consultations on a draft measure only on 8 December 2003. Exhibit EC-76/At. 71. Finally, in the case of NK603 maize (food), a draft measure was presented to the Regulatory Committee on 30 April 2004. Here again, the record does not indicate when the Commission forwarded the draft measure. Exhibit EC-96/At. 42. In the light of the evidence on record, there is therefore no reason to doubt that a general *de facto* moratorium was still in effect on 29 August 2003.

[1174] EC first written submission, paras. 566 *et seq.*; EC second written submission, footnote 213.

[1175] For instance, the Commission did not forward draft measures to the Council when the Regulatory Committee did not reach the required qualified majority. In contrast, the Commission initially did forward draft measures to the Regulatory Committee for a vote.

had reached a certain procedural stage. Specifically, the Commission initially forwarded draft measures to the Regulatory Committee for a vote.[1176] Subsequently, however, the Commission stopped doing so.[1177] This shift from one pattern of conduct to another could be interpreted as a change in implementation practice. Such a change in implementation practice would in no way be inconsistent with the view that there was an effective decision by the Commission not to complete the approval process with respect to any pending or new application.[1178]

7.1278 The Panel now turns to address the European Communities' argument that in cases where, as here, the actions and/or omissions of different entities are alleged to be part of a single measure, it is necessary to show that these entities follow a common plan or course of action. The European Communities asserts in this respect that the term "measure" is defined as "a plan or course of action intended to achieve some object".

7.1279 The Panel considers that by not making full use of its powers to complete the approval process, the Commission knowingly entered into effective (*de facto*) co-operation with the Group of Five countries. Indeed, in the Panel's view, the absence of final approvals during the relevant time period is a direct consequence of effective co-operation between the Group of Five countries and the Commission. The Group of Five countries could not have imposed the desired general moratorium on approvals without the co-operation of the Commission. And it is most unlikely that the Commission would have been dissuaded from making full use of the approval procedures if it had not been of the view that the Group of Five countries constituted a credible and stable "blocking minority".

7.1280 It is important to mention that there is nothing in the record to suggest that the Commission unqualifiedly supported the decision of the Group of Five countries to prevent the final approval of applications pending the adoption of new EC rules on labelling and traceability. To the contrary, the "interim approach" developed by the Commission in July 2000 was intended to allow for the resumption of approvals.[1179] But the record shows that even after July 2000 the Commission failed to make full use of the approval procedures.[1180] In other words, the record supports the conclusion that even after July 2000 there continued to be effective co-operation between the Commission and the Group of Five countries.

7.1281 Based on the foregoing observations, the Panel considers that between June 1999 and August 2003 the Group of Five countries and the Commission did follow a common "plan or course of action".[1181] The relevant "plan" consisted in preventing the final approval of applications pending the adoption of new EC rules on labelling and traceability. The fact that the Commission might have disliked the "plan", or sought to change it, is immaterial as long as the Commission did not actually follow a different "plan". As noted, there is no indication that this was the case.

[1176] For instance, in the case of the approval procedure concerning Falcon oilseed rape.

[1177] For instance, in the case of the approval procedure concerning Bt-11 maize (EC-69).

[1178] There would be no inconsistency even if it were assumed that the Commission initially sought to test the resolve of the Group of Five countries to abide by their June 1999 declaration, by launching votes in the Regulatory Committee. There is no indication in the record that the Commission was the initiator of a moratorium on approvals. The Commission's willingness to implement its effective decision not to complete the approval process with respect to any pending or new application may well have been contingent on the Group of Five countries acting in accordance with their June 1999 declaration.

[1179] For an explanation of the "interim approach", *see supra*, footnote 637.

[1180] *See*, *e.g.*, the approval procedures concerning Bt-531 cotton, RR-1445 cotton , MON809 maize and the Transgenic tomato.

[1181] The Panel is not convinced that the Group of Five countries and the Commission followed a common "plan" prior to June 1999.

7.1282 The European Communities submits, however, that it is not enough for the Group of Five countries and the Commission to have followed a common "plan or course of action". According to the European Communities, the Group of Five countries and the Commission must also have treated their plan of preventing the final approval of applications as *de facto* binding. Otherwise, the European Communities' argument implies, the application of separate decisions by the Group of Five countries and the Commission could not be considered to have produced a new and intended measure, *i.e.*, a general moratorium on approvals.

7.1283 The record does not indicate that either the Group of Five countries or the Commission followed their common plan of preventing the final approval of applications as *de facto* binding. However, there were clear incentives for the common plan to be followed. As we have said earlier, the Group of Five countries could not have imposed the desired general moratorium on approvals without the co-operation of the Commission. And the Commission had grounds for believing that if it did not co-operate with the Group of Five countries, it would have to complete on its own all approval procedures concerning pending applications, due to the "blocking minority" held by the Group of Five countries.

7.1284 At any rate, the European Communities does not explain the basis for its view that the Group of Five countries and the Commission needed to treat their common plan as *de facto* binding. We can see that the question of whether or not the Group of Five countries and the Commission were following their common plan as binding might possibly have an impact on the stability and "lifespan" of the general moratorium on approvals. But we do not consider that, in the case before us, the question of whether the plan at issue was viewed as binding determines whether or not the general moratorium constitutes a measure. We perceive no meaningful difference between a general moratorium on approvals that is applied by the relevant EC entities "voluntarily" and one that is applied pursuant to an enforceable agreement. In neither case, final approvals are granted while the moratorium is being applied. In view of this equivalence of effects, we see no force in the argument that a "binding" moratorium on approvals constitutes a measure for WTO purposes, but that a "voluntary" moratorium on approvals does not. Indeed, were we to accept this argument, Members could evade WTO disciplines governing the application of a moratorium on approvals by applying a "voluntary" rather than a "binding" moratorium.

7.1285 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence submitted by the United States and the European Communities, the Panel concludes that the European Communities applied a general *de facto* moratorium on the approval of biotech products between June 1999 and August 2003.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence submitted by Canada and the European Communities, the Panel concludes that the European Communities applied a general *de facto* moratorium on the approval of biotech products between June 1999 and August 2003.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that the European Communities applied a general *de facto* moratorium on the approval of biotech products between June 1999 and August 2003.

3. Whether the Panel may and should make findings on the WTO-consistency of the general *de facto* moratorium on approvals

7.1286 According to the **European Communities**, even if the Panel finds, as it has, that a general *de facto* moratorium on approvals was being applied by the European Communities between June 1999 and August 2003, this would not automatically mean that the Panel may, or should, make findings on the WTO-consistency of the general moratorium. More particularly, the European Communities argues that the Panel may only make findings on the WTO-consistency of the general moratorium if the moratorium is a challengeable measure under the *WTO Agreement*. And even if that is the case, the Panel should not, in the European Communities' view, make findings on the WTO-consistency of the general moratorium if the moratorium ceased to exist after the date of establishment of the Panel. The European Communities considers that in such circumstances the issue of the WTO-consistency of the general moratorium would be moot and the Panel should refrain from making a ruling on the moratorium.

7.1287 The **Panel** considers that the issues raised by the European Communities are pertinent, and it will therefore examine below (i) whether the moratorium on approvals is a challengeable measure, and if so, (ii) whether the Panel should decline to make findings on the WTO-consistency of the moratorium on approvals if subsequent to the establishment of the Panel the moratorium ceased to exist.

(a) Whether the moratorium on approvals is a challengeable measure

7.1288 The European Communities has argued that the general *de facto* moratorium on approvals cannot be challenged under the *WTO Agreement* because, in its view, the Complaining Parties are not challenging a measure, but a practice – a repeated pattern of suspending consideration of individual applications. The Panel has already dealt with this argument, finding that the general d*e facto* moratorium was the result, not of a mere practice by the Group of Five countries and the Commission, but of separate decisions by these same EC entities, which were intended to be generally applicable.

7.1289 Nevertheless, since the issue was put before us by the European Communities, it is still useful to consider whether the moratorium on approvals, when understood as a measure rather than as a practice, is a challengeable measure. By "challengeable measure" we mean a measure which can be the subject of WTO dispute settlement proceedings. In *US – Carbon Steel*, the Appellate Body had this to say about the measures which may be challenged before a WTO panel:

> "In principle, any act or omission attributable to a WTO Member can be a measure of that Member for purposes of dispute settlement proceedings. The acts or omissions that are so attributable are, in the usual case, the acts or omissions of the organs of the state, including those of the executive branch."[1182]

[1182] Appellate Body Report, *US – Carbon Steel*, para. 81 (footnotes omitted).

7.1290 What sets the moratorium on approvals apart from most other measures challenged before WTO panels are two elements: (i) it is a *de facto* measure, *i.e.*, a measure which was not adopted through a formal EC rule- or decision-making process, and (ii) it is the result of the application of separate decisions by the Group of Five countries and the Commission.

7.1291 We first consider the circumstance that the moratorium is a d*e facto* measure. We note in this regard the Appellate Body's reference to "*any* act or omission attributable to a WTO Member" (emphasis added). In our view, the broad phrase "any act or omission" can encompass both *de jure* measures and *de facto* measures. Reinforcing this view is the circumstance that if *de facto* measures could not be challenged, Members could circumvent their WTO disciplines. For they could then achieve through *de facto* measures what they would not be allowed to achieve through *de jure* measures.

7.1292 As noted, the other particularity of the moratorium is the fact that the moratorium is the result of the application of separate decisions by the Group of Five countries and the Commission. In other words, the moratorium is a measure which is the result of other measures (decisions) applied separately by the Group of Five countries and the Commission. The *WTO Agreement* nowhere says that a measure which is the result of several separate measures is not a challengeable measure. Moreover, the GATT panel in *Japan – Semi-Conductors* found that an inconsistency with Article XI:1 of the GATT 1994 could result from a combination of separate measures:

> "All these factors led the Panel to conclude that an administrative structure had been created by the Government of Japan which operated to exert maximum possible pressure on the private sector to cease exporting at prices below company-specific costs. This was exercised through such measures as repeated direct requests by MITI, *combined with* the statutory requirement for exporters to submit information on export prices, the systematic monitoring of company and product-specific costs and export prices and the institution of the supply and demand forecasts mechanism and its utilization in a manner to directly influence the behaviour of private companies. [...] The Panel considered that the *complex of measures* exhibited the rationale as well as the essential elements of a formal system of export control. [...] The Panel concluded that the *complex of measures* constituted a coherent system restricting the sale for export of monitored semi-conductors at prices below company-specific costs to markets other that the United States, inconsistent with Article XI:1."[1183]

7.1293 We therefore consider that the mere fact that the moratorium is the result of the application of separate decisions by the Group of Five countries and the Commission does not prevent it from being a challengeable measure.

7.1294 We recall, however, the Appellate Body's statement in *US – Carbon Steel* that a measure of a Member can only be challenged if the measure is attributable to that Member. Thus, for the general *de facto* moratorium on approvals to qualify as a challengeable EC measure, it must be attributable to the European Communities. We note that both the Commission and the individual member States which are part of the Group of Five from the perspective of public international law are organs of the European Communities. Accordingly, there can be no doubt that the general moratorium, which is the result of the application of separate decisions by these different EC organs, is attributable to the European Communities.

[1183] GATT Panel Report, *Japan – Semi-Conductors*, para. 117 (emphasis added).

7.1295 In the light of the foregoing considerations, we conclude that the general *de facto* moratorium on approvals constitutes a challengeable EC measure.

(b) Whether the Panel should decline to make findings on the WTO-consistency of the moratorium on approvals if subsequent to the establishment of the Panel the moratorium ceased to exist

7.1296 We now turn to examine the European Communities' further argument that even if the Panel may in principle make findings on the WTO-consistency of the moratorium on approvals because it is a challengeable measure, the Panel nevertheless should not do so if subsequent to the establishment of the Panel the moratorium ceased to exist.

7.1297 Specifically, the **European Communities** argues that if the Panel were to find that as of August 2003 the European Communities applied a general *de facto* moratorium on final approvals, the Panel would need to go on to determine whether that measure subsequently ceased to exist. The European Communities submits that if a measure is no longer in existence, any issues which may have been raised in relation to that measure are moot and a panel should not rule on that measure.[1184]

7.1298 The **United States** argues that the concept of mootness is not relevant to the claims related to the general moratorium on approvals. The measure the United States is requesting the Panel to examine and make findings on is the general moratorium as it existed in August 2003. Any issues relating to whether or not steps taken by the European Communities after August 2003 have brought the European Communities into compliance with its WTO obligations are not before the Panel. In any event, according to the United States, this is not a case in which the measure at issue has terminated. The United States does not agree that two token product approvals – the approvals concerning Bt-11 sweet maize (food) and NK603 maize[1185] – suffice to signal that the European Communities has begun to process other outstanding applications without undue delays. The United States points out that all other applications caught up in the moratorium remain unapproved. The United States submits that biotech product approvals remain a controversial political issue in the European Communities, and the recent expansion of the European Communities from 15 to 25 member States has not simplified the situation. In addition, a number of member States believe that yet additional legislation must be adopted before the granting of new biotech product approvals. And the European Communities has yet to approve a single biotech product for planting in the European Communities. Accordingly, the possibility is substantial that the European Communities – once freed from the pressure of this WTO proceeding – would halt all further approvals. In the view of the United States, it is thus of great import that the Panel issue a finding that the politically-based moratorium is not consistent with WTO rules.

7.1299 Like the United States, **Canada** argues that the question of mootness is not relevant to the claims related to the moratorium, as the moratorium has not ceased to exist. Despite recent Commission Decisions authorizing the placing on the market of two products, Bt-11 sweet maize (food) and NK603 maize, the evidence suggests that the approval of biotech products continues to be delayed and thwarted by the European Communities.[1186] In relation to the two products that have been authorized, the Commission has been forced to adopt decisions authorizing these products after

[1184] The European Communities has also argued that the concept of mootness is not relevant to the claims relating to the general moratorium. However, the European Communities said so under the hypothesis that the Panel finds that a general moratorium never existed.

[1185] We recall that the Commission in 2004 approved the application concerning NK603 maize under Directive 2001/18 and the application concerning NK603 maize (food) under Regulation 258/97.

[1186] Canada's third written submission, para. 196.

failures by both the Regulatory Committee and the Council to take decisions. Canada submits that as long as approvals are invariably granted only after products have gone through every conceivable procedural hoop, the moratorium must be considered to remain in effect. In any event, the continued intransigence on the part of member States, coupled with the complicated political and legal relationship between the member States and the Commission, reflect a very real possibility that, even if it could be said that the moratorium has been lifted, the moratorium could be reinstituted in the future.

7.1300 **Argentina** argues that the approval of Bt-11 sweet maize (food) did not imply the end of the *de facto* general moratorium on approvals. Argentina notes that there are in any event no assurances that the moratorium has ended. Argentina points out in this regard that the approval of Bt-11 sweet maize (food) may have occurred solely because of the establishment of this Panel.

7.1301 The **Panel** notes that the question it is mandated to answer is whether on the date of its establishment, that is to say, on 29 August 2003, the European Communities applied a general *de facto* moratorium on approvals. We have answered this question in the affirmative. The European Communities argues, however, that we should not review the WTO-consistency of that measure on the grounds that the measure has since ceased to exist.

7.1302 At the outset, we examine whether the record of this case indicates that the issue raised by the European Communities – whether the measure at issue, *i.e.*, the general *de facto* moratorium on approvals, ceased to exist after 29 August 2003 – is not merely hypothetical. If the case record indicates that this issue is not merely hypothetical, we think further examination of the EC argument would be warranted.

7.1303 The record shows that the applications concerning Bt-11 sweet maize (food) and NK603 maize (food) were definitively approved by the Commission under Regulation 258/97. Thus, it is not in doubt that after the Panel had been established at least two biotech products – Bt-11 sweet maize (food) and NK603 maize (food) – were definitively approved and hence could be placed on the EC market for specified uses.

7.1304 We note that the moratorium on approvals as alleged by the Complaining Parties was one under which applications were not allowed to move to a positive final approval decision. The Complaining Parties have also alleged that the moratorium applied *across-the-board*, *i.e.*, that it was applicable to *any and all* applications pending between October 1998 and August 2003. We further note that the Complaining Parties referred to the *absence of a single* approval between October 1998 and December 2003 as critical evidentiary support for their claim that the European Communities applied a general moratorium on approvals. In our earlier findings, we determined that the record supported these assertions by the Complaining Parties.[1187]

7.1305 In view of the foregoing, we consider that there is indeed an issue whether the general *de facto* moratorium on approvals which we found to have existed in August 2003 ceased to exist as a measure generally applicable to all biotech products with pending applications when the definitive approvals for Bt-11 sweet maize (food) and NK603 maize (food) were granted in 2004. Indeed, the applications concerning Bt-11 sweet maize (food) and NK603 maize (food) were applications which *were* allowed to move to a positive final approval decision. Therefore, a more detailed examination of the EC argument is, in our view, warranted.

[1187] *See supra*, para. 7.1285.

7.1306 We begin our examination by noting the following statement by the panel in *India – Autos*:

> "A WTO Panel is generally competent to consider measures in existence at the time of its establishment. This power is not necessarily adversely affected simply because a measure under review may have been subsequently removed or rendered less effective."[1188]

7.1307 A similar statement was made by a previous panel in *Indonesia – Autos*:

> "[I]n previous GATT/WTO cases, where a measure included in the terms of reference was otherwise terminated or amended after the commencement of the panel proceedings, panels have nevertheless made findings in respect of such a measure."[1189]

7.1308 It follows from these statements that in principle we have the authority to make findings on a measure within our terms of reference even if that measure subsequently ceased to exist. We note that the European Communities does not appear to contest this.[1190]

7.1309 The question which remains to be examined, therefore, is whether we should make use of our authority to review the WTO-consistency of the general moratorium on approvals as it existed in August 2003, if the general moratorium later ceased to exist. We consider that in determining whether to make findings on a measure no longer in existence on the date of establishment of a panel, panels should notably take account of the object and purpose of the dispute settlement system.[1191] Pursuant to Article 3.7 of the DSU, "[t]he aim of the dispute settlement mechanism is to secure a positive solution to a dispute".

7.1310 The Complaining Parties attach considerable importance to our offering findings on the moratorium as it existed in August 2003, even if it later ceased to exist. They note that most of the applications pending as of August 2003 are still awaiting final approval decisions. The United States and Canada also contend that there is a very real possibility that a general moratorium could subsequently be reintroduced. We consider these to be valid arguments. As numerous applications which were pending in August 2003 have not yet reached the stage of final decision-making, the approvals which were granted in 2004 do not fully address the concerns of the Complaining Parties.[1192] Moreover, the three approvals which were granted in 2004 were possible only because the Commission decided to make full use of the relevant EC approval procedures to complete the

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[1188] Panel Report, *India – Autos*, para. 7.26.

[1189] Panel Report, *Indonesia – Autos*, para. 14.9.

[1190] The European Communities states that the Panel "should" not rule on such a measure, not that it does not have the authority, in principle, to rule on such a measure. EC second written submission, para. 151; EC reply to Panel question No. 7, paras. 26, 28 and 29.

[1191] This approach is consistent with that of the panel in *Chile – Price Band System*. The panel in that case stated that "[a]lthough we do not consider that the termination of a measure before the commencement of panel proceedings deprives a panel of the authority to make findings in respect of that measure, we would only make findings regarding the provisional safeguard measures in this case if we were to consider this necessary in order to 'secure a positive solution' to the dispute." Panel Report, *Chile – Price Band System*, para. 7.115.

[1192] We note, as an additional matter, that the European Communities does not argue that the relevant applications were approved in 2004 in order to address the concerns expressed by the Complaining Parties and, hence, to resolve the dispute in relation to the treatment of the relevant applications. The European Communities argues that the approvals which were granted in 2004 are simply the consequence of these applications having reached the final decision-making stage after being assessed at member State and Community level.

approval process. In all three cases, the relevant Regulatory Committee and the Council failed to achieve the required qualified majority. Also, the votes in all three cases were held after the European Communities adopted new EC rules on labelling and traceability, and in some cases even after these rules had entered into force. Notwithstanding this, some Group of Five countries continued to vote against approvals or abstained. Moreover, the Complaining Parties submit that certain member States stated that there needed to be new rules concerning coexistence and environmental liability before they could approve new applications.[1193]

7.1311 In addition to noting the continuing existence of opposition to approvals amongst member States, we also recall the informal, *de facto* nature of the general moratorium on approvals, which means that it can be re-imposed just as soon as it can be ended. In these circumstances, we agree that that even if the general moratorium ceased to exist after August 2003, if we were to find that the European Communities acted inconsistently with its WTO obligations by applying a general moratorium in August 2003, this could help prevent a WTO-inconsistent general moratorium from being reintroduced and, in this way, secure a positive solution to this dispute.[1194]

7.1312 In the light of the above, we do not agree with the European Communities that we should refrain from making findings on the general *de facto* moratorium on approvals as it existed in August 2003 in the event that it later ceased to exist. For the reasons mentioned, we find it appropriate to offer findings on the WTO-consistency of the general moratorium in effect in August 2003 irrespective of whether that measure subsequently ceased to exist.

7.1313 We now turn to consider the issue raised by the European Communities from the perspective of Article 19.1 of the DSU which states that "where a panel [...] concludes that a measure is inconsistent with a covered agreement, it shall recommend that the Member concerned bring the measure into conformity with that agreement". The United States argues that when a panel finds that a measure is WTO-inconsistent, it must recommend pursuant to Article 19.1 that the responding party bring that measure into conformity with its WTO obligations, regardless of whether the measure has ceased to exist after the panel was established. It should be noted in this connection that in *US – Certain EC Products*, the Appellate Body has stated that "the Panel erred in recommending that the DSB request the United States to bring into conformity a measure which the Panel has found no longer exists".[1195] The United States emphasises that the measure in that case had been terminated shortly before the panel was established. This is correct. But the Appellate Body nowhere suggested that the situation could be different in a case where a measure ceased to exist in the course of panel proceedings.[1196]

7.1314 We further note the panel report on *Canada – Wheat Exports and Grain Imports* wherein the panel refrained from making a recommendation in relation to a WTO-inconsistent measure which had

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[1193] *See supra*, para. 7.530. *See also*, Exhibit EC-69/At. 125.

[1194] We note that if we were not to make findings on the general moratorium, there would effectively be a possibility of shielding it from scrutiny by a panel because this type of *de facto* measure could be ended shortly before or during panel proceedings and promptly re-imposed thereafter.

[1195] Appellate Body Report, *US – Certain EC Products*, para. 81. The Appellate Body in *US – Upland Cotton*, referring to its report on *US – Certain EC Products*, stated that "the fact that a measure has expired may affect what recommendation a panel may make". Appellate Body Report, *US – Upland Cotton*, para. 272.

[1196] The Appellate Body stated that "[a]s we have upheld the Panel's finding that [...] the measure at issue in this dispute [...] *is* no longer in existence, we do not make any recommendation to the DSB pursuant to Article 19.1 of the DSU. Appellate Body Report, *US – Certain EC Products*, para. 129 (emphasis added). In our view, if the Appellate Body had intended to distinguish between measures which ceased to exist before a panel was established and measures which ceased to exist in the course of panel proceedings, it would have used a phrase like "the measure at issue in this dispute was no longer in existence when the panel was established".

been amended in the course of the panel proceedings.[1197] Similarly, in *Dominican Republic – Import and Sale of Cigarettes*, the panel did not find it "appropriate" to make a recommendation in relation to a WTO-inconsistent measure concerning the determination of the tax base for cigarettes because that measure was "no longer in force" as a result of amendments which were made after the panel was established.[1198] While these cases concerned amendments, we think the same approach is logically applicable in a situation where a measure ceased to exist in the course of panel proceedings.[1199] Indeed, the panel in *EC – Commercial Vessels* stated that its recommendation to the European Communities that it bring the relevant measures into conformity with its obligations under the DSU did not apply to certain EC member State aid schemes which had expired soon after the panel had been established. However, the panel's recommendation did cover these expired schemes to the extent they continued to be operational.[1200]

7.1315 Finally, we note that the Appellate Body in *Dominican Republic – Import and Sale of Cigarettes* found that a tax stamp requirement maintained by the Dominican Republic was WTO-inconsistent. It also observed that the parties were in agreement that the tax stamp regime as a whole had been altered by a new decree which came into force after the panel had issued its final report to the parties. The Appellate Body then went on to recommend that the tax stamp requirement be brought into conformity with the GATT 1994 "if, and to the extent that, the [...] modifications to the tax stamp regime have not already done so".[1201]

7.1316 The foregoing WTO jurisprudence supports the inference that panels are to avoid making recommendations which would apply to measures that are no longer in existence or have been amended. Therefore, should we find that the general *de facto* moratorium on approvals was WTO-inconsistent as of August 2003, in formulating any recommendations, we would take appropriate account of the issue raised by the European Communities – that the general moratorium which was in existence in August 2003 might subsequently have ceased to exist.

7.1317 We consider that, in the specific circumstances of this case, we could avoid making recommendations which would apply to measures that are no longer in existence by qualifying any recommendations that we would make in relation to the general moratorium. We recall in this regard that the Appellate Body in *Dominican Republic – Import and Sale of Cigarettes* qualified its recommendation by recommending that the Dominican Republic bring the tax stamp requirement into conformity with the GATT 1994 "if, and to the extent that, the [...] modifications to the tax stamp regime have not already done so".[1202] In the present case, if we were to find that the European Communities breached its WTO obligations by applying a general moratorium, we would similarly recommend that the European Communities bring the general moratorium into conformity with the relevant WTO obligation(s), if, and to the extent that, that measure has not already ceased to exist.[1203]

[1197] Panel Report, *Canada – Wheat Exports and Grain Imports*, paras. 6.258-6.259, 7.3 and 7.6.

[1198] Panel Report, *Dominican Republic – Import and Sale of Cigarettes*, para. 7.363.

[1199] Canada appears to agree with this view. Canada's third written submission, para. 195.

[1200] Panel Report, *EC – Commercial Vessels*, para. 8.4.

[1201] Appellate Body Report, *Dominican Republic – Import and Sale of Cigarettes*, para. 129.

[1202] Appellate Body Report, *Dominican Republic – Import and Sale of Cigarettes*, para. 129. We recall that the panel in *EC – Commercial Vessels* also offered a qualified recommendation, stating that its recommendation that the European Communities bring certain EC member State aid schemes into conformity with its obligations under the DSU did not apply to aid schemes which had expired after the establishment of the panel, except to the extent that those expired schemes continued to be operational. Panel Report, *EC – Commercial Vessels*, para. 8.4.

[1203] We recall that the issue raised by the European Communities is whether the general moratorium which we found to have existed in August 2003 has since ceased to exist, and not whether that measure, if it were found to be WTO-inconsistent, has already been brought into conformity with the *WTO Agreement.*

Accordingly, we are of the view that so long as we appropriately qualify our recommendations, there is no need to decide, in the context of the present proceedings, whether the general moratorium which we found to have existed in August 2003 subsequently ceased to exist.

7.1318 In the light of this, even if we were to agree with the European Communities that we may decide whether the general moratorium which we found to have existed in August 2003 subsequently ceased to exist, we are not convinced that it would be necessary to do so in the context of the present proceedings. We are also not convinced, in view of the findings and conclusions offered by us, that a decision on whether the general moratorium ceased to exist would be necessary to enable the DSB to make sufficiently precise recommendations to the European Communities. We consider that in the circumstances of this case a qualified recommendation would safeguard and preserve the rights and interests of all Parties and hence would be consistent with the aim of securing a positive solution to the dispute referred to the Panel.[1204] We also note in this regard that in the interim review phase of these proceedings, Canada and Argentina stated that the Panel should not determine whether the general moratorium which we found to have existed in August 2003 continued to exist after the date of establishment of the Panel. The United States considers that the Panel is not charged, in these proceedings, with determining whether the general moratorium continues to exist.

7.1319 Thus, on the basis of all of the above considerations, we decline the European Communities' request to decide, in the context of the present proceedings, whether the general moratorium on approvals which was in effect in August 2003 subsequently ceased to exist. As a result, we undertake no further examination of this issue.

4. Claims of inconsistency raised by the Complaining Parties

7.1320 The Complaining Parties have each presented a series of claims of inconsistency in relation to the European Communities' general *de facto* moratorium on final approvals.

7.1321 The **United States** claims that the general *de facto* moratorium on final approvals is inconsistent with, or has given rise to inconsistencies with, the following provisions of the *SPS Agreement*:[1205]

(a) Annex C(1)(a) and, consequently, Article 8;

(b) Annex B(1) and, consequently, Article 7;

(c) Annex C(1)(b) and, consequently, Article 8;

(d) Article 5.1 and, consequently, Article 2.2; and

(e) Article 5.5 and, consequently, Article 2.3.

7.1322 **Canada** claims that the general *de facto* moratorium on final approvals is inconsistent with, or has given rise to inconsistencies with, the following provisions of the *SPS Agreement*:[1206]

Furthermore, it is worth clarifying that if there were no issue in this case whether the general moratorium on approvals applied by the European Communities in August 2003 subsequently ceased to exist, there would, in our view, be neither a need nor a sufficient justification for a qualified recommendation.

[1204] For further relevant considerations, *see supra*, paras. 6.80 *et seq*.

[1205] The claims are listed in the order in which they were developed in the first written submission of the United States.

(a) Article 5.1 and, consequently, Article 2.2;

(b) Article 5.6 and, consequently, Article 2.2;

(c) Article 5.5 and, consequently, Article 2.3;[1207]

(d) Annex C(1)(a) and, consequently, Article 8; and

(e) Annex B(1) and, consequently, Article 7.

7.1323 **Argentina** claims the general *de facto* moratorium on final approvals is inconsistent with, or has given rise to inconsistencies with, the following provisions of the *SPS Agreement*:[1208]

(a) Article 5.1 and, consequently, Article 2.2;

(b) Article 5.5 and, consequently, Article 2.3;

(c) Article 7 and Annex B(1); and

(d) Article 10.1.

7.1324 The **European Communities** argues that none of the claims presented by the three Complaining Parties are founded, and that it has not acted inconsistently with any of the provisions of the *SPS Agreement* which are being invoked by the Complaining Parties.

7.1325 Since it is the European Communities' view that all of the Complaining Parties' claims should be dismissed in their entirety, it is clear that the **Panel** needs to assess the merits of those claims. We will first examine the Complaining Parties' substantive claims under Articles 5 and 2 of the *SPS Agreement*, and, if appropriate, will go on to examine the transparency claim under Annex B of the *SPS Agreement*, the procedural claims under Annex C of the *SPS Agreement* and Argentina's claim that it was denied special and differential treatment contrary to the provisions of Article 10 of the *SPS Agreement*.

5. Consistency of the general *de facto* moratorium on approvals with Article 5.1 of the *SPS Agreement*

7.1326 All three Complaining Parties claim that by applying a general *de facto* moratorium on approvals, the European Communities has acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement*.

7.1327 Article 5.1 of the *SPS Agreement* provides:

> "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations."

[1206] The claims are listed in the order in which they were developed in the first written submission of Canada.

[1207] Canada's claim under Article 5.5 is put forth as an alternative to its claim under Article 5.6.

[1208] The claims are listed in the order in which they were developed in the first written submission of Argentina.

7.1328 The **Complaining Parties** submit that the general moratorium on approvals constitutes a "sanitary or phytosanitary measure" (hereafter "SPS measure") because it is applied, in their view, to protect against certain of the risks identified in Annex A of the *SPS Agreement*. They further allege that the European Communities has not put forth a risk assessment in support of the general moratorium and that the general moratorium is, therefore, an SPS measure which is not "based on" a risk assessment as required under Article 5.1.

7.1329 The **European Communities** argues that certain provisions of the *SPS Agreement* relate to the development of SPS measures while others relate to the application of SPS measures.[1209] According to the European Communities, Article 5.1 contains obligations relating to the development of SPS measures, not their application. SPS measures as defined in Annex A(1) of the *SPS Agreement* presuppose the existence of an act. The European Communities submits that the Complaining Parties' assertions about a moratorium are in reality complaints about delay in the completion of approval procedure. Delay of this kind cannot constitute an SPS measure within the meaning of Annex A(1). Delay is a failure to act in a timely manner. A failure to act in a timely manner can be reviewed under the procedural obligations set out in Article 8 and Annex C(1) of the *SPS Agreement* as an issue of the application of an SPS measure (in this case, the EC approval system).[1210]

7.1330 The European Communities submits that the Complaining Parties describe as an SPS measure the very same failure to take final decisions which they challenge as the application of an SPS measure under Article 8 and Annex C(1). Yet as a matter of logic, it is clear that alleged behaviour cannot at the same time constitute an SPS measure and the application of another SPS measure. The European Communities deduces from these considerations that since, in its view, the Complaining Parties are not complaining about an SPS measure, but its application, and since Article 5.1 does not contain obligations relating to the application of an SPS measure, the alleged general moratorium on approvals is not subject to Article 5.1.

7.1331 The **Panel** notes that, by its clear terms, Article 5.1 applies to SPS measures. Accordingly, for a particular measure to be subject to Article 5.1 it must be an SPS measure. The European Communities contests that the general moratorium on approvals constitutes an SPS measure within the meaning of Article 5.1. It is therefore necessary to examine this issue in detail.

(a) "Sanitary or phytosanitary measure"

7.1332 Article 1 of the *SPS Agreement* states that for the purposes of the *SPS Agreement*, "the definitions provided in Annex A shall apply". Annex A(1) of the *SPS Agreement* contains a definition of the term "sanitary or phytosanitary measure". The definition provided reads as follows:

> *Sanitary or phytosanitary measure* - Any measure applied:
>
> (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

[1209] The European Communities bases this view on Article 1.1 of the *SPS Agreement*, the second sentence of which provides that SPS measures "shall be *developed and applied* in accordance with the provisions of this Agreement" (emphasis added).

[1210] For the text of Article 8 and Annex C(1), *see infra*, sections VII.C.11 and VII.C.12.

(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;

(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety."

7.1333 It is clear from the above definition that all measures are not SPS measures. In other words, not every measure that qualifies as a measure within the meaning of the DSU constitutes, *ipso facto*, an SPS measure.

7.1334 Whether a particular DSU measure constitutes, at the same time, an SPS measure is to be determined, according to the above definition, by reference to such criteria as the objective of the measure, its form and its nature. Regarding the objective of SPS measures, subparagraphs (a) through (d) indicate that SPS measures must "be applied" to protect against certain enumerated risks. Regarding the form of SPS measures, the second paragraph of the definition provides that SPS measures include "all relevant laws, decrees [and] regulations". This enumeration suggests that the *SPS Agreement* does not prescribe a particular legal form and that SPS measures may in principle take many different legal forms. Finally, in relation to the nature of SPS measures, the second paragraph stipulates that SPS measures include "requirements and procedures". The second paragraph then goes on to mention, by way of example, a number of relevant substantive requirements (prescribed end product criteria, prescribed quarantine treatments, certain packaging and labelling requirements, etc.) and procedures (testing procedures, inspection procedures, certification procedures, approval procedures, etc.). We note that the term "requirements" is broad in scope. For instance, both an authorization to market a particular product and a ban on the marketing of a particular product may be considered "requirements", in that one is effectively a requirement to permit the marketing of a product and the other a requirement to ban the marketing of a product.

7.1335 Still in relation to the reference in the second paragraph of Annex A(1) to "requirements and procedures", we note that no reference is made to the "application" of "requirements and procedures".[1211] This omission suggests that whereas requirements and procedures as such may constitute SPS measures, the application of such requirements and procedures would not, itself, meet the definition of an SPS measure. The provisions of the *SPS Agreement* support the view that the omission of a reference to "application" is deliberate, for there are several provisions which establish

[1211] We agree with the European Communities that Article 1.1 of the *SPS Agreement*, which states that SPS measures shall be "developed and applied" in accordance with the provisions of the *SPS Agreement*, confirms that the distinction between SPS measures as such and the application of SPS measures is a relevant one for the purposes of the *SPS Agreement*.

obligations specifically with regard to the "application" of SPS measures. For instance, Article 2.3, second sentence, states that SPS measures "shall not be applied in a manner which constitute a disguised restriction on international trade". Similarly, Article 10.1 states in relevant part that "[i]n the preparation and application of [SPS] measures, Members shall take account of the special needs of developing country Members". Finally, we note that Article 8 draws a distinction between, on the one hand, the "operation" of procedures and, on the other hand, the "procedures", which, themselves, are defined in Annex A(1) as SPS measures.[1212]

7.1336 It should be added in this context that the term "requirements" as it appears in the second paragraph of Annex A(1) is unqualified and thus is applicable both to requirements which are generally applicable and to requirements which have been imposed on specific products.[1213] In our view, the application of a generally applicable SPS "requirement" (e.g., a pre-marketing approval requirement for biotech products) to a specific product may result in a different, product-specific SPS "requirement" (e.g., a ban on the marketing of a specific biotech product). In other words, there may be cases where the application of an SPS "requirement" and, hence, of an SPS measure, may give rise to a new SPS requirement and, hence, a new SPS measure. Applying these considerations to Article 5.1, it could be argued that a generally applicable SPS requirement as set out, *e.g.*, in a law and a product-specific decision based on that requirement might both constitute SPS measures which must be based on a risk assessment.

7.1337 Before proceeding further, a final point should be made. It is important to keep in mind that Annex A(1) is intended to provide a general definition of the term "SPS measure". This general definition must not be applied in mechanistic fashion. In particular, we note that the mere fact that a measure within the meaning of the DSU meets the definition of an "SPS measure" set out in Annex A(1) does not mean that it is, *ipso facto*, subject to every provision of the *SPS Agreement* which applies to "SPS measures". A good illustration of this point is afforded by the chapeau of Annex C(1)(a) of the *SPS Agreement*, which states that "Members shall ensure, with respect to any procedure to check and ensure the fulfilment of [SPS] *measures*, that such procedures are [...] completed without undue delay" (emphasis added). The definition of "SPS measures" given in Annex A says that "SPS measures" include "procedures". Clearly, however, Annex C cannot be read as meaning that "Members shall ensure, with respect to any procedure to check and ensure the fulfilment of [SPS] *procedures*, that such procedures are [...] completed without undue delay". Rather, the term "SPS measures" in Annex C(1)(a) must be interpreted as meaning substantive "SPS requirements".[1214] It is clear from this example that in interpreting the term "SPS measure(s)", in addition to the Annex A(1) definition, account should also be taken of the specific context within which that term appears.

[1212] Article 8 provides:

> Members shall observe the provisions of Annex C in the *operation* of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their *procedures* are not inconsistent with the provisions of this Agreement (emphasis added).

[1213] We note in this respect that the footnote to Annex B(1) defines "[SPS] regulations" as "[SPS] measures [...] which are applicable generally". It follows, *a contrario*, that there can be SPS measures which are not applicable generally.

[1214] This view draws support from a parallel provision in the *TBT Agreement*. Annex 1(3) of the *TBT Agreement* defines conformity assessment procedures as "[a]ny procedure used, directly or indirectly, to determinate that *requirements* in technical regulations […] are fulfilled" (emphasis added).

(b) Nature of the general *de facto* moratorium on approvals

7.1338 For the purposes of establishing whether the general *de facto* moratorium on approvals constitutes an "SPS measure" within the meaning of Annex A(1) and Article 5.1, it is key, in our view, to determine its nature. More particularly, consistent with the language used in Annex A(1), it must be determined whether the general moratorium is a substantive SPS "requirement", a "procedure" or a measure of a different nature.

(i) Was the decision to apply a general moratorium on approvals a decision to reject all applications or did it predetermine such rejections?

7.1339 To determine the nature of the general moratorium on approvals, it is well to recall our earlier findings. We found, *inter alia*:

(a) that the Group of Five countries decided to use their powers in the approval process so as to prevent any and all new applications from being finally approved, until new EC rules on labelling and traceability were adopted, and

(b) that the Commission responded by not making full use of the relevant procedures to complete the approval process, and that in so doing, it knowingly entered into effective co-operation with the Group of Five countries, and

(c) that, consequently, the Group of Five countries and the Commission followed an inexplicit common "plan or course of action" which consisted in preventing the final approval of applications pending the adoption of new EC rules on labelling and traceability.

7.1340 Based on these findings, and the relevant supporting arguments and evidence, we are of the view that the decisions by the Group of Five countries and the Commission to prevent applications from reaching final approval and thus to apply a general moratorium on approvals were, in essence, decisions to delay final positive approval decisions on individual applications until certain conditions were met.[1215] Consistent with what we have done earlier in our findings, we will hereafter refer, not to decisions by the Group of Five countries and the Commission, but to a decision by the European Communities.

7.1341 In principle, it would also be correct to describe the decision to delay final approval decisions as a decision not to approve individual applications until certain conditions were met. We prefer not to use that description, though. This is because the term "decision not to approve applications" could be understood as referring to a decision to reject all applications. However, as we explain below, the decision to apply a general moratorium was not a substantive decision to reject all applications.

7.1342 By deciding to apply a general moratorium, the European Communities did not give a negative substantive reply to the question "May the biotech products with pending or future applications be marketed in the European Communities?". Rather, the reply the European Communities effectively gave to that question was that certain conditions needed to be met before it could provide positive substantive replies.[1216] In that sense, it can be said that the decision to apply a

[1215] To recall, as of August 2003, relevant conditions (new EC rules on labelling and traceability) had not been met.

[1216] We note that, in the meantime, pending and subsequent applications were subject to a provisional marketing ban. However, as we will explain in detail below, that provisional ban was a consequence, not of the

general moratorium was a procedural decision not to make final and favourable substantive decisions on applications until certain conditions were satisfied.

7.1343 Thus, the decision to apply a general moratorium on approvals did not itself constitute a substantive decision to reject all applications. For completeness, we should examine, in addition, whether the decision to apply a general moratorium on approvals predetermined negative substantive decisions on pending and future applications. The June 1999 declaration by the Group of Five countries said that the relevant member States would take steps to "suspend" new approvals, pending the adoption of EC rules on labelling and traceability. The June 1999 declaration did not imply that once the new EC rules were adopted, the Group of Five countries would seek to complete all pending and new approval procedures with a negative approval decision. We note that there are Group of Five countries which subsequently indicated that additional conditions needed to be met before new approvals could be granted.[1217] However, these additional conditions identified by some Group of Five countries did not predetermine the outcome of approval procedures any more than the conditions set out in the June 1999 declaration. At any rate, there is no evidence to suggest that the Commission's effective decision not to complete approval procedures until the adoption of new EC rules on labelling and traceability predetermined the outcome of individual approval procedures. More particularly, there is no evidence to suggest that the Commission would complete all pending and new approval procedures with a negative decision once the new EC rules were adopted. Accordingly, the decision to apply a general moratorium on approvals cannot be considered to have predetermined negative final decisions on all pending and future applications.

7.1344 Whereas it is clear from the foregoing considerations that we are of the view that the European Communities' decision to apply a general moratorium on approvals can be properly characterized as a decision to delay final positive approval decisions[1218], the Complaining Parties are of the view that this is not the most appropriate legal characterization. In the light of this, we suspend a final conclusion on this issue until after we have examined whether the Complaining Parties have offered a more appropriate legal characterization of the European Communities' decision to apply a general moratorium on approvals. The Complaining Parties have put forward two alternative legal characterizations: (i) that the European Communities' decision to apply a general moratorium on approvals was a decision to impose an effective marketing ban on all biotech products subject to approval, and (ii) that the decision in question established a new procedure or amended the existing EC approval procedure. We first these two characterizations in turn.

(ii) Did the decision to apply a general moratorium on approvals impose an effective marketing ban?

7.1345 The **United States** argues that the general moratorium is, effectively, a marketing ban that affects any and all biotech products. More particularly, the United States submits that a decision to delay completion of approval procedures for biotech products for an indefinite period of time – in this case from late 1998 up through at least August 2003 – is effectively equivalent to a decision to adopt a ban on the marketing of all biotech products subject to the EC approval procedures.

7.1346 **Canada** recalls that the European Communities' own pre-marketing approval requirement effectively imposes a ban on biotech products until they are approved. According to Canada, the

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European Communities' decision to apply a general moratorium on approvals, but of the EC pre-marketing approval requirement.

[1217] *See supra*, para. 7.530. *See also*, Exhibit EC-69/At. 125.

[1218] In order to avoid verbiage, we will hereafter be using the phrase "a decision to delay final approval decisions" rather than the longer, more complete phrase "a decision to delay final positive approval decisions".

general moratorium is a conscious decision on the part of the European Communities not to approve biotech products for an unspecified period of time. In Canada's view, the general moratorium thus effectively renders inoperative the EC approval procedures, resulting in an indefinite suspension of the placing on the market of biotech products. This indefinite suspension converts the pre-marketing approval requirement established by EC legislation into a complete, rather than conditional, marketing ban.

7.1347 **Argentina** argues that the general moratorium functions as a ban on the marketing of biotech products.

7.1348 The **European Communities** argues that the Complaining Parties are improperly characterizing the alleged general moratorium as a marketing ban. The only ban in place in the European Communities is the prohibition to market biotech products that have not undergone prior assessment in accordance with the requirements of EC law. The fact that biotech products cannot be marketed until approved is an intrinsic feature of EC legislation and, indeed, of any approval system. The WTO-consistency of the applicable EC legislation, the EC approval system and the ban on the marketing of non-approved biotech products is not an issue before the Panel as none of these measures have been identified in the Complaining Parties' requests for the establishment of a panel.

7.1349 The European Communities submits that the acts of which the Complaining Parties are complaining should be characterized as delay – they cannot, therefore, amount to a ban. The Complaining Parties' submissions blur this fundamental point, and they seem to insinuate that the EC approval procedures for biotech products are little more than a façade to prevent the marketing of biotech products. The European Communities rejects any such allegation as EC legislation and policy are not intended to prevent the marketing of biotech products.

7.1350 The **Panel** notes that, according to the Complaining Parties, the European Communities' decision to apply a general moratorium on approvals should be characterized, for the purposes of the Panel's legal analysis, as a decision to adopt an across-the-board marketing ban on biotech products requiring approval. In considering this argument, it is important to bear in mind that the decision to apply a general moratorium on approvals was made in the context of a pre-marketing approval system. Therefore, before addressing the merits of the Complaining Parties' argument, it is useful to recall the main features of the European Communities' pre-marketing approval system. EC legislation does not provide for a blanket ban on the marketing of biotech products. EC legislation provides that the marketing of biotech products is subject to approval, or authorization.[1219] In other words, EC legislation imposes a pre-marketing approval requirement. Like any pre-marketing approval system, the EC pre-marketing approval system for biotech products envisages a case-by-case assessment of the products for which marketing approval is sought. Consistent with this case-by-case approach, the European Communities conducts a risk assessment for each individual biotech product which is submitted for marketing approval.[1220]

7.1351 As a result of the EC pre-marketing approval requirement, a biotech product for which marketing approval is sought cannot be legally marketed in the European Communities until the time a final substantive decision has been made on whether or not to approve the marketing of the product. In other words, the pre-marketing approval requirement imposes a provisional ban on the marketing

[1219] Articles 6, 10, 11 and 13 and preambular paragraphs 17, 18 and 20 of Directive 90/220; Articles 4, 6, 13, 15 and 19, and preambular paragraphs 28 and 47 of Directive 2001/18; Articles 3, 4, 6 and 7 and preambular paragraph 2 of Regulation 258/97.

[1220] Articles 12 and 13 of Directive 90/220; Articles 4, 14 and 18 of Directive 2001/18; and Articles 6 and 7 of Regulation 258/97.

of a biotech product for which marketing approval is sought.[1221] The provisional ban remains in effect until a final approval decision has been made.[1222]

7.1352 While applicable EC legislation imposes some deadlines on EC entities charged with carrying out approval procedures, in our understanding, EC legislation does not provide that if approval procedures are not completed within a specified maximum time-period, the relevant application must, as a matter of law, be accepted or rejected. This means, for example, that a failure by a relevant EC entity to observe deadlines imposed on it, while possibly constituting a breach of EC legislation, will normally translate into a delay in the completion of the relevant approval procedure.[1223] Simply put, it can thus be said that in the European Communities the marketing of biotech products is subject to a provisional ban until such time as a final approval decision has been made, regardless of how long it takes to reach a final approval decision.

7.1353 It is important to note that the Complaining Parties in this case chose not to challenge the EC pre-marketing approval system as such. In other words, they chose not to challenge the fact that the European Communities maintains a pre-marketing approval requirement for biotech products. Thus, for the purposes of these proceedings, we must presume that the pre-marketing approval requirement is WTO-consistent. One of the consequences which flows from the EC pre-marketing approval requirement is the fact that the marketing of biotech products for which approval is sought is provisionally banned until such time as a final approval decision has been made. Since this is a direct and necessary consequence of the EC pre-marketing approval requirement, logic dictates that if the pre-marketing approval requirement must be presumed to be WTO-consistent, the same holds true for the provisional ban.

7.1354 With the foregoing observations in mind, we now turn to address the merits of the Complaining Parties' argument that the European Communities' decision to apply a general moratorium on approvals was effectively a decision to adopt an across-the-board marketing ban. Canada has gone furthest in developing this argument. According to Canada, the European Communities' decision to apply a general moratorium on approvals "converted" the EC pre-marketing approval requirement into a definitive marketing ban.[1224] As we understand it, the core of this argument is that as a result of its decision to apply a general moratorium on approvals, the European Communities no longer operated a pre-marketing approval system, but imposed an outright marketing ban. Canada argues that the decision to apply a general moratorium on approvals essentially rendered the EC approval procedure irrelevant, in the sense that it prevented the biotech products with outstanding applications from being approved regardless of the scientific evidence.

7.1355 As an initial matter, we recall our view that, properly understood, the decision to apply a general moratorium on final approvals was a decision to delay final approval decisions. We found that the Group of Five countries and the Commission followed a common "plan", which consisted in

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[1221] Instead of saying that the European Communities maintains a pre-marketing approval requirement, one could say with equal justification that the European Communities maintains a conditional marketing ban on biotech products, with the applicable condition being the absence of formal EC marketing approval.

[1222] We use the term "provisional ban" to reflect the fact that this is a provisional measure which is replaced by a final, or definitive, measure upon completion of the approval procedure for the biotech product in question.

[1223] We recall in this context that both at Community and at member State level applicants have the possibility of seeking judicial review of the legality of the actions/inaction by relevant EC entities.

[1224] We note that Canada does not use the term "definitive ban", but instead refers to a "complete, rather than conditional, ban". Canada's reply to Panel question No. 67. We find the term "complete ban" problematic in that it might suggest that the provisional ban effectively imposed by the pre-marketing approval requirement is something other than a complete ban.

preventing the final approval of applications pending the adoption of new EC rules on labelling and traceability. Thus, the "plan" was precisely to prevent final, or definitive, approval decisions. It is consistent with this view that between June 1999 and August 2003 no applications were rejected, and that it was not until after the adoption of the aforementioned EC rules that the Commission approved three applications. In fact, Canada itself acknowledges that the European Communities' decision to apply a general moratorium on final approvals was a "decision not to decide", or a "decision not to approve" applications, and that this type of decision is not the same as a substantive decision definitively to reject any and all applications.[1225] In the light of this, we do not consider that the European Communities' decision to apply a general moratorium on final approvals was designed to convert the pre-marketing approval requirement into a definitive marketing ban.

7.1356 The question thus becomes whether the decision to apply a general moratorium on approvals, while not designed to convert the pre-marketing approval requirement into a definitive marketing ban, nonetheless had the effect of doing so. It is therefore necessary to consider the effect of the decision to apply a general moratorium on approvals. In this regard, we recall once more that the decision we are concerned with in essence was a decision to delay final approval decisions. The decision to delay final approval decisions had the effect of extending the time-period during which non-approved biotech products were subject to the provisional marketing ban flowing from the pre-marketing approval requirement.[1226] For clarity, two observations should be made in relation to this effect. *First*, the effect in question is not an inherent effect of a decision to delay final approvals. If the decision to delay final approval decisions effectively extended the time-period during which the provisional ban was in effect for individual applications, this was because that decision was made in the context of the EC pre-marketing approval system. Had the European Communities opted for a system under which biotech products could be provisionally marketed until a final approval decision was made, a decision to delay final approvals would not have had the effect of extending a provisional marketing ban, but of extending a provisional marketing authorization. *Secondly*, the effect in question is an indirect one. The direct effect of the decision to delay final approval decisions was to delay the completion of individual approval procedures. Under the EC pre-marketing approval system, the marketing of biotech products is banned until it has been approved. Hence, if a decision is made to delay final approvals, this indirectly has an effect, via the principle of "banned until approved", on how long the marketing of the relevant biotech products is provisionally banned.

7.1357 It is clear from the preceding paragraph that the decision to delay final approval decisions and the decision provisionally to ban biotech products are separate and distinct measures. It is also clear that the decision to delay final approval decisions did not impose a new ban. The decision to delay final approval decisions merely had the effect of extending the duration of the provisional ban on the marketing of all non-approved biotech products. That ban was already there, as a consequence of the pre-marketing approval requirement. The provisional marketing ban did not expire prior to the European Communities' decision to delay final approval decisions, and that decision consequently cannot be said to have re-imposed it.

7.1358 It follows from the foregoing considerations that the decision to delay final approval decisions did not have the effect of converting the pre-marketing approval requirement into a definitive

[1225] *See*, *e.g.*, Canada's reply to Panel question No. 172.

[1226] We recall that under the European Communities' general moratorium on final approvals, applications were allowed to make some progress in the approval process. Thus, for all those applications which were not affected by the decision to delay final approvals, there was no effective extension of the provisional marketing ban. In contrast, for all applications which as of August 2003 had been affected by the decision to delay final approvals, there had been an effective extension of the provisional marketing ban, but its duration varied from application to application.

marketing ban in the sense of imposing a new ban. But the decision in question had an effect on an already existing ban, the provisional marketing ban flowing from the pre-marketing approval requirement. Accordingly, we need to examine whether, through its effect on the provisional marketing ban, the European Communities' decision to delay final approval decisions converted the EC pre-marketing approval requirement into a definitive marketing ban. More specifically, we need to examine whether the decision to delay final approval decisions effectively converted the pre-marketing approval requirement into an instrument with the same effect as a definitive marketing ban.

7.1359 We note in this regard that if the provisional marketing ban effectively imposed by the EC pre-marketing approval requirement is applied for three years, the practical effect of this is much the same as that of a definitive marketing ban imposed for three years. In either case, the producer seeking to market the relevant biotech product cannot lawfully do so for a three-year period.[1227] Similarly, if a provisional ban is in effect indefinitely, practically speaking, this is little different from a definitive ban imposed for an indefinite period of time.[1228] Thus, the EC pre-marketing approval requirement inherently produces very similar effects as a definitive marketing ban. The European Communities' decision to delay final approval decisions had an effect on the time-period during which the provisional marketing ban was applicable. But it did not lead to the EC pre-marketing approval requirement producing a different kind of effects. Consequently, it cannot be said that the European Communities' decision to delay final approval decisions "converted" the EC pre-marketing approval requirement into an instrument with the same effect as a definitive marketing ban.

7.1360 We accept that the European Communities' decision to delay final approval decisions for an unspecified period of time had the indirect effect of extending the provisional marketing ban for an unspecified period of time. However, as we have stated, the source of the provisional marketing ban, including of the effectively extended ban, is not the decision to delay, but the EC pre-marketing approval requirement. Or to put it differently, what prevents applicants from marketing their biotech product at a given point in time is the European Communities' substantive decision to ban biotech products until they have been approved. If the Complaining Parties had been of the view that the effective extension of the provisional marketing ban in some instances rendered the imposition of that ban inconsistent with Article 5.1, it was open to them to challenge the imposition of that ban (*i.e.*, the pre-marketing approval requirement as the source of the provisional marketing ban). The Complaining Parties chose not to do so in this case.

7.1361 Instead, the Complaining Parties decided to challenge the European Communities' decision to delay final approval decisions. The fact that this procedural decision had an impact on how long the provisional marketing ban resulting from the EC pre-marketing approval requirement was in effect for each application does not turn that decision into a substantive decision provisionally to ban biotech products. A procedural decision to delay final approval decisions does not cease to be procedural merely because it has a substantive impact. Indeed, procedural decisions virtually always have some substantive impact.

7.1362 Within this context, we need to address another argument put forward by Canada. According to Canada, a decision to delay final approval decisions, if it gives rise, as in the present case, to

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[1227] We note that while in the case of the provisional marketing ban, the ultimate approval decision could be positive or negative, in the case of the three-year definitive marketing ban, the relevant product could be lawfully marketed upon expiry of the three-year period, unless the ban was re-imposed.

[1228] We note that an indefinite definitive marketing ban, on the one hand, and an indefinite provisional marketing ban, on the other, may have a different economic impact on producers of biotech products. For example, the adverse effect on long-term investments might be smaller in the case of the provisional ban, provided applicants expect that approval decisions will be resumed at some point in the future.

prolonged delays, may be equated with a substantive decision to ban biotech products on the basis that, at some point, a delay effectively becomes a ban. In support of this argument, Canada points to the fact that numerous applications were withdrawn between June 1999 and August 2003. While this is correct, it should also be noted that almost none of the applicants withdrawing their applications cited undue delays in the processing of their application as a reason for the withdrawal.[1229] Nonetheless, we agree with Canada that the absence of a reference to the moratorium or to undue delays does not necessarily indicate that undue delays did not cause, or contribute to, the withdrawals.

7.1363 Canada notes that some applicants in their letters of withdrawal invoked "commercial reasons" and submits that this is a reference to the limited commercial life of biotech products. Canada contends that the biotech products at issue in this dispute have a short life-cycle, such that if they are not approved within reasonable periods of time, the marketing of these products may no longer be of any commercial interest. While this may well be true for some biotech products, the record does not support the view that this is the case generally. In fact, many applicants maintained their applications despite lengthy delays in their processing.[1230] Furthermore, while numerous applications were withdrawn between June 1999 and August 2003, quite a few others were submitted for approval during the same time-period.[1231] If these applicants did not believe that they would eventually be able to have their applications approved, it is difficult to see why the applicants would spend time and money on these applications. Thus, in our view, the facts do not support the general conclusion that, practically speaking, there is no distinction between the European Communities' procedural decision to delay final approval decisions and a substantive decision definitively to ban all biotech products for which approval had been sought.

7.1364 As we have said, we recognize the possibility that, due to short product life-cycles, prolonged delays in the completion of approval procedures could, in some instances, leave applicants with no choice but to withdraw their applications. However, this potential effect of a procedural decision to delay final approval decisions does not provide sufficient grounds for equating that decision with a substantive decision to ban biotech products. The distinction between substance and procedure is a fundamental legal distinction and we see no justification for disregarding it in this case. Annex C(1)(a) of the *SPS Agreement* specifically requires Members to complete their approval procedures without undue delay. A Member is therefore not allowed to cause prolonged delays in the completion of an approval procedure, unless there is a justification for doing so. And if there is a justification, we do not think it would be appropriate to equate delay with a negative substantive decision based on product life-cycle considerations. Where a Member has legitimate reasons for delaying an approval decision, *e.g.*, in order to obtain scientific information required in order to complete a risk assessment, it should not be deemed to have completed its approval procedure with a negative decision (and thus be exposed to the risk of a successful challenge to that presumed decision based on Article 5.1 of the *SPS Agreement*) merely because the applicant's product is nearing the end of its life-cycle. Provided a Member completes an approval procedure without undue delay, the fact that the time taken significantly diminishes the applicant's market opportunities is of no particular relevance.

7.1365 In conclusion, we note that, for the reasons set out above, we are unable to accept the Complaining Parties' argument that the European Communities' decision to apply a general moratorium on approvals was effectively equivalent to a decision to impose an across-the-board marketing ban.

[1229] The application concerning RR oilseed rape (EC-79) is a notable exception. Exhibit EC-79/At. 30.

[1230] For instance, the application concerning Bt-531 cotton was submitted in December 1996 and was still pending in August 2003 and beyond.

[1231] *See, e.g.*, Exhibits EC-94, EC-95, EC-96, EC-104, EC-106 and EC-107.

(iii) Did the decision to apply a general moratorium on approvals itself establish a procedure or amend the existing EC approval procedures?

7.1366 In addition to asserting that the decision to apply a general moratorium on approvals effectively banned the marketing of all biotech products with pending or future applications, the Complaining Parties present arguments which present the issue of whether that decision could be considered either to have established a new procedure or to have amended the existing EC procedures. As this issue is directly relevant to the legal characterization of the decision to apply a general moratorium on approvals, it is necessary to address it.

7.1367 The **United States** argues that the decision to apply a general moratorium on approvals modified the European Communities' approval regime. More specifically, the United Stats argues that the suspension by the European Communities of the consideration of applications for, or granting of, approval of biotech products is a procedure within the meaning of Annex A(1) of the *SPS Agreem*ent, although an unwritten one. The United States points out in this regard that the *New Shorter Oxford English Dictionary* defines the term "procedure" as a "particular mode or course of action" or a "set of instructions for performing a specific task which may be invoked in the course of a [computer] program".

7.1368 **Canada** does not argue that the decision to apply a general moratorium on approvals established an unwritten procedure. Canada contends, however, that that decision led to a significant departure from the existing EC approval procedure in that it resulted in the European Communities moving from approvals based on risk assessment to no approvals regardless of the scientific evidence. According to Canada, the decision to apply a general moratorium on approvals amounted to a mis- or non-application of the applicable legislation and essentially rendered the approval procedure irrelevant. Canada submits that the moratorium superseded the EC approval procedure as the measure that exerted effective control over applications.

7.1369 Like Canada, **Argentina** does not argue that the decision to apply a general moratorium on approvals established an unwritten procedure. Argentina nevertheless argues that that decision modified the existing EC approval procedures by introducing additional procedural stages not envisaged in the relevant legislation. Specifically, Argentina contends that the inter-service consultations launched and held by the Commission in the context of some individual approval procedures have no legal basis in the legislation.

7.1370 The **Panel** begins by recalling its view that the decision to apply a general moratorium on approvals was a decision to delay final approval decisions. The first issue to be examined in view of the United States' argument is whether the decision to delay final approval decisions laid down a "procedure". Relevant dictionary definitions of the term "procedure" are: "[a] particular mode or course of action"[1232] or "an established or official way of doing something"[1233].

7.1371 In our view, the decision to delay final approval decisions did not itself establish a procedure for approving biotech products or, more to the point, for preventing the final approval of biotech products. To begin with, it did not establish "[a] particular mode or course of action" to be followed by the Group of Five countries and/or the Commission. Nor did it establish an "[un]official way" of approving, or not approving, applications. It is instructive in this regard to recall the June 1999 declaration by the Group of Five countries, which states in relevant part that "in exercising the powers

[1232] *The New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. 2, p. 2363.

[1233] *The Concise Oxford Dictionary*, 10th edn., J. Pearsall (ed.) (Clarendon Press, 1999), p. 1139.

vested in them regarding the growing and placing on the market of genetically modified organisms […] they [the Group of Five countries] will take steps to have any new authorizations for growing and placing on the market suspended".[1234] The declaration itself does not establish a procedure, as it does not specify the steps to be taken to bring about a suspension of approvals. We also recall that the general moratorium on approvals was given effect through various types of action and/or omission by the Group of Five countries and/or the Commission. But the record does not support the conclusion that the relevant acts and/or omissions were a reflection of an established procedure.[1235]

7.1372 It remains to be examined, then, whether the decision to delay final approval decisions effectively amended the relevant EC approval procedures. The relevant approval procedures are set out in Directive 90/220 and its successor, Directive 2001/18, as well as Regulation 258/97. The main elements and similarities of these approval procedures have been described earlier in Section VII.C.

7.1373 We do not consider that the decision to delay final approvals resulted in the European Communities applying a different type of approval procedure between June 1999 and August 2003. Indeed, it can be seen from our earlier findings that applications continued to be assessed in accordance with the procedures set out in Directives 90/220 and 2001/18, as well as Regulation 258/97. Accordingly, applications were still being assessed first at member State level and subsequently at Community level. Lead CAs continued to prepare initial assessment reports. The Commission continued to seek the assistance of EC scientific committees and, at least initially, submitted draft measures to the Regulatory Committee for a vote. While it is correct that the Commission conducted inter-service consultations in the context of some of the approval procedures in question, we have previously found that such consultations were not an additional procedural stage devised by the Commission to prevent the approval of biotech products.[1236]

7.1374 Moreover, it has not been explained to us precisely how the decision to delay final approval decisions would have modified the approval procedures set out in the applicable EC legislation. It is not clear to us what was the particular "mode or course of action" to be followed under the supposedly modified EC approval procedures, or what was the newly established "[un]official way" of approving, or not approving, applications. As we have noted, the June 1999 declaration by the Group of Five countries does not predetermine any particular "mode or course of action" to be followed. The mere fact that some applications did not reach Community level or were not put to a vote in the Regulatory Committee, and that no approval procedure was completed with a final approval decision does not demonstrate that the European Communities applied a different type of approval procedure. In our view, a more appropriate conclusion to be drawn from the absence of final approvals and the delays in the processing of applications is that the European Communities applied its existing approval procedures, but that it intentionally did not make full use of these procedures to complete the approval

[1234] Declaration by the Danish, Greek, French, Italian and Luxembourg delegations concerning the suspension of new GMO authorizations, 2194th Council Meeting - Environment-, Luxembourg, 24/25 June 1999. Exhibits US-76 and 77; Exhibit CDA-3; Exhibit ARG-12.

[1235] We have noted earlier that the Commission's conduct might possibly be considered to reflect an (evolving) implementation practice. *See supra*, para. 7.1277.

[1236] *See supra*, para. 7.1260. We note that these earlier findings concerned inter-service consultations held in the context of an approval procedure conducted pursuant to Directive 90/220. However, the same considerations apply equally to inter-service consultations held in the context of an approval procedures conducted pursuant to Directive 2001/18 and Regulation 258/97.

process.[1237] To our minds, this is a natural and logical way of implementing a decision to delay final approval decisions.

7.1375 Canada argues that the decision to delay final approval decisions led to "a significant departure from the existing EC approval procedure" or "superseded the EC approval procedure as the measure that exerted effective control over applications". As we see it, the decision to delay final approval decisions neither led to a departure from the existing approval procedures nor superseded them. Based on the information on the record, we are of the view that the decision to delay final approval decisions was implemented through, and within the framework of, the existing approval procedures. As pointed out by Canada, this resulted in at least a partial "non-application" of the existing approval procedures. However, non-application of one particular approval procedure does not logically imply application of a different approval procedure.

7.1376 We note, as an additional matter, Canada's contention that "the measure that exerted effective control over applications" was the decision to delay final approval decisions, and not the existing approval procedures. The first observation to be made in relation to this contention is that, legally speaking, applications remained fully subject to the approval procedures in force. However, it is clear that the approval procedures set out in the applicable EC legislation left member States and the Commission a degree of discretion with regard to the application, or operation, of these approval procedures. A decision by a relevant EC entity relating to the application, or operation, of the applicable approval procedures may have – and, indeed, may be intended to have – an impact on the manner and/or speed of assessment of applications. If it does, that decision plainly would exert a degree of "effective control" over applications.

7.1377 In our analysis, the European Communities' decision to delay final approval decisions was such a decision relating to the application, or operation, of the EC approval procedures.[1238] It essentially was a decision to operate the EC approval procedures in such a way that there would be no final approval decisions until certain conditions were met. Moreover, since the objective of that decision was to delay final approval decisions, it is inevitable that it exerted a degree of effective control over individual applications. However, as we have noted above, we do not think that applications were effectively no longer controlled, at all, by the EC approval procedures set out in the legislation. If in practice the decision to delay final approval decisions nonetheless exerted a significant degree of effective control, this was in part a consequence of the objective of that decision, which was to prevent final approval decisions. Quite possibly, the fact that applicants chose not to seek judicial review, either before member State courts or the European Court of Justice, of action taken, or not taken, by lead CAs or the Commission in the context of individual approval procedures was another reason why in practice the decision to delay final approval decisions exerted a significant degree of effective control over individual applications.[1239]

7.1378 In the light of the foregoing, we conclude that the European Communities' decision to apply a general moratorium on approvals did not itself establish a procedure for approving, or not approving, applications, and that it did not effectively amend the existing EC approval procedures either. We

[1237] We recall in this regard the European Communities' argument that the EC legislation which sets out the relevant approval procedures was considered inadequate by some member States and segments of public opinion.

[1238] We recall that the EC approval procedures as such have not been challenged by the Complaining Parties.

[1239] We recall that according to an uncontested statement by the European Communities no complaints were brought before the European Court of Justice in respect of the products subject to these proceedings. Only one case was instituted before a member State court, but that case concerned a member State safeguard measure.

nonetheless consider that the decision to apply a general moratorium on approval was procedural in nature, in that it was a decision relating to the application, or operation, of the existing EC approval procedures.

(iv) Conclusion

7.1379 It is clear from the preceding analysis that we are unable to accept either of the alternative legal characterizations of the general moratorium on approvals which the Complaining Parties have put forward. Accordingly, we confirm the view and conclusion we offered at the beginning of our analysis, namely that the European Communities' decision to apply a general moratorium on approvals should be characterized as a procedural decision to delay final substantive approval decisions. The decision was procedural in nature insofar as it was a decision relating to the application, or operation, of the existing EC approval procedures.

7.1380 We recall that the second paragraph of Annex A(1) of the *SPS Agreement* provides that SPS measures include "requirements and procedures". We have stated above that in order to establish whether the general moratorium on approvals constitutes an "SPS measure" within the meaning of Article 5.1 and Annex A(1), it must be determined whether the general moratorium is a substantive SPS "requirement", a "procedure" or a measure of a different nature. Our findings above on the nature of the general moratorium on approvals enable us to make that determination.

7.1381 We have found above that the decision to apply a general moratorium on approvals did not impose an effective marketing ban. If it had, it could have been considered to impose a substantive "requirement", on the basis that a ban is effectively equivalent to a negative requirement, *i.e.*, a requirement not to permit the marketing of a product. We further found that the decision to apply a general moratorium on approvals neither established nor amended a procedure. If it had established or amended a procedure, it might have been considered to lay down a "procedure".

7.1382 We have characterized the decision to apply a general moratorium on approvals as a procedural decision to delay final substantive approval decisions. In our assessment, this procedural decision did not impose a substantive "requirement" in relation to biotech products with pending or future applications. It neither approved nor rejected applications. Similarly, we are of the view that the decision to delay final substantive approval decisions cannot appropriately be viewed as providing for a "procedure", considering that it did not itself establish a new procedure or amend the existing EC approval procedures. We have said that the decision to delay final approval decisions was procedural in nature insofar as it was a decision relating to the application, or operation, of the existing EC approval procedures. However, the mere fact that the decision in question related to the application, or operation, of procedures does not turn that decision into a procedure for the purposes of Annex A(1).[1240]

7.1383 Based on these considerations, we conclude that the European Communities' decision to apply a general moratorium on approvals was a decision concerning the application, or operation, of procedures. As such, it did not provide for "requirements [or] procedures" within the meaning of Annex A(1).

[1240] We recall in this regard that the second paragraph of Annex A(1) makes no reference to the "application" of "[substantive] requirements and procedures".

(c) Applicability of Article 5.1 to the European Communities' decision to apply a general *de facto* moratorium on approvals

7.1384 Having ascertained the nature of the European Communities' decision to apply a general moratorium on approvals, we can now proceed to determine whether that decision was an "SPS measure" within the meaning of Article 5.1 and Annex A(1). We recall in this regard that for a particular measure to be subject to Article 5.1 it must be an "SPS measure".

7.1385 In relation to the Annex A(1) definition of the term "SPS measure", we note once again that the second paragraph of Annex A(1) of the *SPS Agreement* provides that SPS measures include "requirements and procedures". We have found above that the European Communities' decision to apply a general moratorium on approvals did not provide for "requirements [or] procedures" within the meaning of Annex A(1). We found that the decision in question was a decision concerning the application, or operation, of "procedures".

7.1386 We have observed earlier that the second paragraph of Annex A(1) does not refer to the "application" of "requirements and procedures" and that this omission must be given meaning in view of the distinction made in various provisions of the *SPS Agreement* between SPS measures and their "application", or "operation". We consequently found that although requirements and procedures as such may in accordance with the Annex A(1) definition constitute SPS measures, the application of such requirements and procedures would not, itself, meet the definition of an SPS measure.[1241] Since we determined that the European Communities' decision to apply a general moratorium on approvals was a decision concerning the application, or operation, of the EC approval procedures, it follows from the preceding considerations that that decision does not meet all of the constitutive elements of the definition of the term "SPS measure" as provided in Annex A(1).

7.1387 The Annex A(1) definition is directly applicable to Article 5.1. However, we have stated earlier that in interpreting the term "SPS measure", in addition to the Annex A(1) definition, account should be taken of the specific context within which that term appears. For this reason, we now go on to analyse whether the provisions of Article 5.1 render the provisional conclusion we have reached on the basis of the Annex A(1) definition inappropriate.

7.1388 Article 5.1 requires that an SPS measure applied by a Member be based on a risk assessment. In our view, the term "SPS measure" in Article 5.1 should be taken to refer to a measure applied for achieving the relevant Member's appropriate level of sanitary or phytosanitary protection. We note in this regard that Article 5.3 of the *SPS Agreement* provides in relevant part that "[i]n determining the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection, Members shall take into account [certain] economic factors". Thus, Article 5.3 establishes a link between the assessment of risk and the determination of "the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from *such* risk" (emphasis added). Indeed, as we see it, one of the purposes of a risk assessment is to allow the importing Member to determine "the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection".[1242] And one of the purposes of the requirement that SPS measures be based on a risk assessment is to ensure that the measure

[1241] We have pointed out, however, that in some circumstances the application of a requirement may result in another requirement.

[1242] We note that Annex A(4) of the *SPS Agreement* defines the term "risk assessment" as meaning an assessment of risk "according to the [SPS] measures which might be applied".

actually applied for achieving the appropriate level of sanitary or phytosanitary protection bears a rational relationship to the risk.[1243]

7.1389 The view that the term "SPS measure" in Article 5.1 should be interpreted to refer to a measure applied for achieving the relevant Member's appropriate level of sanitary or phytosanitary protection draws further support from Article 5.6. Pursuant to Article 5.6, "when establishing or maintaining *[SPS] measures to achieve the appropriate level of sanitary or phytosanitary protection*, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection" (emphasis added). We think that Article 5.6 states explicitly what is implied in Article 5.1 and that the two provisions therefore use the term "SPS measures" in the same sense. We note in this regard that Article 5.6 follows Article 5.1 and builds on it, inasmuch as Article 5.6 lays down an obligation that goes beyond the obligation laid down in Article 5.1. Indeed, an SPS measure applied for achieving a Member's appropriate level of protection may be based on a risk assessment, but at the same time may be more trade-restrictive than required to achieve the appropriate level of protection.

7.1390 It follows from the preceding observations that we need to examine whether the European Communities' decision to apply a general moratorium on approvals was a measure applied to achieve the European Communities' appropriate level of sanitary or phytosanitary protection. In addressing this issue, we recall that the European Communities' decision was made in the context of the EC pre-marketing approval system. In our view, the pre-marketing approval requirement which results in a provisional marketing ban may be properly considered a measure that is applied for achieving the European Communities' appropriate level of protection. Moreover, it is not open to doubt that final substantive approval decisions on individual applications are also measures applied for achieving the European Communities' appropriate level of protection.[1244]

7.1391 In contrast, we do not consider that the European Communities' decision to apply a general moratorium on approvals was, as such, a measure applied to achieve the European Communities' appropriate level of protection. We recall in this regard that that decision was a procedural decision to delay final approval decisions. As we explained above, the practical effect of that decision was to extend the time-period during which non-approved biotech products were subject to the provisional marketing ban flowing from the pre-marketing approval requirement. The pre-marketing approval requirement which imposes the provisional marketing ban is a measure applied to achieve the European Communities' level of protection, but that requirement is a separate measure from the decision to delay final approval decisions. By itself, the procedural decision to delay final approval decisions did not achieve or imply a particular level of protection.[1245]

[1243] According to the Appellate Body, the requirement of a risk assessment "was intended as a countervailing factor in respect of the right of Members to set their appropriate level of protection". Appellate Body Report, *EC – Hormones*, para. 177.

[1244] We recall our view that the application of a "requirement" may result in another "requirement" within the meaning of Annex A(1) of the *SPS Agreement*. Specifically, the application of the EC pre-marketing approval requirement to a specific biotech product for which marketing approval has been sought results in a final approval decision on that product which may be considered a "requirement" – either a requirement to permit the marketing of the relevant product or a requirement to prohibit the marketing of the relevant product.

[1245] Had the European Communities opted for a system under which biotech products could be provisionally marketed until a final approval decision was made, a decision to delay final approval decisions would not have had the effect of extending a provisional marketing ban, but of extending a provisional marketing authorization. But in this scenario as well, it would be the decision to grant provisional marketing authorization which achieves a particular level of sanitary or phytosanitary protection, not the decision to delay final approval decisions.

7.1392 As the European Communities' decision to apply a general moratorium on approvals was not, itself, a measure applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection, it cannot, in our view, be considered an "SPS measure" within the meaning of Article 5.1. As a result, the provisions of Article 5.1 do not cast doubt on the provisional conclusion we have reached on the basis of the Annex A(1) definition. Rather, they reinforce our provisional conclusion.

7.1393 Based on the above considerations, we thus determine that the European Communities' decision to apply a general moratorium on approvals was not an "SPS measure" within the meaning of Article 5.1 and Annex A(1). It follows that since only "SPS measures" are subject to the provisions of Article 5.1, the provisions of Article 5.1 are not applicable to the European Communities' decision to apply a general moratorium on approvals.

7.1394 In view of this conclusion, we need not continue our analysis of the Complaining Parties' claim under Article 5.1.

(d) Conclusions

7.1395 In the light of the above, the Panel reaches the following conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence submitted by the United States and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence submitted by Canada and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

6. Consistency of the general *de facto* moratorium on approvals with Article 5.6 of the *SPS Agreement*

7.1396 Canada claims that by applying a general *de facto* moratorium on approvals between June 1999 and August 2003, the European Communities has acted inconsistently with its obligations under Article 5.6 of the *SPS Agreement*.

7.1397 Article 5.6 of the *SPS Agreement* provides:

> "Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility."(footnote omitted)

7.1398 **Canada** submits that the general moratorium on approvals is more trade-restrictive than required to achieve the European Communities' appropriate level of protection. According to Canada, an obvious alternative measure to the moratorium is for the European Communities to comply with its existing approval legislation and permit biotech products to be considered for, and granted or denied, approval. For the purposes of its claim with respect to Article 5.6, Canada assumes that the European Communities' appropriate level of protection is that which the European Communities has expressed in its approval legislation for biotech products. The EC approval procedures continue to serve as an adequate framework for determining whether biotech products pose risks to human health and the environment. In Canada's view, it is therefore reasonable to conclude that the European Communities' own approval procedure, properly functioning, would achieve its appropriate level of protection. Finally, Canada submits that compliance by the European Communities with its own approval procedures would be significantly less trade-restrictive than the existing moratorium.

7.1399 The **European Communities** argues that certain provisions of the *SPS Agreement* relate to the development of SPS measures while others relate to the application of SPS measures.[1246] According to the European Communities, Article 5.6 contains obligations relating to the development of SPS measures, not their application. SPS measures as defined in Annex A(1) of the *SPS Agreement* presuppose the existence of an act. The European Communities submits that the Complaining Parties' assertions about a moratorium are in reality complaints about delay in the completion of approval procedure. Delay of this kind cannot constitute an SPS measure within the meaning of Annex A(1). Delay is a failure to act in a timely manner. A failure to act in a timely manner can be reviewed under the procedural obligations set out in Article 8 and Annex C(1) of the *SPS Agreement* as an issue of the application of an SPS measure (in this case, the EC approval system).[1247]

7.1400 The European Communities submits that the Complaining Parties describe as an SPS measure the very same failure to take final decisions which they challenge as the application of an SPS measure under Article 8 and Annex C(1). Yet as a matter of logic, it is clear that alleged behaviour cannot at the same time constitute an SPS measure and the application of another SPS measure. The European Communities deduces from these considerations that since, in its view, the Complaining Parties are not complaining about an SPS measure, but its application, and since Article 5.6 does not contain obligations relating to the application of an SPS measure, the alleged general moratorium on approvals is not subject to Article 5.6.

7.1401 The **Panel** notes the European Communities' argument that the European Communities' decision to apply a general moratorium on approvals does not fall to be assessed under Article 5.6. In view of this argument, we must first examine whether the provisions of Article 5.6 are applicable.

[1246] The European Communities bases this view on Article 1.1 of the *SPS Agreement*, the second sentence of which provides that SPS measures "shall be *developed and applied* in accordance with the provisions of this Agreement" (emphasis added).

[1247] For the text of Article 8 and Annex C(1), *see infra*, section VII.C.11 and VII.C.12.

(a) Applicability of Article 5.6 to the European Communities' decision to apply a general *de facto* moratorium on approvals

7.1402 We note that, by its clear terms, Article 5.6 applies to "[SPS] measures". Accordingly, for a particular measure to be subject to Article 5.6 it must be an SPS measure. Pursuant to Article 1 of the *SPS Agreement*, the Annex A(1) definition of the term "SPS measure" is directly applicable to Article 5.6. We have found above that the European Communities' decision to apply a general moratorium on approvals does not meet the definition of the term "SPS measure" as it appears in Annex A(1). However, we also stated that in interpreting the term "SPS measure", in addition to the Annex A(1) definition, account should be taken of the specific context within which that term appears. For this reason, we proceed to analyse whether the provisions of Article 5.6 render the provisional conclusion we have reached on the basis of the Annex A(1) definition inappropriate.

7.1403 When analysing the Complaining Parties' claim under Article 5.1, we have highlighted the fact that Article 5.6 explicitly refers to "[SPS] measures to achieve the appropriate level of sanitary or phytosanitary protection". It is therefore clear that the SPS measures at issue in Article 5.6 are those applied for achieving the appropriate level of protection.

7.1404 We found above that the European Communities' decision to apply a general moratorium on approvals was not, as such, a measure applied to achieve the European Communities' appropriate level of protection.[1248] It follows that that decision cannot be considered an "SPS measure" within the meaning of Article 5.6. Reinforcing this view is the fact that the procedural decision to delay final approval decisions did not itself restrict trade. Trade was restricted as a result of a distinct measure, namely, the pre-marketing approval requirement which imposes a provisional marketing ban on biotech products. Consequently, the provisions of Article 5.6 support rather than undermine the provisional conclusion we have reached on the basis of the Annex A(1) definition.

7.1405 Based on the above considerations, we thus determine that the European Communities' decision to apply a general moratorium on approvals was not an "SPS measure" within the meaning of Article 5.6 and Annex A(1). As only "SPS measures" are subject to the provisions of Article 5.6, we consider that the provisions of Article 5.6 are not applicable to the European Communities' decision to apply a general moratorium on approvals.

7.1406 In view of this conclusion, we need not continue our analysis of Canada's claim under Article 5.6.

(b) Conclusions

7.1407 In the light of the above, the Panel reaches the following conclusions:

(i) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence submitted by Canada and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.6 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

[1248] *See supra*, para. 7.1371.

7. Consistency of the general *de facto* moratorium on approvals with Article 5.5 of the *SPS Agreement*

7.1408 All three Complaining Parties claim that by applying a general *de facto* moratorium on approvals, the European Communities has acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement*.

7.1409 Article 5.5 of the *SPS Agreement* provides:

> "With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision."

7.1410 The **Complaining Parties** submit that the European Communities has adopted different appropriate levels of protection in three different situations that can be compared. The United States argues that the European Communities has identified a different level of protection for biotech products and products produced with biotech processing aids. Canada and Argentina argue that the European Communities has identified a different level of protection for biotech products that have been stalled as a result of the general moratorium, biotech products that were approved for marketing prior to the imposition of the general moratorium, and novel non-biotech products such as those produced by conventional plant breeding techniques. The Complaining Parties further argue that the identified differences in appropriate levels of protection in comparable situations are "arbitrary or unjustifiable". Finally, the Complaining Parties argue that the general moratorium as the measure embodying the differences in the levels of protection has resulted in discrimination or a disguised restriction on international trade.

7.1411 **Canada** notes that it is making a claim under Article 5.5 in the alternative, in the event that contrary to Canada's assumption, the European Communities' appropriate level of protection is reflected, not in the applicable EC approval legislation, but in the general moratorium itself.

7.1412 The **European Communities** argues that certain provisions of the *SPS Agreement* relate to the development of SPS measures while others relate to the application of SPS measures.[1249] According to the European Communities, Article 5.5 is premised on, and requires, the existence of an SPS measure. It does not refer to the application of an SPS measure. SPS measures as defined in Annex A(1) of the *SPS Agreement* presuppose the existence of an act. The European Communities submits that the Complaining Parties' assertions about a moratorium are in reality complaints about delay in the completion of approval procedure. Delay of this kind cannot constitute an SPS measure within the meaning of Annex A(1). Delay is a failure to act in a timely manner. A failure to act in a timely manner can be reviewed under the procedural obligations set out in Article 8 and Annex C(1)

[1249] The European Communities bases this view on Article 1.1 of the *SPS Agreement*, the second sentence of which provides that SPS measures "shall be *developed and applied* in accordance with the provisions of this Agreement" (emphasis added).

of the *SPS Agreement* as an issue of the application of an SPS measure (in this case, the EC approval system).[1250]

7.1413 The European Communities submits that the Complaining Parties describe as an SPS measure the very same failure to take final decisions which they challenge as the application of an SPS measure under Article 8 and Annex C(1). Yet as a matter of logic, it is clear that alleged behaviour cannot at the same time constitute an SPS measure and the application of another SPS measure. The European Communities deduces from these considerations that since, in its view, the Complaining Parties are not complaining about an SPS measure, but its application, and since Article 5.5 does not refer to the application of an SPS measure, the alleged general moratorium on approvals is not subject to Article 5.5.

7.1414 The **Panel** notes the European Communities' argument that the European Communities' decision to apply a general moratorium on approvals is not subject to the provisions of Article 5.5. In view of this argument, we must first examine whether the provisions of Article 5.5 are applicable.

(a) Applicability of Article 5.5 to the European Communities' decision to apply a general *de facto* moratorium on approvals

7.1415 Article 5.5 contains obligations relating to the application of the concept of the appropriate level of sanitary or phytosanitary protection. However, we note that the "Guidelines to Further the Practical Implementation of Article 5.5", adopted by the SPS Committee in accordance with the second sentence of Article 5.5, state in this regard that "the concept of appropriate level of protection is applied in practice through sanitary or phytosanitary measures".[1251] This statement is consistent with relevant Appellate Body jurisprudence. In *EC – Hormones*, the Appellate Body found that three elements must be demonstrated to establish an inconsistency with Article 5.5:

> "The first element is that the Member imposing the measure complained of has adopted its own appropriate levels of sanitary protection against risks to human life or health in several different situations. The second element to be shown is that those *levels of protection* exhibit arbitrary or unjustifiable differences ('distinctions' in the language of Article 5.5) in their treatment of different situations. The last element requires that the arbitrary or unjustifiable differences result in discrimination or a disguised restriction of international trade. We understand the last element to be referring to the *measure* embodying or implementing a particular level of protection as resulting, in its application, in discrimination or a disguised restriction on international trade."[1252]

7.1416 In the light of this, we consider that although Article 5.5 does not explicitly refer to "SPS measures", implicitly it envisages that the "measure complained of" is an "implementing measure"[1253]. In other words, the measure complained of must be an SPS measure applied for achieving a particular level of sanitary or phytosanitary protection. In this respect, there is therefore no difference between Article 5.5, on the one hand, and Articles 5.1 and 5.6, on the other hand.

7.1417 If, as Appellate Body jurisprudence leads us to believe, Article 5.5 implies a reference to "SPS measures", the general definition of that term set out in Annex A(1) of the *SPS Agreement* must

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[1250] For the text of Article 8 and Annex C(1), *see infra*, section VII.C.11 and VII.C.12.
[1251] G/SPS/15, B.1.
[1252] Appellate Body Report, *EC – Hormones*, para. 214 (italics in original; underlining added).
[1253] *Ibid*., para. 215.

be applicable in the context of Article 5.5 as well. We have found above that the European Communities' decision to apply a general moratorium on approvals does not meet the definition of the term "SPS measure" as it appears in Annex A(1). However, we also stated that in interpreting the term "SPS measure", in addition to the Annex A(1) definition, account should be taken of the specific context within which that term appears. For this reason, we proceed to analyse whether the provisions of Article 5.5 render the provisional conclusion we have reached on the basis of the Annex A(1) definition inappropriate.

7.1418 As we have pointed out, the SPS measures at issue in Article 5.5 are those applied for achieving a particular level of protection. We found above that the pre-marketing approval requirement which results in a provisional marketing ban may be properly considered a measure which is applied for achieving the European Communities' appropriate level of protection. Similarly, we found that final substantive approval decisions on individual applications are measures applied for achieving the European Communities' appropriate level of protection. But, most importantly, we found that the European Communities' decision to apply a general moratorium on approvals was not, as such, a measure applied to achieve a particular level of protection, and did not imply a particular level of protection either. That decision cannot, therefore, be considered an "implementing measure". This being so, it is clear that the provisions of Article 5.5 as interpreted by the Appellate Body and the SPS Committee do not undermine, but reinforce the provisional conclusion we have reached on the basis of the Annex A(1) definition.

7.1419 Based on the above considerations, we thus determine that the European Communities' decision to apply a general moratorium on approvals was not an implementing "SPS measure" within the meaning of Annex A(1) and Article 5.5 as interpreted by the Appellate Body. As Article 5.5 implies that the measure complained of is an implementing "SPS measure", we consider that Article 5.5 is not applicable to the European Communities' decision to apply a general moratorium on approvals.

7.1420 In view of this conclusion, we need not continue our analysis of the Complaining Parties' claim under Article 5.5.

(b) Conclusions

7.1421 In the light of the above, the Panel reaches the following conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence submitted by the United States and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence submitted by Canada and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

8. Consistency of the general *de facto* moratorium on approvals with Article 2.2 of the *SPS Agreement*

7.1422 All three Complaining Parties claim that by applying a general *de facto* moratorium on approvals between June 1999 and August 2003, the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement*.

7.1423 Article 2.2 of the *SPS Agreement* provides in relevant part:

> "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5."

7.1424 It is apparent from the text of Article 2.2 that this provision contains three separate requirements: (i) the requirement that SPS measures be applied only to the extent necessary to protect human, animal or plant life or health; (ii) the requirement that SPS measures be based on scientific principles; and (iii) the requirement that SPS measures not be maintained without sufficient scientific evidence.

7.1425 The **Complaining Parties** consider that Article 2.2 is applicable to the general moratorium on approvals. The United States submits that the general moratorium is inconsistent with the second and third requirements in Article 2.2, while Canada and Argentina submit that it is inconsistent with all three requirements contained in Article 2.2.

7.1426 The **European Communities** argues that certain provisions of the *SPS Agreement* relate to the development of SPS measures while others relate to the application of SPS measures.[1254] According to the European Communities, Article 2.2 contains obligations concerning the development of SPS measures, not their application. The European Communities submits that by challenging the way in which applications are dealt with under the EC approval system, the Complaining Parties are challenging the application of an SPS measure. The European Communities therefore considers that Article 2.2 is not applicable to the alleged general moratorium on approvals.[1255]

7.1427 The **Panel** will first analyse the claims under the first requirement in Article 2.2. The claims under the second and third requirements will be analysed subsequently, in a joint subsection.

[1254] The European Communities bases this view on Article 1.1 of the *SPS Agreement*, the second sentence of which provides that SPS measures "shall be *developed and applied* in accordance with the provisions of this Agreement" (emphasis added).

[1255] It should be noted that the European Communities initially remarked that one could argue on whether Article 2.2 contains obligations relating to the application of an SPS measure rather than to its development. The European Communities submitted that the question could be left open in this case.

(a) First requirement in Article 2.2

7.1428 **Canada** argues that there is a relationship between the first requirement in Article 2.2 and Article 5.6. Canada notes that the panel in *Australia – Salmon* stated that "Article 5.6 should, in particular, be read in light of Article 2.2".[1256] Canada also submits that Article 5.6 is a more specific expression of the general obligation found in Article 2.2 that SPS measures may be applied only to the extent necessary to protect human, animal or plant life or health. Canada considers, therefore, that an SPS measure found to be in violation of Article 5.6 must be presumed to violate the first requirement in Article 2.2. As previously noted, in Canada's view the general moratorium on approvals is inconsistent with Article 5.6. Canada concludes from this that the general moratorium must also be presumed to be contrary to the first requirement in Article 2.2.

7.1429 **Argentina** considers that the requirement that SPS measures be applied only "to the extent necessary" applies to the imposition of an SPS measure and is valid for any SPS measure. Regarding the general *de facto* moratorium on approvals, Argentina notes that it has been implemented generally, that is to the extent of all biotech products. Argentina argues that the general moratorium is therefore an SPS measure which has been applied to an unjustifiably broad extent. Argentina points out in this regard that the applicable EC legislation itself states that the safety of biotech products must be assessed on a case-by-case basis. In Argentina's view, the unjustifiably broad application of the general moratorium is contrary to the first requirement set out in Article 2.2.

7.1430 The **Panel** begins its analysis with Canada's claim. Canada's claim based on the first requirement in Article 2.2 is in the nature of a consequential claim. Canada submits that an inconsistency with the first requirement in Article 2.2 follows by implication from a demonstrated inconsistency with Article 5.6. We begin our consideration of Canada's claim by recalling our earlier finding that Article 5.6 is not applicable to the European Communities' decision to apply a general moratorium on approvals and that, consequently, the European Communities has not acted inconsistently with its obligations under Article 5.6 by applying a general *de facto* moratorium on approvals between June 1999 and August 2003. Since the European Communities has not acted inconsistently with Article 5.6, and since Canada's claim under the first requirement in Article 2.2 is premised on the existence of a breach of Article 5.6 by the European Communities, Canada's claim under the first requirement in Article 2.2 cannot succeed.

7.1431 We now turn to consider Argentina's claim. Argentina claims that the European Communities' general *de facto* moratorium on approvals is a measure that has been applied to an unjustifiably broad extent, and that this is contrary to the first requirement in Article 2.2. More specifically, Argentina argues that the moratorium should not have been applied to all biotech products in respect of which applications were pending during the relevant time period, given that the EC approval legislation states that the safety of biotech products should be assessed on a case-by-case basis.

7.1432 Argentina argues that for the purposes of its claim under the first requirement in Article 2.2 the general *de facto* moratorium on approvals should be considered as an "SPS measure". However, based on the Annex A(1) definition of the term "SPS measures", we have found earlier that the European Communities' decision to apply a general *de facto* moratorium on approvals was a decision relating to the application, or operation, of the existing EC approval procedures and that, as such, it

[1256] Panel Report, *Australia – Salmon*, para. 8.165.

did not constitute an "SPS measure" within the meaning of Annex A(1).[1257] This view seems to us to be appropriate also in the specific context of the first requirement in Article 2.2.

7.1433 We note in this regard that the panel in *EC - Hormones* stated that Article 5.1 may be viewed as a specific application of the basic obligations contained in Article 2.2.[1258] Furthermore, the panel in *Japan – Agricultural Products II* stated that the more specific language of Article 5.6 should be read in the light of the more general language in the first requirement of Article 2.2.[1259] If, as the aforementioned panels suggested, Article 2.2 and Article 5.6 are to be read together, and if Article 5.6 is a specific application of the first obligation provided for in Article 2.2, then our previous considerations as to why we believe the provisions of Article 5.6 are not applicable to the European Communities' decision to apply a moratorium are relevant also in the context of the first requirement of Article 2.2. Therefore, as is the case with Article 5.6, we are of the view that the first requirement in Article 2.2 is applicable to measures applied for achieving a Member's appropriate level of sanitary or phytosanitary protection.[1260]

7.1434 We have already found that the European Communities' procedural decision to delay final approval decisions did not itself constitute a measure which is applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection. Accordingly, we consider that that decision does not constitute an SPS measure within the meaning of Article 2.2. It follows that the particular claim presented by Argentina under the first requirement of Article 2.2 cannot succeed.

(b) Second and third requirements in Article 2.2

7.1435 The **United States** and **Canada** note that the Appellate Body in *Australia – Salmon* agreed with the panel in that case that "in the event a sanitary measure is not based on a risk assessment as required in Articles 5.1 and 5.2, this measure can be presumed, more generally, not to be based on scientific principles or to be maintained without sufficient scientific evidence".[1261] As previously noted, in the United States' and Canada's view the general moratorium on approvals is inconsistent with Article 5.1. The United States and Canada conclude from this that the general moratorium must also be presumed not to be based on scientific principles and to be maintained without sufficient scientific evidence, contrary to Article 2.2.

7.1436 **Argentina** argues that the European Communities has no scientific basis for maintaining a general moratorium on approvals. Argentina submits that there is no known scientific evidence that might support the moratorium. In Argentina's view, the lack of any scientific basis means that the general moratorium is inconsistent with Article 2.2. Argentina further argues that according to the Appellate Body there must be a reasonable relationship between the SPS measure at issue and the scientific evidence.[1262] Argentina argues that the general moratorium has been maintained for a period of more than five years (1998 – 2004) without sufficient scientific evidence. Argentina considers that this demonstrates the lack of the required reasonable relationship.

[1257] We recall that in accordance with Article 1.1 of the *SPS Agreement* the definitions provided in Annex A are applicable to Article 2.2.

[1258] Panel Report, *EC – Hormones* (*Canada*), para. 8.96.

[1259] Panel Report, *Japan – Agricultural Products II*, para. 8.71.

[1260] We note that Argentina is not arguing that for the purposes of its claim under the first requirement in Article 2.2 the EC approval procedures are the relevant SPS measures. Therefore, we need not, and do not, determine whether approval procedures as such can be subject to the first requirement in Article 2.2.

[1261] Appellate Body Report, *Australia – Salmon*, paras. 137-138.

[1262] Argentina refers to Appellate Body Report, *Japan – Agricultural Products II*, para. 73.

7.1437 The **Panel** first considers the United States' and Canada's claim based on the second and third requirements in Article 2.2. This claim is in the nature of a consequential claim. The United States and Canada submit that an inconsistency with the second and third requirements in Article 2.2 follows by implication from a demonstrated inconsistency with Article 5.1. It is correct that the Appellate Body in *Australia – Salmon* found that by maintaining an SPS measure in violation of Article 5.1, Australia as the responding party in that case, by implication, also acted inconsistently with the second and third requirements in Article 2.2.[1263] However, we have determined above that Article 5.1 is not applicable to the European Communities' decision to apply a general moratorium on approvals and that, consequently, the European Communities has not acted inconsistently with its obligations under Article 5.1 by applying a general *de facto* moratorium on approvals between June 1999 and August 2003. Since the European Communities has not acted inconsistently with Article 5.1, and since the United States' and Canada's claim under the second and third requirements in Article 2.2 is premised on the existence of a breach of Article 5.1 by the European Communities, the United States' and Canada's claim under the second and third requirements in Article 2.2 cannot succeed.

7.1438 Argentina claims that the European Communities maintained its general *de facto* moratorium on approvals without sufficient scientific evidence, contrary to the third requirement in Article 2.2. Under this claim, the general *de facto* moratorium on approvals is considered as an "SPS measure". Based on the Annex A(1) definition of the term "SPS measures", we have found earlier that the European Communities' decision to apply a general *de facto* moratorium on approvals was a decision relating to the application, or operation, of the existing EC approval procedures and that, as such, it did not constitute an "SPS measure" within the meaning of Annex A(1).[1264] This view seems to us to be appropriate also in the specific context of the second and third requirement in Article 2.2.

7.1439 We note in this regard that in *EC - Hormones* the Appellate Body agreed with a statement by the panel in that case that Article 5.1 may be viewed as a specific application of the basic obligations contained in Article 2.2 and that Articles 2.2 and 5.1 should "constantly be read together".[1265] If Article 2.2 and Article 5.1 must be read together, and if Article 5.1 is a specific application of the second and third obligations provided for in Article 2.2, then our earlier considerations as to why we believe the provisions of Article 5.1 are not applicable to the European Communities' decision to apply a moratorium on approvals are relevant also in the context of the second and third requirements of Article 2.2. Therefore, we are of the view that the second and third requirements in Article 2.2 are applicable to measures applied for achieving a Member's appropriate level of sanitary or phytosanitary protection.[1266]

7.1440 We have already found that the European Communities' procedural decision to delay final approval decisions did not itself constitute a measure which is applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection. Accordingly, we consider that that decision does not constitute an SPS measure within the meaning of Article 2.2. It follows that the particular claim presented by Argentina under the second and third requirements of Article 2.2 cannot succeed.

[1263] *Ibid*., para. 138.

[1264] We recall that in accordance with Article 1.1 of the *SPS Agreement* the definitions provided in Annex A are applicable to Article 10.1.

[1265] Appellate Body Report, *EC – Hormones*, para. 180. *See also* Appellate Body Report, *Japan – Agricultural Products II*, para. 82.

[1266] We note that Argentina is not arguing that for the purposes of its claim under the second and third requirements in Article 2.2 the relevant SPS measures are the EC approval procedures. Therefore, we need not, and do not, determine whether approval procedures as such can be subject to the second and third requirements in Article 2.2.

(c) Conclusions

7.1441 In the light of the above, the Panel reaches the following conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence submitted by the United States and the European Communities, the Panel concludes that the United States has not established that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence submitted by Canada and the European Communities, the Panel concludes that Canada has not established that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that Argentina has not established that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

9. Consistency of the general *de facto* moratorium on approvals with Article 2.3 of the *SPS Agreement*

7.1442 All three Complaining Parties claim that by applying a general *de facto* moratorium on approvals, the European Communities has acted inconsistently with its obligations under Article 2.3 of the *SPS Agreement*.

7.1443 Article 2.3 of the *SPS Agreement* provides in relevant part:

> "Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade."

7.1444 The **Complaining Parties** note that, according to the Appellate Body, in cases where all three elements under Article 5.5 of the *SPS Agreement* have been fulfilled, and, therefore, Article 5.5 has been violated, the relevant SPS measure, by implication, necessarily violates the more general obligations set out in Article 2.3.[1267] The Complaining Parties recall their view that the European Communities has, by maintaining the general *de facto* moratorium on approvals, acted inconsistently

[1267] The Complaining Parties refer to Appellate Body Report, *Australia – Salmon*, paras. 248-252.

with its obligations under Article 5.5. The Complaining Parties submit that, in the light of this, the European Communities has, by implication, also acted inconsistently with its obligations under Article 2.3.

7.1445 The **European Communities** argues that certain provisions of the *SPS Agreement* relate to the development of SPS measures while others relate to the application of SPS measures.[1268] According to the European Communities, Article 2.3 contains obligations concerning the development of SPS measures, not their application. The European Communities submits that by challenging the way in which applications are dealt with under the EC approval system, the Complaining Parties are challenging the application of an SPS measure. The European Communities therefore considers that Article 2.3 is not applicable to the alleged general moratorium on approvals.[1269]

(a) Evaluation

7.1446 The **Panel** notes that the Complaining Parties' claim under Article 2.3 is in the nature of a consequential claim. The Complaining Parties submit that an inconsistency with Article 2.3 follows by implication from a demonstrated inconsistency with Article 5.5. We note that this argument draws support from Appellate Body jurisprudence, for in *Australia – Salmon*, the Appellate Body observed that "a finding of violation of Article 5.5 will necessarily imply a violation of Article 2.3, first sentence, or Article 2.3, second sentence".[1270]

7.1447 We have determined above that Article 5.5 is not applicable to the European Communities' decision to apply a general moratorium on approvals and that, consequently, the European Communities has not acted inconsistently with its obligations under Article 5.5 by applying a general *de facto* moratorium on approvals between June 1999 and August 2003. Since the European Communities has not acted inconsistently with Article 5.5, and since the Complaining Parties' claim under Article 2.3 is premised on the existence of a breach of Article 5.5 by the European Communities, the Complaining Parties' claim under Article 2.3 cannot succeed.

(b) Conclusions

7.1448 In the light of the above, the Panel reaches the following conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence submitted by the United States and the European Communities, the Panel concludes that the United States has not established that the European Communities has acted inconsistently with its obligations under Article 2.3 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

[1268] The European Communities bases this view on Article 1.1 of the *SPS Agreement*, the second sentence of which provides that SPS measures "shall be *developed and applied* in accordance with the provisions of this Agreement" (emphasis added).

[1269] It should be noted that the European Communities initially remarked that one could argue on whether Article 2.3 contains obligations relating to the application of an SPS measure rather than to its development. The European Communities submitted that the question could be left open in this case.

[1270] Appellate Body Report, *Australia – Salmon*, para. 252.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence submitted by Canada and the European Communities, the Panel concludes that Canada has not established that the European Communities has acted inconsistently with its obligations under Article 2.3 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that Argentina has not established that the European Communities has acted inconsistently with its obligations under Article 2.3 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

10. Consistency of the general *de facto* moratorium on approvals with Article 7 and Annex B(1) of the *SPS Agreement*

7.1449 All three Complaining Parties claim that the European Communities has failed to publish the existence of the general *de facto* moratorium on approvals and that it has thereby acted inconsistently with its obligations under Article 7 and Annex B(1) of the *SPS Agreement*.

7.1450 Article 7 of the *SPS Agreement* provides:

> "Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B."

7.1451 Annex B(1) of the *SPS Agreement* provides:

> "Members shall ensure that all sanitary and phytosanitary regulations[1271] which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them."

7.1452 The **Complaining Parties** submit that the general moratorium on approvals is subject to the publication requirement in Annex B(1). *First*, the general moratorium is an "adopted" measure as it has existed since October 1998 and remains in effect. *Secondly*, the general moratorium is "applicable generally", in that it has applied to all new biotech products subject to the EC approval procedures. *Thirdly*, the general moratorium constitutes a "sanitary or phytosanitary regulation". The Complaining Parties recall in this regard that, in their view, the *de facto* general moratorium is an "SPS measure" and has a similar effect as a law, decree or ordinance. The Complaining Parties further contend that the existence of the general moratorium has not been published, let alone "promptly". The Complaining Parties argue that by failing to publish promptly the existence of the general moratorium, the European Communities has acted inconsistently with its obligations under Annex B(1) and Article 7.

[1271] (*original footnote*) Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally.

7.1453 The **European Communities** argues that Article 7 contains procedural obligations (publication) regarding an SPS measure. Thus, the applicability of Article 7 is premised on the existence of an SPS measure. SPS measures as defined in Annex A(1) of the *SPS Agreement* presuppose the existence of an act. The European Communities submits that the Complaining Parties' assertions about a moratorium are in reality complaints about delay in the completion of approval procedures. Delay of this kind cannot constitute an SPS measure within the meaning of Annex A(1). Delay is a failure to act in a timely manner. The European Communities deduces from these considerations that the alleged general moratorium on approvals is not subject to Article 7.

7.1454 The **Panel** notes that the Complaining Parties allege an inconsistency of the general *de facto* moratorium on approvals with Annex B(1) and use the alleged inconsistency with Annex B(1) to make a consequential claim of inconsistency under Article 7. Accordingly, we will begin our analysis with the Complaining Parties' claim under Annex B(1).

(a) "Sanitary and phytosanitary regulations"

7.1455 Annex B(1) applies to "sanitary and phytosanitary regulations" (hereafter "SPS regulations") which have been "adopted". An explanatory footnote to Annex B(1) indicates that the term "SPS regulations" should be understood as meaning "[s]anitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally". That SPS regulations are "SPS measures" is confirmed by Article 7 which states that Members must notify changes in their "SPS measures" and provide information on their "SPS measures" "in accordance with the provisions of Annex B". It can be inferred from this that the "SPS regulations" at issue in Annex B(1) are a sub-category of "SPS measures". Regarding the meaning of the term "SPS measures", we recall Article 1 of the *SPS Agreement*. It states that for the purposes of the *SPS Agreement*, "the definitions provided in Annex A shall apply". We further note that Article 1.3 of the *SPS Agreement* states that the annexes to the *SPS Agreement* – which include Annex B – are an integral part of the *SPS Agreement*. This means that the reference in the footnote to Annex B(1) to "SPS measures" must be interpreted in accordance with the Annex A(1) definition of the term "SPS measures".

7.1456 It follows from the foregoing that a threshold issue before us is whether the general *de facto* moratorium on approvals was a generally applicable "SPS measure" which had been adopted. It is clear from our earlier findings that the moratorium on final approvals was applicable generally inasmuch as it was applicable to all applications which were pending between June 1999 and August 2003.

7.1457 Our earlier findings have also addressed in detail the question of whether the general *de facto* moratorium on approvals met the definition of an "SPS measure" set out in Annex A(1). We found that it was a measure relating to the application, or operation, of the existing EC approval procedures and that such a measure did not constitute an "SPS measure" within the meaning of Annex A(1). However, we also stated that in interpreting the term "SPS measure", in addition to the Annex A(1) definition, account should be taken of the specific context within which that term appears. For this reason, we now go on to analyse whether the provisions of Annex B(1) render the conclusion we have reached on the basis of the Annex A(1) definition inappropriate.

7.1458 Annex B(1) read in conjunction with the accompanying footnote provides that a generally applicable "SPS measure" which has been adopted must be published promptly. We recall that according to Annex A(1) the term "SPS measures" includes "requirements and procedures". It can be deduced from this that a generally applicable measure imposing a substantive SPS requirement or establishing an SPS procedure is to be published, since such a measure would itself be an "SPS measure". In contrast, neither Annex B(1) nor its accompanying footnote suggests that a generally

applicable measure concerning the administration, or operation, of an SPS measure – such as a measure providing for a particular operation of an SPS approval procedure – is, also, to be published.

7.1459 Article 7 supports this view. It requires Members to notify changes in their "SPS measures" and provide information on their "SPS measures". It does not require Members to notify changes in the administration of SPS measures and provide information on the administration of their SPS measures.

7.1460 We attach meaning to the absence in the text of Annex B(1) and Article 7 of any reference to the administration, or operation, of SPS measures. We find instructive in this regard the provisions of Article 18.5 of the *Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994*, which parallel those of Article 7. Article 18.5 provides that "[e]ach Member shall inform the [Anti-dumping] Committee of any changes in its laws and regulations relevant to this Agreement and in the *administration* of such laws and regulations" (emphasis added). In view of the provisions of Article 18.5, it has to be assumed that where the publication requirement was intended to extend to the administration of generally applicable measures, this was made explicit in the text of the relevant WTO provision.[1272]

7.1461 The Appellate Body in *Japan – Agricultural Products II* stated that the scope of application of the publication requirement of Annex B(1) "should be interpreted in the light of [its] object and purpose".[1273] According to the Appellate Body, "[t]he object and purpose of paragraph 1 of Annex B is 'to enable interested Members to become acquainted with' the sanitary and phytosanitary regulations adopted or maintained by other Members and thus to enhance transparency regarding these measures".[1274] We would agree that extending the publication requirement contained in Annex B(1) to measures concerning the administration, or operation, of SPS regulations would serve the purpose of enhancing transparency. But the object and purpose of Annex B(1) does not entitle us to expand the scope of the publication requirement negotiated by Members, even if we were to consider that it might in principle be desirable to do so.[1275] At any rate, the Appellate Body has made it clear that the principles of treaty interpretation set out in Article 31 of the *Vienna Convention* "neither require nor condone the imputation into a treaty of words that are not there".[1276] As we have said, neither the text of Annex B(1) nor that of Article 7 refers to the administration, or operation, of SPS regulations or SPS measures.

7.1462 In view of the above considerations, we find our earlier conclusion – that the general *de facto* moratorium on approvals was not an "SPS measure" within the meaning of Annex A(1) – to be appropriate also in the specific context of Annex B(1) and Article 7. We thus determine that the general *de facto* moratorium on approvals was not an "SPS measure" within the meaning of the footnote to Annex B(1). Consequently, we also find that the general *de facto* moratorium on approvals was not an "SPS regulation" within the meaning of Annex B(1). This finding in turn makes it unnecessary for us to consider whether the general *de facto* moratorium on approvals had been "adopted" within the meaning of Annex B(1). Since the provisions of Annex B(1) apply only to "SPS regulations", and since the European Communities' general *de facto* moratorium on approvals was not

[1272] We note that the text of Article 32.6 of the *Agreement on Subsidies and Countervailing Measures* is identical to that of Article 18.5 of the *Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994*.

[1273] Appellate Body Report, *Japan – Agricultural Products II*, para. 106.

[1274] *Ibid*., para. 106.

[1275] Pursuant to Article 19.2 of the DSU, panels cannot add to the obligations provided in the covered agreements.

[1276] Appellate Body Report, *India – Patents (US)*, para. 45.

an "SPS regulation", it follows that the provisions of Annex B(1) are not applicable to the general moratorium.

7.1463 We recall that the Complaining Parties seek to establish an inconsistency with Article 7 on the basis of an alleged inconsistency with Annex B(1). As we have found that the provisions of Annex B(1) are not applicable to the general *de facto* moratorium on approvals, there can be no inconsistency with these provisions. Under the approach followed by the Complaining Parties, there can then logically be no inconsistency with Article 7 either, even assuming that Article 7 is applicable to the general moratorium.

7.1464 In connection with the preceding findings, it is well to point out that Annex C(1) of the *SPS Agreement* contains additional transparency requirements which apply specifically to the operation of approval procedures. In particular, Annex C(1)(b) provides that "upon request, the applicant [must be] informed of the stage of the procedure, with any delay being explained". Thus, to the extent the application by the European Communities of a general *de facto* moratorium on approvals led to delays, the European Communities was under an obligation to explain, upon request from an applicant, that these delays were the consequence of a general moratorium. Accordingly, the European Communities was required to provide information on the general moratorium to those directly affected by it. We note that only the United States has alleged that the European Communities has acted inconsistently with the aforementioned transparency requirement of Annex C(1)(b) by applying a general *de facto* moratorium on approvals.[1277]

(b) Conclusions

7.1465 In the light of the above, the Panel reaches the following conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence submitted by the United States and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Annex B(1) and Article 7 of the *SPS Agreement* in respect of the general *de facto* moratorium on approvals which it applied between June 1999 and August 2003.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence submitted by Canada and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Annex B(1) and Article 7 of the *SPS Agreement* in respect of the general *de facto* moratorium on approvals which it applied between June 1999 and August 2003.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Annex B(1) and Article 7 of the *SPS Agreement* in respect of the general *de facto* moratorium on approvals which it applied between June 1999 and August 2003.

[1277] *See infra*, para. 7.1571.

11. Consistency of the general *de facto* moratorium on approvals with Article 8 and Annex C(1)(a), first clause, of the *SPS Agreement*

7.1466 The United States and Canada, but not Argentina, claim that the general *de facto* moratorium on approvals has led to a failure by the European Communities to comply with the requirements of Article 8 and Annex C(1)(a), first clause, of the *SPS Agreement*.

7.1467 Article 8 of the *SPS Agreement* provides:

> "Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement."

7.1468 Annex C(1)(a), first clause, of the *SPS Agreement* provides:

> "1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:
>
> (a) such procedures are undertaken and completed without undue delay [...]."

7.1469 The **United States** argues that the European Communities' approval procedures for biotech products must comply with Article 8 and Annex C(1)(a), which refers to "undue delay". The United States notes that the ordinary meaning of "undue" is "inappropriate, unsuitable, improper; unrightful; unjustifiable[;] [g]oing beyond what is warranted or natural; excessive; disproportionate".[1278] The United States further notes that the ordinary meaning of "delay" is "hindrance to progress; (a period of) time lost by inaction or inability to proceed".[1279] Thus, in the United States' view, the ordinary meaning of "undue delay" under Annex C(1)(a) is the "unjustifiable" and "excessive" "hindrance" in undertaking or completing an approval procedure. According to the United States, the ordinary meaning of "undue delay" suggests that both the reason for the delay and its duration are relevant considerations in determining whether the delay is "undue".

7.1470 The United States argues that although it may be difficult in particular cases to decide whether approval procedures are undertaken without undue delay, an across-the-board suspension of final approvals must be considered an "undue delay" under Annex C(1)(a). The United States submits that it has been recognized by EC officials that there was no scientific basis for the failure to move forward under the procedures and timelines provided in the European Communities' own legislation.[1280] The United States also notes that many of the biotech products caught up in the general moratorium on approvals have been subject to positive assessments by the lead CA and the European Communities' own scientific committees.

7.1471 The United States considers that where the European Communities' own legislation provides procedures and timelines for the approval of biotech products, an indefinite suspension of that

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[1278] The *New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. II, p. 3480.

[1279] *Ibid*., Vol. I, p. 623.

[1280] The United States refers to the above-mentioned October 2001 news report about a statement attributed to Environment Commissioner Wallström.

approval procedures, without any scientific justification, must be considered "undue delay" under Annex C(1)(a). In the light of this, the United States submits that the imposition of a general moratorium on approvals has resulted in the European Communities breaching Annex C(1)(a) and, as a consequence, Article 8.

7.1472 **Canada** argues that the EC approval procedures suspended by the general moratorium on approvals are "approval procedures" to "check and ensure the fulfilment of sanitary or phytosanitary measures" and that the European Communities must therefore comply with Annex C(1)(a). Canada notes that Annex C(1)(a) requires that the European Communities both "undertake" and "complete" the approval procedures without "undue delay". Regarding the term "undertake", Canada submits that that term should be interpreted in the light of the steps that WTO Members are obligated to take in processing an approval application outlined in Annex C(1)(b). Annex C(1)(b) provides that Members shall ensure that:

> "[T]he standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained."

7.1473 Thus, in Canada's view, in undertaking an approval procedure, the European Communities is obligated to take the steps outlined in Annex C(1)(b) in the processing of applications under that procedure. In respect of the approval of biotech products, the European Communities is obligated to ensure that an application is examined and that the applicant is informed promptly of deficiencies identified in the application that may hinder progress through the procedure. Canada notes that the European Communities is also obligated to "complete" the approval procedures for biotech products. According to Canada, "complete" in the sense used in Annex C(1)(a) means to take a decision as to whether or not the biotech product in question will be permitted to be placed on the market.

7.1474 Regarding the term "undue delay", like the United States, Canada considers that the ordinary meaning of "undue delay" under Annex C(1)(a) is the "unjustifiable" and "excessive" "hindrance" in undertaking or completing an approval procedure. Canada considers that this interpretation suggests that both the reason for the delay and its duration are relevant considerations in determining whether the delay is "undue".

7.1475 Canada is of the view that the requirements of Annex C(1)(b) are relevant to determining whether a delay is excessive. Canada notes that Annex C(1)(b) obligates Members to ensure: that standard processing times are published; that the competent body *promptly* examines the applications for completeness and informs the applicant of deficiencies; that the competent body transmits the results of the procedures *as soon as possible*; that where there are deficiencies the competent body proceeds as far as practicable with the procedure; and that any delay is *explained* to the applicant. According to Canada, the purpose of Annex C(1)(b) is to ensure that the processing of an application proceeds as promptly as possible in the circumstances. Thus, the competent body reviewing the application is obligated to undertake the specific steps outlined in Annex C(1)(b) to process the application, in particular, the obligation to explain any delay. Canada notes that, to its knowledge, the

European Communities has failed to provide applicants for biotech products with a justifiable explanation for the delay in processing biotech approvals.[1281]

7.1476 Canada further submits that in the context of Annex C(1), the justification for a delay must be consistent with the provisions of the *SPS Agreement*, namely, that SPS measures must be based on scientific evidence. Article 2.2 of the *SPS Agreement* specifically requires that all SPS measures be "based on scientific principles" and not "maintained without sufficient scientific evidence". Thus, a delay in undertaking and completing an approval procedure is "unjustified" if the delay is caused by a measure that is not based on scientific evidence.

7.1477 According to Canada, there is no sound justification for the European Communities' failure to undertake and complete the approval procedures for biotech products. Canada considers that there is no scientific evidence upon which the general moratorium on approvals is based. Rather, the moratorium undermines the scientific inquiry required as a part of the approval procedures. Canada submits that not only is there no scientific evidence to justify the across-the-board moratorium, for many of the pending applications there is scientific evidence from the European Communities' own experts which support the approval of the product in question. Thus, in Canada's view, the delay, resulting from the moratorium, in undertaking and completing the approval procedures for biotech products is "unjustified" and "excessive". Canada considers that the fact that the general moratorium has been in place for more than five years compounds the excessiveness of the delay.

7.1478 Canada submits that, in the case of the general moratorium, the delay in undertaking and completing the approval procedures for biotech products was caused by a general suspension of those procedures. According to Canada, the *SPS Agreement* does not permit a Member to suspend existing SPS approval procedures, thereby effectively banning products with pending applications, every time that Member seeks to update its legislation. Canada considers that a suspension of an approval regime may be warranted in some circumstances, for example, if there was credible scientific evidence that the continued processing of applications under the existing regime would give rise to actual risks to human health or the environment. However, in Canada's view, this is not the case here. Canada submits that the legislative amendments, for the most part, were to implement measures to identify the occurrence of hypothetical adverse effects or to facilitate the removal of a product from the marketplace in the unlikely event of a hypothetical risk materializing, *e.g.*, monitoring for unanticipated adverse effects.

7.1479 For these reasons, Canada is of the view that, as a result of the general moratorium, the European Communities has failed to undertake and complete its approval procedures for biotech products without undue delay in violation of Annex C(1)(a). Canada further submits that as Article 8 of the *SPS Agreement* requires Members to observe the provisions of Annex C, the failure by the European Communities to adhere to the requirements of Annex C(1)(a) to undertake and complete the approval procedures for biotech product without undue delay violates Article 8.

7.1480 The **European Communities** accepts that, to the extent it addresses risks coming under Annex A(1) of the *SPS Agreement*, the approval system set up under the relevant EC legislation is a "procedure to check and ensure the fulfilment of sanitary or phytosanitary measures" within the meaning of Annex C(1). Regarding the meaning of the term "undue delay", the European Communities argues that out of the rather lengthy list of meanings of the words "undue" and "delay" as offered by the *New Shorter Oxford English Dictionary*, the United States and Canada arbitrarily

[1281] Canada notes that the unjustifiable delay to which it refers does not include the time necessary for the applicant to respond to *bona fide* questions from the competent authority or bodies responsible for the approval procedure.

settle on the choice of "an unjustifiable and excessive hindrance". While not objecting to the choice of "unjustifiable", the European Communities does not see the necessity of adding "excessive", nor does it agree with the choice of "hindrance" as opposed to, for example, "period of time lost by inaction or inability to proceed". It does, however, agree that both the reason for the delay and its duration are relevant considerations in determining whether any delay is "undue".

7.1481 Regarding Canada's argument based on Annex C(1)(b), the European Communities argues that the purpose of Annex C(1)(b) is one of transparency and is not linked in any way to the concept of "undue" in Annex C(1)(a). Annex C(1)(b) only requires Members to publish the "standard", *i.e.*, average or indicative, processing period, or to communicate to the applicant the anticipated processing period. The European Communities notes that nowhere does it say that Members must always abide by the standard processing periods foreseen in their legislation.

7.1482 The European Communities also rejects the United States' argument that an "undue delay" exists when and because the procedural deadlines set forth in the EC legislation have been exceeded. The European Communities considers it clear from a plain reading of Annex C(1)(a) that the meaning of the words "undue delay" is not to be inferred from the domestic legislation of the Members. Had the drafters of the *SPS Agreement* intended to give the words "undue delay" meaning by reference to domestic law, they would have used different wording. The European Communities submits that it is not the purpose of the *SPS Agreement* to elevate national legislation to the level of international law. Equally, it is not the role of the dispute settlement organs (but that of national courts) to enforce that legislation.

7.1483 The European Communities believes that the question of when a period of time becomes a delay is a matter of fact to be established on a case-by-case basis. In particular, in the case of approval procedures for novel products, each specific product presents characteristics and specificities that are peculiar to it. These also vary according to the specific habitat/environment in which the product is to be produced and/or marketed. In the European Communities' view, the question of time cannot, therefore, be separated from the scientific issues associated with an individual product. For the European Communities, this also confirms that any time-limits provided for in legislation setting up an approval procedure cannot be but "standard".

7.1484 The European Communities rejects the United States' and Canada's assertion that a delay is "unjustified" if it is caused by a measure that is not based on scientific evidence. The European Communities submits that delays may occur for reasons completely outside the realm of science. The European Communities offers the example of a case of *force majeure*: an earthquake destroying the building of a competent authority including all archives containing the pending applications. In the European Communities' view, any delays in re-constituting the application files would not be considered "undue" or "unjustifiable". The European Communities argues that, for the same reason, other causes for delay of a non-scientific nature, such as legislative changes or lack of resources, need to be assessed on their own merits.

7.1485 The European Communities further submits that delays caused by legitimate requests for additional information are justified and therefore not "undue". In the European Communities' view, it is legitimate to request additional information necessary for the completion of a risk assessment and/or the compliance with certain standards of risk management and risk communication which have been established by a regulator and which apply to the product in question. According to the European Communities, this applies *a fortiori* when the product at issue is based on a new technology which is generally untried and untested and which is recognised by the international community to have characteristics which inherently require prudence and caution. The European Communities

submits in this regard that the precautionary principle is to be taken into account when assessing "undueness" under Annex C(1)(a).

7.1486 In relation to the United States' and Canada's assertions that an unjustified general suspension of an approval procedure is on its face an "undue delay" within the meaning of Annex C(1)(a), the European Communities submits that, in the present case, no "undue delays" have occurred in any of the pending applications. More specifically, none of the relevant applications for the approval of biotech products has been subject to a "general suspension", and none were stalled in the approval process. In all cases, there have been scientifically valid reasons to delay the approval procedure.

7.1487 The European Communities argues that what has happened in many of these applications is that, at different stages of the procedure, requests for additional information have been put to the applicants. The European Communities submits that all of these requests were related to issues of risk assessment, risk management and sometimes risk communication concerning the individual product in question. Those requests were justified on the basis of standards of risk assessment, risk management and risk communication which not only the European Communities, but the international community has endorsed.[1282] Some of the requests focussed on risk issues falling outside the scope, others on risk issues coming within the scope of Annex A(1) of the *SPS Agreement*. Some requests were based on existing legislation, others on (stricter) requirements as set out in the European Communities' new legislation. Where requests were based on new legislation at a time where that legislation had not yet entered into force, they were conditioned on the applicant's voluntary agreement or were slightly delayed to await the entry into force of that legislation.[1283] According to the European Communities, there is nothing unusual about such an approach, which is common to many legal systems facing transitional arrangements where one set of rules is to be replaced by another.

7.1488 Moreover, the European Communities contends that to the extent there were delays, sometimes this was for reasons lying in the sphere of the applicant. In the European Communities' view, delays caused by the applicant would be justified. Where delays were caused by requests for additional information, the European Communities considers that only those delays which were caused by requests focussing on risk issues falling within the scope of Annex A(1) of the *SPS Agreement* can be reviewed by the Panel in the light of Annex C(1)(a).

[1282] The European Communities refers to the example of Codex Alimentarius, *Principles for the risk analysis of foods derived from modern biotechnology* (Exhibit EC-44). The European Communities notes that these Principles provide (i) that "a pre-market safety assessment should be undertaken following a structured and integrated approach and be performed on a case-by-case basis. The data and information, based on sound science, obtained using appropriate methods and analysed using appropriate statistical techniques, should be of a quality and, as appropriate, of a quantity that would withstand scientific peer review" (paragraph 12); (ii) that "risk management measures may include, as appropriate, food labelling, conditions for marketing approvals and post-market monitoring" (paragraph 19); and (iii) that "specific tools may be needed to facilitate the implementation and enforcement of risk management measures. These may include appropriate analytical methods; reference materials" (paragraph 21). The European Communities submits that it is clear from the detailed chronologies submitted by the European Communities that the delays – if any – in the processing of applications for the authorization of GM food under Regulation 258/97 in most, if not all, cases result either from the failure or time taken by the applicant in supplying either the qualitatively or quantitatively appropriate data for the purpose of the safety assessment, and/or the reference materials, and/or the analytical methods required for the purpose of risk management measures.

[1283] In the European Communities' view, the question of whether or not such requests could be made under the existing legislation is a question of EC law and, as such, a matter for courts in the European Communities. The European Communities submits that for the Panel, the question is whether such requests are legitimate under the standards of the *SPS Agreement*.

7.1489 Further, the European Communities submits that even if any "undue delays" may have occurred in the past, which the European Communities denies, no such "undue delays" are occurring under the new EC legislative framework.

7.1490 The **Panel** notes that the claims by the United States and Canada under Article 8 are in the nature of consequential claims. The United States and Canada claim that the European Communities has failed to observe the provisions of Annex C(1)(a), first clause, and that, as a consequence, the European Communities has also acted inconsistently with the provisions of Article 8. Therefore, the Panel will begin its analysis with the claims under Annex C(1)(a).

(a) Annex C(1)(a), first clause

7.1491 Annex C(1) establishes obligations "with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures". We have determined earlier that Directives 90/220 and 2001/18 as well as Regulation 258/97 (to the extent it seeks to prevent novel foods from being a danger for the consumer) are SPS measures within the meaning of Annex A(1). We have also determined that Directives 90/220 and 2001/18 as well as Regulation 258/97 set out procedures to check and ensure the fulfilment of one or more SPS requirements the satisfaction of which is a prerequisite for the approval to place a product on the market. It follows from these previous findings that the procedures set out in Directives 90/220 and 2001/18 as well as Regulation 258/97 (to the extent it is an SPS measure) constitute procedures "to check and ensure the fulfilment of sanitary or phytosanitary measures" within the meaning of Annex C(1). As such, they are subject to the provisions of Annex C(1), and notably those of Annex C(1)(a), first clause. Therefore, in accordance with the provisions of Annex C(1)(a), the European Communities was required during the relevant time-period (June 1999 to August 2003) to "undertake and complete" the approval procedures set out in Directives 90/220 and 2001/18 as well as Regulation 258/97 (to the extent it is an SPS measure) "without undue delay".

7.1492 We understand the United States and Canada to claim that the European Communities has failed to undertake and complete its approval procedures for biotech products without undue delay, as a result of the adoption and application of the general *de facto* moratorium on approvals. Thus, the measure being challenged is the general *de facto* moratorium on approvals, since the United States and Canada allege that the general moratorium has been the cause of undue delays in the processing of applications under the relevant EC approval legislation.

7.1493 Before evaluating the merits of the claim put forward by the United States and Canada under Annex C(1)(a), first clause, we address a number of interpretative issues.

(i) Interpretation

7.1494 Annex C(1)(a), first clause, requires Members to ensure that approval procedures are "undertaken and completed without undue delay". We first consider the meaning of the phrase "undertake and complete". The verb "undertake" makes clear that Members are required to begin, or start, approval procedures after receiving an application for approval.[1284] The verb "complete", on the

[1284] The dictionary meanings of the verb "undertake" include "[t]ake on (an obligation, duty, task, etc.); commit oneself to perform; begin (an undertaking, enterprise, etc.)". The *New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. II, p. 3476. The French and Spanish versions of Annex C(1)(a), first clause, also support this reading. The French version uses the verb "engager", the Spanish version the verb "iniciar". We also note that Annex C(1)(b) requires Members to ensure, *inter alia*, that "when receiving an application, the competent body promptly examines the completeness of the documentation and

other hand, indicates that approval procedures are not only to be undertaken, but are also to be finished, or concluded.[1285] Thus, in our view, the phrase "undertake and complete" covers all stages of approval procedures and should be taken as meaning that, once an application has been received, approval procedures must be started and then carried out from beginning to end.

7.1495 It is clear from the text of Annex C(1)(a), first clause, that not every delay in the undertaking or completion of approval procedures which is caused by a Member is contrary to the provisions of Annex C(1)(a), first clause. Only "undue" delay is.[1286] Regarding the meaning of the phrase " undue delay", we consider that of the dictionary meanings of the term "delay" which have been identified by the United States, there is one which fits naturally with the provisions of Annex C(1)(a), first clause, namely, "(a period of) time lost by inaction or inability to proceed"[1287]. So far as concerns the term "undue", of the dictionary meanings referred to by the United States we find two to be particularly relevant in the specific context of Annex C(1)(a), first clause – "[g]oing beyond what is warranted […]" and "unjustifiable". We note that the United States, Canada and the European Communities have all identified "unjustifiable" as a relevant meaning of "undue". This view is supported also by the French version of Annex C(1)(a), first clause, which refers to "retard injustifié". Thus, based on the ordinary meaning of the phrase "without undue delay", we consider that Annex C(1)(a), first clause, requires that approval procedures be undertaken and completed with no unjustifiable loss of time.

7.1496 According to the United States, Canada and the European Communities, both the reason for a delay and its duration are relevant considerations in determining whether a delay is "undue". We recall in this regard that, in our view, Annex C(1)(a), first clause, requires that there not be any unjustifiable loss of time. Thus, what matters is whether there is a legitimate reason, or justification, for a given delay, not the length of a delay as such. Accordingly, if a Member causes a relatively short, but unjustifiable delay, we do not consider that the mere fact that the delay is relatively short would, or should, preclude a panel from finding that it is "undue".[1288] Similarly, we do not consider that a demonstration that a particular approval procedure has been delayed by, say, two years would always and necessarily be sufficient to establish that the relevant procedure has been "unduly" delayed. Having said this, we note that a lengthy delay for which no adequate explanation is provided might in some circumstances permit the inference that the delay is "undue".

7.1497 In our view, a determination of whether a particular approval procedure has been undertaken and/or completed "without undue delay" must be made on a case-by-case basis, taking account of relevant facts and circumstances. We therefore consider that it would be neither possible nor useful to attempt to define the reasons which would render a given delay "undue", and those which would not render it "undue". Nevertheless, it may be noted that a Member is not legally responsible for delays

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informs the applicant in a precise and complete manner of all deficiencies". Thus, it is clear that approval procedures are "undertaken" upon receipt of an application from an applicant.

[1285] The dictionary meanings of the verb "complete" include "[b]ring to an end, finish, conclude". The *New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. I, p. 460. The French and Spanish versions of Annex C(1)(a), first clause, also support this reading. The French version uses the verb "achever", the Spanish version the verb "ultimar".

[1286] Indeed, if this had been the intended result, the text of Annex C(1)(a), first clause, would have stated that approval procedures must be undertaken and completed "without any delay".

[1287] We note that the phrase "inability to proceed" may refer to an objective inability to proceed or a perceived inability to proceed.

[1288] Indeed, we consider that where there is no justification for a delay, the provisions of Annex C(1)(a), first clause, do not permit a Member deliberately to proceed at a delayed pace, even if this is done for only a short period of time. In addition, we note that the cumulative effect of a series of short, but unjustifiable delays could be equally prejudicial to the interests of applicants as the effect of a single, long delay.

which are not attributable to it. Hence, delays attributable to action, or inaction, of an applicant must not be held against a Member when a determination is made regarding whether that Member has undertaken or completed approval procedures "without undue delay".

7.1498 Furthermore, it is pertinent to call attention to the introductory paragraph of Annex C(1). It indicates that approval procedures serve to "check and ensure the fulfilment of [SPS] measures". We consider that if approval procedures serve to check and ensure the fulfilment of SPS requirements, then Members applying such procedures must in principle be allowed to take the time that is reasonably needed to determine with adequate confidence whether their relevant SPS requirements are fulfilled, at least if these requirements are WTO-consistent. Put another way, we view Annex C(1)(a), first clause, essentially as a good faith obligation requiring Members to proceed with their approval procedures as promptly as possible, taking account of the need to check and ensure the fulfilment of their relevant SPS requirements. Consequently, delays which are justified in their entirety by the need to check and ensure the fulfilment of a Member's WTO-consistent SPS requirements should not, in our view, be considered "undue". To offer an example, if new or additional information becomes available at a late stage in an approval procedure and that information may appropriately be considered to have a potential impact on a Member's determination on whether an application fulfils that Member's relevant SPS requirements, it might be justifiable for the Member concerned to delay the completion of the procedure and give itself the additional time needed to assess the information.

7.1499 On the other hand, to offer another example, if the time taken by a Member to complete an approval procedure, or a particular stage thereof, exceeds the time that is reasonably needed to check and ensure the fulfilment of its relevant SPS requirements, for instance because the Member concerned did not proceed as expeditiously as could be expected of it in the circumstances, the delay caused in this way would, in our view, be "undue". This interpretation of Annex C(1)(a) is supported by the object and purpose of the *SPS Agreement*. The fourth preambular paragraph of the *SPS Agreement* states that one particular object and purpose of the *SPS Agreement* is "the establishment of a multilateral framework of rules and disciplines to guide the […] enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade". Annex C(1)(a), first clause, establishes disciplines concerning the "enforcement" of SPS measures, namely, approval procedures. If Annex C(1)(a), first clause, were interpreted to mean that Members need not undertake and complete their approval procedures as soon as possible under the circumstances, we think the object and purpose of minimizing negative trade effects of approval procedures could not be achieved.

7.1500 Canada argues that a delay in undertaking and completing an approval procedure must be considered "undue" if the delay is caused by a measure which is not based on scientific evidence. We would agree that delays caused by measures which are not based on scientific evidence may in some cases be considered "undue".[1289] However, we do not agree that such delays must in all cases be considered "undue". A delay in undertaking and completing an approval procedure may be caused by a temporary government shutdown in the wake of a natural disaster or civil unrest. Likewise, if a Member is confronting an unforeseeable and sharp increase in the number of products submitted for approval, this could cause a short delay in the processing of some or all pending applications, due to the need for that Member to reallocate existing resources, or to obtain additional resources, to deal

[1289] This could be the case, for example, if a delay is caused by a request for additional information which has nothing to do with the issue of whether the relevant product meets the SPS requirements concerned.

with the new situation.[1290] In both examples provided, the delay would be caused by government action, or inaction, which is not supported by scientific evidence. Yet, in our view, there is a convincing argument to be made that the delay would be needed for the Member to be able to check and ensure the fulfilment of relevant SPS requirements. Therefore, we consider that, in both cases, the delay in undertaking and completing approval procedures could properly be viewed as not "undue" and hence not inconsistent with Annex C(1)(a), first clause.

7.1501 There is one additional aspect of Annex C(1)(a), first clause, which it is appropriate to address before examining the merits of the claims before us. The phrase "without undue delay" follows the phrase "undertake and complete". We consider that the phrase "without undue delay" relates, not just to the immediately preceding verb "complete", but to both elements of the phrase "undertake and complete". In other words, we consider that Annex C(1)(a), first clause, should be read as requiring that Members must "undertake" approval procedures "without undue delay" and, subsequently, "complete" them "without undue delay". Were it otherwise, a Member could easily circumvent the requirement to complete approval procedures without undue delay by causing undue delay in the undertaking of approval procedures.

7.1502 The view that the phrase "without undue delay" relates to both elements of the phrase "undertake and complete" implies that if a Member causes undue delay at any stage in an approval procedure, this would constitute a breach of the provisions of Annex C(1)(a), first clause. In our view, there would be a breach of Annex C(1)(a) even if the Member concerned completed one or more previous stages of the approval procedure sooner than could be expected. If, contrary to our view, a Member could balance undue delay in the completion of a particular procedural stage against a period of time "saved" at an earlier stage in the approval procedure, the implication would be that in some cases a Member could temporarily delay the completion of an approval procedure even though there is no need to do so. We consider that such an interpretation of Annex C(1)(a), first clause, would not be supported by the object and purpose of the *SPS Agreement.* In particular, we consider that interpreting Annex C(1)(a), first clause, as permitting a Member temporarily to delay the completion of an approval procedure even when there is no need for a delay would not be consistent with the previously mentioned object and purpose of minimizing negative trade effects of approval procedures.

(ii) Application

7.1503 We now proceed to examine the claims of "undue delay" presented by the United States and Canada. As we have observed earlier, we understand the United States and Canada to claim that, as a result of the general *de facto* moratorium on approvals, the European Communities has failed to undertake and complete its approval procedures for biotech products without undue delay and therefore has acted inconsistently with the requirements of Annex C(1)(a), first clause. As we have also pointed out, the United States and Canada are challenging the general moratorium because they view it as a measure which has caused undue delay in the processing of applications under the relevant EC approval legislation. We recall that, for the purposes of the present dispute, the relevant EC approval legislation consists of Directives 90/220 and 2001/18 as well as Regulation 258/97.

7.1504 We consider that for the United States' and Canada's claims to succeed, the United States and Canada need not establish that each and every approval procedure which was pending at some point between June 1999 and August 2003 (the time-period for which we accepted the Complaining Parties'

[1290] Needless to say, it is Members' responsibility to allocate sufficient resources to their competent authorities so that they are in a position to discharge the obligations they have assumed under the *WTO Agreement.*

assertion about EC application of a general *de facto* moratorium on approvals) had been unduly delayed as a result of the general *de facto* moratorium on approvals. In our view, for the purposes of establishing that the European Communities has acted inconsistently with its obligations under Annex C(1)(a), first clause, it is sufficient for the United States and Canada to establish that the general *de facto* moratorium on approvals caused undue delay in at least one instance, that is to say, that it caused undue delay in the undertaking or completion of at least one approval procedure conducted in respect of a biotech product at issue in this dispute.

7.1505 We will begin our analysis by examining whether the United States and Canada have established that at least one approval procedure conducted under Directive 90/220 and/or 2001/18 was unduly delayed. If this were the case, it would have been established that, as a result of applying a general *de facto* moratorium on approvals, the European Communities acted inconsistently with its obligations under Annex C(1)(a), first clause, and we would end our inquiry under Annex C(1)(a), first clause. Otherwise, we would go on to examine, in addition, whether the United States and Canada have established that at least one approval procedure conducted under Regulation 258/97 was unduly delayed.[1291]

7.1506 Before turning to examine a particular approval procedure, however, it is well to consider whether the European Communities' reason for applying a general moratorium on final approvals could provide a justification for any delays which may have occurred in individual approval procedures as a result of the application of the moratorium.

Reason for general EC moratorium as a justification for delay

7.1507 Initially, we recall that the European Communities categorically denied that it applied a general *de facto* moratorium on approvals between June 1999 and August 2003.

7.1508 In determining the reason behind the application of the general EC moratorium, we find instructive the June 1999 declaration by the Group of Five countries. As noted by us previously, the Declaration states that, pending the adoption of new EC rules ensuring labelling and traceability of GMOs and GMO-derived products, in accordance with preventive and precautionary principles, the Group of Five countries will take steps to have any new authorizations for growing and placing on the market suspended. We infer from this that the Group of Five countries perceived the EC approval legislation in force at the time as inadequate and considered that in these circumstances prudence and caution warranted the suspension of new final approvals.[1292] Regarding the Commission, we recall our view that there is nothing to suggest that it unqualifiedly supported the decision of the Group of Five countries to prevent the final approval of applications pending the adoption of new EC rules on labelling and traceability, but that it nonetheless effectively (*de facto*) co-operated with the Group of Five countries by not making full use of the relevant, mandatory procedures to complete the approval process.

7.1509 Furthermore, we note the European Communities' assertion before this Panel that during the relevant time period (June 1999 to August 2003) relevant science was evolving and in a state of flux,

[1291] It is useful to recall that regardless of the number of approval procedures we need to examine in order to reach a conclusion on whether the application of the general EC moratorium on approvals has led to a breach of the provisions of Annex C(1)(a), first clause, there are numerous approval procedures which we are required to address in the light of the provisions of Annex C(1)(a), first clause, as part of our evaluation of the Complaining Parties' product-specific claims. *See infra*, Section VII.E.

[1292] We recall our view that the June 1999 declaration by the Group of Five countries was intended to also apply to applications concerning biotech products submitted for approval under Regulation 258/97.

and that the European Communities therefore applied a prudent and precautionary approach to identifying, assessing and managing risks to human health and the environment arising from biotech products for which marketing approval had been sought.

7.1510 In view of these elements, we will address below whether (i) the perceived inadequacy of then-existing EC approval legislation and (ii) evolving science and the application of a prudent and precautionary approach would provide a justification for delays which might have occurred as a result of the application of the general EC moratorium on final approvals.

Perceived inadequacy of EC approval legislation in force between June 1999 to August 2003

7.1511 We turn first to address the perceived inadequacy of the EC approval legislation in force between June 1999 to August 2003. As is clear from the June 1999 declaration by the Group of Five countries, the perceived inadequacy of the then-existing EC approval legislation related to the absence of EC-level legislation ensuring labelling and traceability of GMOs and GMO-derived products.[1293] The concern appears to have been that under the existing EC approval legislation it was not possible for the European Communities to impose, as a condition attached to the granting of marketing approval for GMOs and GMO-derived products, adequate requirements regarding the labelling and traceability of these products.

7.1512 Thus, the issue presented is whether it was justifiable for the European Communities to delay the completion of its approval procedures until the date of adoption of the new EC legislation ensuring labelling and traceability of GMOs and GMO-derived products.[1294] In addressing this issue, we note at the outset that, during the relevant time period (June 1999 to August 2003), approval legislation was in force in the European Communities. As the European Communities has repeatedly stated, the application of the approval legislation in question had never been suspended by a formal EC decision, *e.g.*, by the Commission or the Council and European Parliament. Nor had the granting of final approvals ever been suspended by a formal EC decision.

7.1513 We have stated above that in principle the European Communities was entitled, in conducting approval procedures concerning the biotech products at issue in this dispute, to take the time reasonably needed to determine with adequate confidence whether its relevant SPS requirements were fulfilled. However, given that the new legislation on labelling and traceability was not adopted until September 2003, any requirements set out therein were not EC requirements the fulfilment of which the European Communities could have checked during the relevant time period (June 1999 to August 2003).[1295] Furthermore, the lack of EC-level legislation ensuring labelling and traceability did not affect the European Communities' ability to *check* the fulfilment of its existing SPS requirements. Finally, even if the European Communities considered that new and additional requirements relating to labelling and traceability needed to be imposed as conditions attached to approval decisions, to *ensure* the fulfilment of existing SPS requirements (*e.g.*, the requirement to avoid long-term adverse

[1293] We recall that both Directives 90/220 (and subsequently Directive 2001/18) and Regulation 258/97 contained labelling provisions, and that Directive 2001/18 imposed a traceability obligation on member States. However, these provisions were considered inadequate.

[1294] We recall that the new legislation in question was not adopted until September 2003.

[1295] We note that Annex C(1)(h) of the *SPS Agreement* refers to "applicable" SPS regulations with which compliance is to be ensured. We further note that the European Communities did not claim that it effectively imposed the requirements later included in the new EC legislation. Rather, the European Communities stated that it sought voluntary commitments from applicants which would have ensured the labelling and traceability of GMOs and GMO-derived products.

effects on the environment), there is no reason for believing that the need for, and modalities of, such conditions could only be established in September 2003.

7.1514 Thus, we are of the view that delays in the completion of approval procedures which might have occurred as a result of the lack of EC-level legislation ensuring labelling and traceability of GMOs and GMO-derived products would not have been delays which were justified by the need to check and ensure the fulfilment of the European Communities' relevant SPS requirements.

7.1515 If the European Communities considered that it was important not to grant final approvals without imposing additional requirements of the type set out in the new EC legislation ensuring labelling and traceability of GMOs and GMO-derived products, it was open to it to try to obtain from applicants either voluntary commitments or a request for suspension of the relevant approval procedure pending the adoption of the new EC legislation.[1296] Alternatively, it could have imposed such requirements as conditions attached to approval decisions, provided the imposition of such requirements was WTO-consistent. We note the possibility that the existing EC approval legislation did not provide a clear or sufficient legal basis for imposing such new and additional requirements relating to labelling and traceability of GMOs and GMO-derived products, and that imposing such requirements might have exposed the European Communities to the risk of a domestic legal challenge. However, the European Communities has repeatedly told this Panel that it should not enforce EC law, and that the issue of compliance of certain EC action, or inaction, with EC law was a matter for EC courts to address, not this Panel. We agree and consider that following the same logic we should not make our determination of EC compliance with the requirements of Annex C(1)(a), first clause, turn on whether or not EC law permitted the European Communities to impose the new and additional requirements regarding labelling and traceability prior to the entry into force of the new legislation. The constraints imposed by EC law would not provide a justification for delays which might have occurred for this reason in the completion of approval procedures.

7.1516 Two further considerations militate in favour of our view that the lack of legislation ensuring labelling and traceability of GMOs and GMO-derived products would not have provided an *eo ipso* justification for delays which might have occurred for this reason in the completion of approval procedures. To begin with, putting in place new legislation is by nature a time-consuming process which not infrequently takes one or more years to complete.[1297] The European Communities itself stated that completing and updating its legislation "inevitably took quite some time to be completed in the light of the serious social and political debate on the issues linked to GMOs and GM food production".[1298] We also note the EC statement that legislation concerning GMOs and GMO-derived products needs to keep pace with the "constant evolution of the scientific and regulatory debate"[1299] on these products, which suggests that a need for regular adjustment and amendment of relevant legislation is to be expected. The evolution of relevant EC legislation would appear to support this statement. In these circumstances, we are concerned that if a Member could suspend and, consequently, delay the granting of final approvals essentially every time it completes and updates its approval legislation, there might be frequent and long periods of time during which final approval decisions are suspended. Incidentally, given the time required to revise legislation, a need for further revision and updating might in some cases be identified even before the previous revision has made its way through the legislative process.

[1296] The record shows that the European Communities did so in a number of approval procedures.

[1297] We note that proposals for new legislation need to be elaborated, the legislation needs to be passed by the legislature and, in some countries, there may also be a need for a popular vote on the legislation before it can be finally adopted.

[1298] EC first written submission, para. 195.

[1299] *Ibid*.

7.1517 The other consideration to be noted relates to the use of procedural delay as an instrument to manage or control risks. It is useful to illustrate this using an example. For instance, if the European Communities delayed the completion of a particular approval procedure because existing legislation precluded it from imposing a traceability requirement for a GMO which would facilitate the withdrawal of the product in the event of unforeseen adverse effects on human health or the environment, the European Communities would effectively use procedural delay as a substitute for a substantive risk management measure (the traceability requirement) that would not be imposable under existing approval legislation. In our view, however, the pursuit of a risk management objective would not justify a delay in the completion of an approval procedure and hence would be inconsistent with Annex C(1)(a), first clause. If procedural delay could be used, directly or indirectly, as an instrument to manage or control risks, then Members could evade the obligations to be observed in respect of substantive SPS measures, such as Article 5.1, which requires that SPS measures be based on a risk assessment. Clearly, we cannot interpret Annex C(1)(a), first clause, in a manner which would nullify or impair the usefulness and intended effect of other provisions of the *SPS Agreement*. Indeed, as we see it, a central purpose of Annex C(1)(a), first clause, is precisely to prevent a situation where Members avoid the substantive disciplines which Articles 2 and 5 of the *SPS Agreement* impose with respect to substantive SPS decisions by not reaching final substantive decisions on applications for marketing approval.

7.1518 In the light of the above, we conclude that the lack of EC legislation ensuring labelling and traceability of GMOs and GMO-derived products would not have provided a justification for delays which might have occurred for this reason between June 1999 and August 2003 in the completion of approval procedures.

Evolving science and application of a prudent and precautionary approach

7.1519 We now turn to consider whether evolving science and the consequent application by the European Communities of a prudent and precautionary approach would provide a justification for delays which may have occurred due to the European Communities' general suspension of final approvals between June 1999 and August 2003.

7.1520 According to the European Communities, GMOs are characterized by scientific complexity and uncertainty. The European Communities contends that during recent years scientific understanding of, and knowledge about, risks potentially arising from GMOs and GMO-derived products has evolved, but remains incomplete. The European Communities notes that many questions remain unanswered, and that there is limited experience with GMOs in terms of time and quality. The European Communities points out in this regard that only very few systematic studies have so far been conducted on indirect and long-term effects of large-scale cultivation of GMOs.

7.1521 The European Communities observes that, in view of the fact that the underlying science is still in a great state of flux, it has chosen to apply a prudent and precautionary approach to identifying, assessing and managing risks to human health and the environment arising from GMOs and GMO-derived products for which marketing approval has been sought.

7.1522 As an initial matter, we note that, in our view, Annex C(1)(a), first clause, does not preclude the application of a prudent and precautionary approach to identifying, assessing and managing risks to human health and the environment arising from GMOs and GMO-derived products. As we have said, we consider that Annex C(1)(a), first clause, allows a Member to take the time that is reasonably needed to determine with adequate confidence whether its relevant SPS requirements are fulfilled. Consistent with this, we consider that a Member which finds it appropriate to follow a prudent and precautionary approach in assessing and approving applications concerning GMOs and GMO-derived

products, might, for instance, be justified in requesting further information or clarification of an applicant in a situation where another Member considers that the information available is sufficient to carry out its assessment and reach a decision on an application.[1300] Whether a particular request is a reflection of genuine caution and prudence or whether it is a pretext to delay the completion of an approval procedure would need to be determined in the light of all relevant facts and circumstances.

7.1523 It is apparent from the foregoing observations that we perceive no inherent tension between the obligation set out in Annex C(1)(a), first clause, to complete approval procedures without undue delay and the application of a prudent and precautionary approach to assessing and approving GMOs or GMO-derived products. Nevertheless, it is clear that application of a prudent and precautionary approach is, and must be, subject to reasonable limits, lest the precautionary approach swallow the discipline imposed by Annex C(1)(a), first clause. Indeed, if a Member could endlessly defer substantive decisions on the grounds of a perceived need for caution and prudence in the assessment of applications, Annex C(1)(a), first clause, would be devoid of any meaning or effect. In applying the provisions of Annex C(1)(a), first clause, it is therefore important always to bear in mind that Annex C(1)(a), first clause, implies as a core obligation the obligation to come to a decision on an application.

7.1524 The European Communities argues that in the case of applications concerning GMOs and GMO-derived products it is difficult to come to a decision, in view of evolving science and a body of available scientific information and data that is still limited. Even if we were to accept this as an accurate description of the situation as it prevailed between June 1999 and August 2003, we consider that in the light of the provisions of Annex C(1)(a), first clause, this situation in and of itself would not warrant delays in the completion of approval procedures.

7.1525 We note in this regard that if relevant scientific evidence were insufficient to perform a risk assessment as defined in Annex A(1) of the *SPS Agreement* and as required by Article 5.1 of the *SPS Agreement*, pursuant to Article 5.7 of the *SPS Agreement*, a Member may provisionally adopt an SPS measure on the basis of available pertinent information.[1301] Contrariwise, in situations where relevant scientific evidence is sufficient to perform a risk assessment, a Member must base its SPS measure on a risk assessment. Of course, the mere fact that relevant scientific evidence is sufficient to perform a risk assessment does not mean that the result and conclusion of the risk assessment are free from uncertainties (*e.g.*, uncertainties linked to certain assumptions made in the course of the performance of a risk assessment). Indeed, we consider that such uncertainties may be legitimately taken into account by a Member when determining the SPS measure, if any, to be taken.[1302] In view of these uncertainties, a given risk assessment may well support a range of possible measures. Within this range, a Member is at liberty to choose the one which provides the best protection of human health and/or the environment, taking account of its appropriate level of protection, provided that the measure chosen is reasonably supported by the risk assessment and not inconsistent with other applicable provisions of the *SPS Agreement*, such as Article 5.6.

7.1526 As is clear from the preceding paragraph, evolving science, scientific complexity and uncertainty, and limited available scientific information or data are not, in and of themselves, grounds for delaying substantive approval decisions, and that the *SPS Agreement* does not envisage that Members in such cases defer making substantive SPS decisions. Indeed, even in cases where relevant scientific evidence does not permit the performance of a risk assessment, the *SPS Agreement*

[1300] We recall that pursuant to Annex C(1)(c) of the *SPS Agreement* information requirements must be limited to what is necessary for appropriate approval procedures.

[1301] For further analysis and explanation of the provisions of Article 5.7, *see infra*, Section VII.F.

[1302] For further analysis and explanation of the provisions of Article 5.1, *see infra*, Section VII.F.

envisages that Members take substantive SPS decisions. Certainly, such factors as evolving science and limited availability of scientific evidence affect the confidence which Members can have in the results of their assessments. But they do not inherently affect a Member's ability to reach substantive decisions on an application, particularly since a Member may take account of such factors in reaching substantive decisions.

7.1527 It is quite possible that in the situation described by the European Communities where science evolves and there is limited available scientific evidence, a deferral of substantive decisions might allow for better decisions at a later point in time, provided that appropriate analyses and research are undertaken. However, we do not consider that Annex C(1)(a), first clause, can or should be interpreted to allow Members to go into a sort of holding pattern while they or other entities undertake research with a view to obtaining additional scientific information and data. As we have stated earlier, the core obligation implied by Annex C(1)(a), first clause, is for Members to come to a substantive decision. This view is entirely consistent, and fits well with the aforementioned provisions of Article 5.1 and Article 5.7.[1303] It is important to note in this regard that the *SPS Agreement* nowhere states that substantive decisions on applications need to give a straight yes or no answer to applicants. Members may in principle grant time-limited approvals or approvals subject to other appropriate conditions. Alternatively, they may in principle decide to reject an application subject to the possibility of a review of that decision if and when relevant circumstances change. Relevant circumstances could include the state of scientific knowledge. Thus, there is no reason to consider that our interpretation of Annex C(1)(a), first clause, would prejudice Members' ability to take differentiated, proportionate action to protect human health and/or the environment from potential risks arising from GMOs or GMO-derived products.

7.1528 The European Communities argues that it did not go as far as certain other States (or parts of States) which actually adopted outright bans on trade in, and cultivation of, GMOs and/or GMO-derived products. We accept that in certain circumstances an applicant might conceivably prefer it if instead of making a prompt, but negative final approval decision, the European Communities held off on making a final approval decision and undertook further analysis, etc., which might lead to a positive approval decision. However, in our view, this does not provide a justification for delays which might have occurred as a result of the European Communities' decision unilaterally to suspend all final approval decisions. If a Member considers that a delay in the completion of an approval procedure might allow for a positive decision, it can communicate this assessment to the applicant which can then decide whether to accept a delay and ask for a suspension of the approval procedure.

7.1529 In view of the foregoing considerations, we do not consider that the mere fact that science may have been evolving during the relevant time period (June 1999 to August 2003) and the consequent adoption by the European Communities of a prudent and precautionary approach would provide a justification for delaying the completion of approval procedures by imposing a general EC moratorium on final approvals.

Conclusion

7.1530 We have concluded that (i) the perceived inadequacy of the existing EC approval legislation and (ii) evolving science and the application of a prudent and precautionary approach would not

[1303] Indeed, if a Member could delay a final approval decision on the grounds that available scientific evidence is insufficient, that Member could avoid the disciplines imposed by Article 5.7, including the requirement to seek to obtain additional information and to conduct a review of a provisional measure within a reasonable period of time.

provide a justification for delays which might have occurred as a result of the application of the general EC moratorium on final approvals.

7.1531 This conclusion does not imply, however, that the general EC moratorium on final approvals led to undue delay in the undertaking or completion of particular approval procedures. Therefore, our conclusion above does not dispense with the need to go on to examine whether the general EC moratorium led to undue delay in the undertaking or completion of at least one approval procedure conducted under Directive 90/220 and/or 2001/18.

7.1532 Before undertaking this task, we wish to note that our conclusion above should not be construed to mean that it would under no circumstances be justifiable, in the light of the provisions of Annex C(1)(a), first clause, to delay the completion of approval procedures by imposing a general moratorium on final approvals of biotech products. We consider that there may conceivably be circumstances where this could be justifiable. For instance, if new scientific evidence comes to light which conflicts with available scientific evidence and which is directly relevant to all biotech products subject to a pre-marketing approval requirement, we think that it might, depending on the circumstances, be justifiable to suspend all final approvals pending an appropriate assessment of the new evidence. The resulting delay in the completion of approval procedures might then be considered not "undue".

Approval procedure concerning MS8/RF3 oilseed rape

7.1533 We now turn to examine whether the United States and Canada have established that the general *de facto* moratorium on approvals led to undue delay in the undertaking or completion of a particular approval procedure conducted under Directive 90/220 and/or 2001/18. The United States and Canada did not express a view on which of the many relevant approval procedures conducted under Directive 90/220 and 2001/18 we should examine first. For the sake of efficiency, we have decided to begin our examination with the approval procedure concerning MS8/RF3 oilseed rape, since both the United States and Canada have also presented a product-specific claim that the completion of this particular approval procedure has been unduly delayed, contrary to the requirements of Annex C(1)(a), first clause. We will analyse these product-specific claims in Section VII.E below, when we address the various product-specific measures being challenged by the Complaining Parties.

Relationship of the approval procedure conducted under Directive 90/220 and that conducted under Directive 2001/18

7.1534 Prior to considering whether the approval procedure concerning MS8/RF3 oilseed rape has been unduly delayed as a result of the general *de facto* moratorium, we need to address the fact that like many other approval procedures, the approval procedure concerning MS8/RF3 oilseed rape was begun under Directive 90/220 but not completed by the date of repeal of Directive 90/220 (17 October 2002). To recall, applications which were pending on the date of repeal of Directive 90/220 (17 October 2002) became subject to Directive 2001/18 and therefore had to be "complemented" by the applicant in the light of the provisions of Directive 2001/18. If the applicant did so by a specified deadline (17 January 2003), approval procedures were to be undertaken in accordance with the

provisions of Directive 2001/18.[1304] In the case of MS8/RF3 oilseed rape, approval procedures were undertaken under Directive 2001/18 after the applicant had complemented its application.[1305]

7.1535 The question arises whether approval procedures undertaken under Directive 2001/18 in respect of applications which had previously been assessed under Directive 90/220 should be viewed as new approval procedures or as a continuation of the approval procedures which were not completed under Directive 90/220. In considering this issue, we find instructive that applications which were pending on the date of repeal of Directive 90/220 had to be "complemented" in accordance with Directive 2001/18. According to the European Communities, this means that applicants had to provide certain additional information as required under Directive 2001/18. They did not need to re-submit their applications in their entirety. This contention is consistent with the ordinary meaning of the term "complement". The European Communities further told the Panel that in principle a new assessment under Directive 2001/18 was required only for the additional information submitted in accordance with Directive 2001/18. Based on these elements, we consider that approval procedures undertaken under Directive 2001/18 in respect of applications which had previously been assessed under Directive 90/220 were a continuation of the approval procedures previously conducted under Directive 90/220.

7.1536 The factual determination that an approval procedure not completed under Directive 90/220 was continued under Directive 2001/18 if the applicant complemented its application leads us to the view that, for the purposes of Annex C(1)(a), first clause, an approval procedure begun under Directive 90/220 and continued under Directive 2001/18 constitutes one single approval procedure. It follows that for the purposes of our inquiry under Annex C(1)(a), first clause, it is not necessary to distinguish between undue delays which may have occurred in the processing of an application under Directive 90/220 and undue delays which may have occurred when the procedure was continued under Directive 2001/18. In either case, the relevant approval procedure would have been unduly delayed. Accordingly, we consider that in the case of the approval procedure concerning MS8/RF3 oilseed rape, a failure to observe the provisions of Annex C(1)(a), first clause, can be established on the basis of the impact of the general moratorium on that approval procedure when it was conducted pursuant to the provisions of Directive 90/220. Likewise, a failure to observe the provisions of Annex C(1)(a), first clause, can be established on the basis of the impact of the general moratorium on the approval procedure concerning MS8/RF3 oilseed rape when it was conducted pursuant to the provisions of Directive 2001/18.

Adoption of Directive 2001/18 as a justification for delay

7.1537 An additional issue relating to the revision of Directive 90/220 which we briefly need to consider is whether the adoption in March 2001 of Directive 2001/18 could have justified delaying the completion of approval procedures conducted under Directive 90/220 so that as of October 2002 they would become subject to the new provisions of Directive 2001/18.

7.1538 We note that this issue is similar to the one we have already examined above concerning the lack of EC-level legislation ensuring labelling and traceability of GMOs and GMO-derived products, and we therefore offer only a few additional observations.

[1304] Article 35 of Directive 2001/18. None of the Complaining Parties questioned the WTO-consistency of Article 35.

[1305] It should be noted, however, that in the case of MS8/RF3 the applicant had voluntarily updated its Directive 90/220 application to comply with requirements set out in Directive 2001/18 even before the entry into force of Directive 2001/18.

7.1539 We have stated above that in principle the European Communities was entitled, in conducting approval procedures concerning the biotech products at issue in this dispute, to take the time reasonably needed to determine with adequate confidence whether its relevant SPS requirements were fulfilled. However, given that Directive 2001/18 did not enter into force until October 2002, any requirements set out therein were not, in our view, EC requirements the fulfilment of which the European Communities needed to check and ensure as of March 2001 in order to complete approval procedures pending under Directive 90/220, the Directive in force at the time.[1306] We further note that the European Communities did not claim that it effectively imposed the requirements of Directive 2001/18 as of the time of their adoption in March 2001.[1307] Rather, the European Communities stated that it sought voluntary commitments from applicants.

7.1540 Thus, we consider that the adoption in March 2001 of Directive 2001/18 could not have justified delaying the completion of approval procedures conducted under Directive 90/220 so that as of October 2002 they would become subject to the new provisions of Directive 2001/18, given that such delay would not have been needed to check and ensure the fulfilment of the European Communities' relevant SPS requirements. However, we consider that in those cases where approval procedures could not be completed while Directive 90/220 was still in force, delays in the completion of these procedures might have been justifiable.

Examination of the approval procedure concerning MS8/RF3 oilseed rape

7.1541 With the preceding observations in mind, we now turn to examine whether the approval procedure concerning MS8/RF3 oilseed rape has been unduly delayed, and if so, whether this was as a result of the application of the general *de facto* moratorium, as the United States and Canada claim.

7.1542 The **United States** initially argued that the progress of the application concerning MS8/RF3 oilseed rape stalled when the Commission refused to submit a draft measure to the Regulatory Committee as required by the approval process. Later, the United States argued that the Regulatory Committee twice failed to vote on a draft measure, and that after the second attempt the Commission never submitted a draft measure to the Regulatory Committee again. The United States submits that the resulting delay was undue.

7.1543 The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years. In contrast, the application concerning MS8/RF3 oilseed rape had been pending for almost seven years on the date this Panel was established. The United States contends that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning MS8/RF3 oilseed rape is undue.

[1306] We note that Annex C(1)(h) of the *SPS Agreement* refers to "applicable" SPS regulations with which compliance is to be ensured. We further note that the European Communities did not claim that it effectively imposed the requirements later included in the new EC legislation. Rather, the European Communities stated that it sought voluntary commitments from applicants which would have ensured the labelling and traceability of GMOs and GMO-derived products. Finally, we note that if the European Communities effectively imposed such requirements, then compliance would these requirements should have resulted in the completion of relevant approval procedures. However, the record does not indicate that this was the case.

[1307] We note that if the European Communities had effectively imposed such requirements, then compliance would these requirements should have resulted in the completion of relevant approval procedures. However, the record does not indicate that this was the case, even though there were applicants which voluntarily complied with requirements set out in Directive 2001/18.

7.1544 **Canada** submits that the applicant proposed and continuously revised its risk management measures in response to concerns expressed by member States, the SCP and the Commission. Regardless of these efforts by the applicant, the processing of the application has been delayed, which Canada believes demonstrates that the European Communities was and is intent on blocking the approval of this product for cultivation and is intent on imposing such onerous and unnecessary conditions as to make the importation of the product for processing uneconomical.

7.1545 Canada argues that since the application went to the Community level, member States took approximately 12 months to put forth their objections to the application, and after the SCP issued its positive opinion on the application, the European Communities took another 12 months to address recommendations contained in the SCP opinion, including a monitoring plan. Although the application was discussed at the Regulatory Committee in the summer of 1999, no vote was taken. Canada notes that in August 1999 the applicant proposed to voluntarily agree to meet the requirements of the Council's June 1999 Common Position. On the basis of these commitments, the Commission invited the applicant to present its proposal to the Regulatory Committee in October 1999. However, while the Regulatory Committee again considered the proposal, it failed to hold a vote. Subsequently, the applicant made further proposals as a further attempt to address concerns expressed by member States. However, although the matter went yet again before the Regulatory Committee in March 2000, it failed to hold a vote.

7.1546 Canada also claims that any delay in the completion of the approval procedure following the failure of the Regulatory Committee to adopt the draft measure approving MS8/RF3 oilseed rape in March 2000 should be considered "undue". Canada notes in this regard the efforts made by the applicant to respond to further requests by the lead CA. Canada observes that while the lead CA finally accepted the applicant's proposed post-marketing monitoring plan and agricultural guidelines in May 2002, the European Communities provided no information to explain the delay between May 2002 and early January 2003, when the applicant submitted a further updated dossier under Article 35 of Directive 2001/18.

7.1547 Finally, Canada observes that more than eight years after the application was initially submitted for approval to the lead CA in 1996 and more than six years after the SCP issued its opinion in May 1998, MS8/RF3 oilseed rape remains unapproved either for import and processing or cultivation, despite reasonably available risk management measures. Canada submits that by any reasonable standard, the extraordinary length of time to process this application constitutes "undue delay".

7.1548 The **European Communities** argues that the United States is mistaken in saying that the Commission failed to submit a draft measure to the Regulatory Committee. The Commission launched a voting procedure in the Regulatory Committee in June 1999, and the Regulatory Committee met twice on the matter. According to the European Communities, the Regulatory Committee did not vote on 9 March 2000 because Italy raised scientific issues regarding the effects of the product in question on biogeochemical cycles and on food chains and the likelihood of spreading. The European Communities also states that in May 2001, the applicant modified the scope of its application, and that after that, the application proceeded with further submissions by the applicant of additional information.

7.1549 **Canada** notes that Italy's questions had already been addressed in the application dossier and by the SCP. Further, the attempts to raise concerns about impacts of herbicide use on farmland biodiversity inappropriately linked concerns related to herbicide use to approval of a seed variety. Canada notes that: 1) for all other seed varieties, seed approval legislation is distinct from the pesticide approval legislation; 2) herbicide use is one of many factors that may have an impact on

farmland biodiversity; and 3) EC member States have actually authorized the use of glufosinate-ammonium for general use as well as for specific use on genetically modified herbicide-tolerant crops. Canada also counters that the European Communities fails to point out that the submission of further information by the applicant was necessary because the information requirements were either unclear or changing.

7.1550 The **Panel** begins its analysis by addressing the United States' and Canada's arguments concerning the Commission's failure to re-convene the Regulatory Committee for a further meeting.

7.1551 We recall in this regard that the Regulatory Committee met twice, on 29 October 1999 and on 9 March 2000, to consider a draft measure submitted by the Commission. No vote was taken on the draft measure at either meeting and the Regulatory Committee did not meet again for another attempt at taking a vote on the application.

7.1552 The record does not indicate why the Regulatory Committee did not proceed to a vote on MS8/RF3 oilseed rape at the March 2000 meeting.[1308] One reason may have been a request for information from the Italian CA. Italy transmitted its request to the lead CA on 14 March 2000, and the lead CA then forwarded it to the applicant.[1309] In November 2000 the applicant provided the lead CA with answers to the questions raised by Italy indicating that all the issues raised had been previously addressed by the SCP as well as the update of the application provided by the applicant in November 1999. This communication was also circulated to the other CAs and the Commission.[1310]

7.1553 It should further be noted that in June 2001 the applicant sent a letter to the lead CA which clarified certain aspects of the application, including its scope. There is no indication that this clarification had been requested. However, the applicant's letter noted that following the March 2000 meeting of the Regulatory Committee the clarification appeared necessary.[1311] In a separate letter of the same date, "following the revision of Directive 90/220/EEC", the applicant also submitted updated information to the lead CA, including an updated environmental risk assessment, a post-market monitoring plan, agricultural guidelines, additional information regarding identification and labelling and information for the public concerning the product in question.[1312] The letter stated that this information confirmed that the application was already "in line with the main provisions" of Directive 2001/18, which had been adopted in March 2001. The letter requested the lead CA to inform the other member States about the new set of documents at the next Regulatory Committee meeting.[1313] There is no indication that the lead CA ever forwarded the new documents to the other member States and the Commission. A meeting of CAs was held two weeks after the applicant submitted the additional information, but the Panel has no information about what was discussed at that meeting. It is clear from the record, however, that the lead CA confirmed receipt of the new documents only in July 2001. The lead CA informed the applicant that it had forwarded the documents to the relevant scientific committee of the Belgian Biosafety Council (hereafter the "BBC") for an opinion.[1314] No reason was given for why an opinion had been requested.

[1308] The record contains a summary of the conclusions for the October 1999 Regulatory Committee meeting, but not for the March 2000 meeting.

[1309] Exhibit EC-63/At. 87. This fax of 14 March 2000 from the Italian CA to the lead CA specifically "refer[s] to the conclusion of the last meeting of the Regulatory Committee meeting".

[1310] Exhibit EC-63/At. 89 and 90.

[1311] Exhibit EC-63/At. 92.

[1312] Exhibit EC-63/At. 91.

[1313] *Ibid*.

[1314] Exhibit EC-63/At. 93.

7.1554 The Panel notes that after the March 2000 meeting of the Regulatory Committee, it was incumbent on the Commission to take action. Specifically, Article 21 of Directive 90/220 indicates that the action to be taken by the Commission was to convene another meeting with a view to obtaining a vote on its draft measure. The question thus arises whether the Commission was justified in not convening another meeting at any point prior to the repeal of Directive 90/220 in October 2002.

7.1555 In approaching this question, the Panel takes note of the following elements. In November 2000 the applicant had met all requests for information conveyed to it following the March 2000 Regulatory Committee. The additional information was circulated to all CAs and the Commission in December 2000. As noted, however, in June 2001 the applicant provided additional clarification and updated information to the lead CA. The record does not indicate that the Commission was made aware of the existence of the June 2001 information. At the same time, there is nothing in the record to suggest that the Commission was "waiting" for the June 2001 information.

7.1556 Regarding the clarification provided by the applicant in June 2001, we note that if the Commission was not waiting for that clarification, then that clarification could not provide a justification for the Commission's failure to re-convene the Regulatory Committee sometime between December 2000 and June 2001. On the other hand, if the Commission had been waiting for clarification from the applicant, it should have inquired with the lead CA whether the applicant had provided clarification. There is no evidence that the Commission did so.

7.1557 Regarding the updated information also provided by the applicant in June 2001, it is important to remember that the applicant provided that information, not pursuant to a requirement flowing from the provisions of Directive 90/220, but in an effort to convince member States to vote in favour of approving its application. Also, the lead CA had not been requested to offer an assessment of that additional information before transmitting it to the other member States and the Commission. Notwithstanding this, the lead CA requested an opinion of the BBC. However, it seems that for the BBC, it was not obvious that an opinion was needed. In November 2001, the BBC discussed the information in question. According to the minutes of the internal discussion, "no opinion on the part of the Biosafety Advisory Council was necessary prior to the forwarding of these documents to the European Commission; and in the past such additional information had already been sent straight to the Commission on several occasions."[1315] However, as this was the first time a company had submitted a monitoring plan, agricultural guidelines and public dossier, the BBC "thought it advisable to ask the Biosafety Advisory Council to discuss these documents before forwarding them to the European Commission."[1316] It was noted that in this way the relevant experts would have an opportunity to gain experience in the evaluation of such documents.[1317]

7.1558 We are not convinced that a lead CA assessment of the updated information was required before that information could be transmitted to the Commission and the other CAs, and that the Commission therefore needed to wait for the lead CA's assessment before re-convening the Regulatory Committee. Indeed, we note that in a parallel situation, a different lead CA did not find it necessary to make an assessment of additional information submitted by an applicant to demonstrate that its application was already in line with the main provisions of Directive 2001/18.[1318]

[1315] Exhibit EC-63/At. 102.
[1316] *Ibid*.
[1317] *Ibid*.
[1318] *See* our earlier analysis in Section VII.D of the approval procedure concerning Falcon oilseed rape.

7.1559 In any event, in the approval procedure concerning MS8/RF3 oilseed rape, the applicant replied to the last pending question of the BBC in early May 2002.[1319] The record shows no further developments in this approval procedure until October 2002, when Directive 90/220 was repealed. Thus, there is no indication that the BBC ever provided its opinion on the June 2001 information to the lead CA. Even assuming that the Commission knew about the updated information of June 2001, and even assuming that it was justifiable in principle for the Commission to let the lead CA undertake some assessment of the information, it remained the Commission's responsibility to seek a vote by the Regulatory Committee on its draft measure. Yet even as the date of repeal of Directive 90/220 was approaching, the Commission apparently did not request the lead CA promptly to finish its assessment of the updated information and to circulate it together with that information so that a further attempt at completing the approval procedure under Directive 90/220 could be made.[1320]

7.1560 In view of these elements, we consider that if the Commission had sought the circulation of the additional information once the applicant had replied to the last pending question in May 2002, it should have been possible for the information to be circulated promptly and for a Regulatory Committee meeting to be held in the summer of 2002 at the latest. As Directive 90/220 was not repealed until mid-October 2002, we think this would have left enough time for the Commission to adopt its draft measure in the event of a favourable vote in the Regulatory Committee and for the lead CA to give its written consent.[1321]

7.1561 In earlier findings, the Panel observed that the Commission could have considered that some member States simply did not wish to see the Commission call another vote on its draft measure, or that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not have achieved the required qualified majority, with the consequence that the Commission would have to complete the procedure by adopting its own draft measure. In the Panel's view, neither consideration would provide a justification for the Commission's failure to re-convene the Regulatory Committee for a third meeting.

7.1562 Anticipated member State opposition might well have been a concern for the Commission in view of the consequences it could have had for the legitimacy and acceptability of an eventual decision by the Commission to approve its own draft measure. However, this would not have justified the Commission in suspending the approval process until it was confident that its draft

[1319] Exhibit EC-63/At. 108. The applicant also indicated readiness to follow a suggestion by the BBC regarding information to the public, subject to further clarification by the BBC. *Ibid.*

[1320] If the Commission did not know about the updated information submitted by the applicant in June 2001, then the existence of that information could not provide a justification for the Commission's failure to re-convene the Regulatory Committee after December 2000.

[1321] The Commission might have considered that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority and that the Commission would then have to complete the procedure by adopting its draft measure. Even assuming that in this scenario there was not enough time for the Commission to complete the procedure in question while Directive 90/220 was still in force, the Panel does not consider that this would have justified the Commission's failure to re-convene the Regulatory Committee for a vote. The Commission might have anticipated a "blocking minority" on the basis of the June 1999 declaration by the Group of Five countries. As pointed out above, there is no indication that the June 1999 declaration was intended to bind the Governments of the Group of Five countries *vis-à-vis* other member States or the Commission. In other words, the Group of Five countries retained the freedom under EC law to vote in favour of applications in the Regulatory Committee and Council. In the light of this, the Commission could not have legitimately invoked the June 1999 declaration as a justification for not re-convening the Regulatory Committee.

measure would achieve a qualified majority in the Regulatory Committee.[1322] Were it otherwise, the obligation to complete approval procedures without undue delay would impose no real discipline as the Commission could then suspend approval procedures every time it anticipates significant member State opposition and regardless of whether there are valid reasons for such opposition.

7.1563 Regarding the possibility that certain member States might have been reluctant to proceed to a vote on the Commission's draft measure, it should also be noted that if the Commission was aware of the existence of the updated information of June 2001, then that information would have provided it with additional arguments for seeking a vote on its draft measure in the Regulatory Committee. To recall, the applicant submitted the June 2001 information to demonstrate that the application concerning MS8/RF3 was already in accordance with the main provisions of the new Directive 2001/18.

7.1564 Based on the above considerations, the Panel is of the view that at the very latest in the summer of 2002 the Commission should have re-convened the Regulatory Committee for a vote on the application concerning MS8/RF3 oilseed rape. Accordingly, the Panel concludes that the time actually taken by the Commission to convene the Regulatory Committee for a further meeting – no meeting was held between March 2000 and October 2002 – was unjustifiably long.

7.1565 Turning now to the reason for the Commission's failure to act, we recall the United States' and Canada's claim that the approval procedure concerning MS8/RF3 oilseed rape was delayed as a result of the application by the European Communities of the general *de facto* moratorium on approvals. We recall in this respect our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to re-convene the Regulatory Committee for a vote on the application concerning MS8/RF3 oilseed rape after November 2001 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States and Canada that it is reasonable to infer that the Commission's inaction was a consequence of the general moratorium on approvals.

7.1566 In view of our conclusion with regard to the Commission's failure to re-convene the Regulatory Committee for a vote on a draft measure, we do not go on to address other arguments put forward by the United States and Canada in support of their assertion that the approval procedure concerning MS8/RF3 oilseed rape was unduly delayed as a result of the application of a general *de facto* moratorium on approvals.

Conclusions

7.1567 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to convene the Regulatory Committee for a further meeting – no meeting was convened between March 2000 and October 2002 – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's inaction was a consequence of the general moratorium on approvals.

[1322] The record does not indicate, and the European Communities did not argue, that the Commission after the March 2000 meeting of the Regulatory Committee launched inter-service consultations to reconsider the relevant draft measure.

Based on these findings, the Panel accepts the United States' contention that the application by the European Communities of a general *de facto* moratorium on approvals led to "undue delay" in the completion of the approval procedure concerning MS8/RF3 oilseed rape and, consequently, to a breach of the European Communities' obligations under Annex C(1)(a), first clause, of the *SPS Agreement*.

(ii) DS292 (Canada)

With reference to DS292, the Panel recalls its findings that the time taken by the Commission to convene the Regulatory Committee for a further meeting – no meeting was convened between March 2000 and October 2002 – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's inaction was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts Canada's contention that the application by the European Communities of a general *de facto* moratorium on approvals led to "undue delay" in the completion of the approval procedure concerning MS8/RF3 oilseed rape and, consequently, to a breach of the European Communities' obligations under Annex C(1)(a), first clause, of the *SPS Agreement*.

7.1568 Since we have concluded that the general *de facto* moratorium on approvals led to undue delay in the completion of at least one approval procedure conducted in respect of a biotech product at issue in this dispute, we need not, and thus do not, proceed to examine whether the general *de facto* moratorium on approvals led to undue delay in the undertaking or completion of other individual approval procedures conducted under either Directives 90/220 and 2001/18 or Regulation 258/97.

(b) Article 8

7.1569 We recall that the United States and Canada seek to establish an inconsistency with Article 8 of the *SPS Agreement* on the basis of an inconsistency with Annex C(1)(a). Article 8 requires, *inter alia*, that Members observe the provisions of Annex C in the operation of their approval procedures. It follows that a failure to observe the provisions of Annex C(1)(a) implies a breach of Article 8. We have determined above that, as a result of the general *de facto* moratorium on approvals, the European Communities has failed, in at least one approval procedure conducted under Directives 90/220 and 2001/18, to observe the provisions of Annex C(1)(a), first clause. Accordingly, we conclude that in respect of the aforementioned approval procedure, the European Communities has, by implication, also acted inconsistently with the provisions of Article 8.

(c) Overall conclusions

7.1570 The foregoing findings and conclusions lead the Panel to the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence submitted by the United States and the European Communities, the Panel concludes that as a result of the application of a general *de facto* moratorium on approvals between June 1999 and August 2003 the European Communities has failed to observe the provisions of Annex C(1)(a), first clause, of the *SPS Agreement* and, consequently, has also acted inconsistently with its obligations under Article 8 of the *SPS Agreement*.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence submitted by Canada and the European Communities, the Panel concludes that as a result of applying a general *de facto* moratorium on approvals between June 1999 and August 2003 the European Communities has failed to observe the provisions of Annex C(1)(a), first clause, of the *SPS Agreement* and, consequently, has also acted inconsistently with its obligations under Article 8 of the *SPS Agreement*.

12. Consistency of the general *de facto* moratorium on approvals with Article 8 and Annex C(1)(b) of the *SPS Agreement*

7.1571 Only the United States claims that by applying a general *de facto* moratorium on approvals, the European Communities has acted inconsistently with its obligations under Article 8 and Annex C(1)(b) of the *SPS Agreement*.

7.1572 Article 8 of the *SPS Agreement* provides:

> "Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement."

7.1573 Annex C(1)(b) of the *SPS Agreement* provides:

> "Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:
>
> [...]
>
> (b) the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained [...]."

7.1574 Annex C(1)(b) essentially sets out five separate, but related, obligations to be observed by Members in the operation of approval procedures. These obligations relate to:

(i) the publication or communication to applicants of the processing period of each procedure;

(ii) the examination of the completeness of the documentation and the communication to applicants of deficiencies;

(iii) the transmission of the results of the procedure;

(iv) the processing of applications which have deficiencies; and

(v) the provision of information about the stage of a procedure and the provision of an explanation of any delay.

7.1575 The **United States** argues that the general moratorium on approvals is an unpublished, non-transparent measure under which the European Communities does not allow its approval procedures to proceed to conclusion. As such, the general moratorium is inconsistent, in the United States' view, with each of the related procedural obligations in Annex C(1)(b) and, consequently, with Article 8 as well.

7.1576 Regarding the *first obligation* (publication or communication of processing period), the United States submits that although the applicable EC approval legislation contain processing periods, under the general moratorium on approvals those processing periods are not followed. Instead, the European Communities has imposed an indefinite delay. However, since the European Communities does not acknowledge the moratorium, the standard processing period is not published, and the anticipated processing period is not communicated to the applicant.

7.1577 Regarding the *second obligation* (completeness of documentation), the United States argues that under the general moratorium on approvals the European Communities does not promptly examine documentation and inform the applicant of all deficiencies. To the contrary, applications under the applicable EC legislation are stalled, without explanation.

7.1578 Regarding the *third obligation* (transmission of results), the United States argues that under the general moratorium on approvals results of procedures are not promptly communicated to applicants so that corrective action may be taken. Instead, applications are stalled in the approval process without explanation.

7.1579 Regarding the *fourth obligation* (processing of deficient applications), the United States argues that under the general moratorium on approvals the European Communities does not proceed as far as practicable in the approval process. Instead, applications are stalled in the approval process.

7.1580 Regarding the *fifth obligation* (explanation of delay), the United States argues that under the general moratorium on approvals delays are not explained. To the contrary, the European Communities does not even inform applicants of the existence of the general moratorium.

7.1581 The **European Communities** submits that the United States has offered a mere assertion that the European Communities has not done what it is required to do under the different obligations contained in Annex C(1)(b). The United States considers it sufficient simply to allege that applications were stalled in the approval process and gives no explanations. However, it is a complaining party's burden to establish a prima facie case. In any event, in the European Communities' view, the detailed chronologies of individual approval procedures and other documents submitted by the European Communities demonstrate that the allegations of the United States are unfounded.

7.1582 The **Panel** notes that in accordance with the lead-in to Annex C(1) the provisions of Annex C(1)(b) apply "with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures". We have previously found that the procedures set out in Directives 90/220 and 2001/18 as well as Regulation 258/97 (to the extent it is an SPS measure) constitute procedures

"to check and ensure the fulfilment of sanitary or phytosanitary measures" within the meaning of Annex C(1) and, as such, are subject to the provisions of Annex C(1), which include those of Annex C(1)(b).

7.1583 The measure being challenged by the United States is the European Communities' general *de facto* moratorium on approvals. We understand the United States to claim that the adoption and application of the general *de facto* moratorium on approvals has resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(b).

7.1584 We also note that the United States relies on the alleged breach of the provisions of Annex C(1)(b) to make a consequential claim of inconsistency under Article 8. Accordingly, we will begin our analysis with the United States' claims under Annex C(1)(b).

(a) First obligation in Annex C(1)(b) (publication or communication of processing period)

7.1585 In relation to the first obligation contained in Annex C(1)(b) (publication or communication of processing period), the United States puts forward two main arguments. The first argument is that as a result of the general moratorium on approvals, the European Communities did not follow the standard processing periods which are published in the applicable EC approval legislation. The United States appears to infer from this that the effective standard processing periods have not been published.

7.1586 We understand the United States to argue that the failure by the European Communities to consider a particular application for final approval meant that it was not following the published standard processing period for the relevant type of procedure and that the effective standard processing period for the relevant type of procedure was no longer published.

7.1587 Even if we were to accept that what has to be published in accordance with the first obligation in Annex C(1)(b) is the "effective" standard processing period, and that the general moratorium on approvals effectively modified the European Communities' published standard processing periods, the fact that they were unpublished would not be a consequence of the measure at issue, *i.e.*, the general moratorium. Rather, it would be a consequence of a separate and independent failure by the European Communities to publish the new standard processing periods. This is confirmed by the fact that the European Communities could apply the general moratorium on approvals and at the same time publish any new standard processing periods.

7.1588 In the light of this, we conclude that the United States has failed to establish its claim under the first obligation contained in Annex C(1)(b), insofar as that claim is based on the requirement to publish standard processing periods.

7.1589 The United States' second argument in support of its claim under Annex C(1)(b) is that since the European Communities does not acknowledge the moratorium, the anticipated processing period is not communicated to the applicant. We note that pursuant to Annex C(1)(b) the anticipated processing period is to be communicated to the applicant "upon request". The United States has provided no evidence to show (i) that an applicant requested that the anticipated processing period be communicated to it, (ii) that the request was denied by a relevant EC entity, and (iii) that this was because of the general moratorium on approvals. Moreover, we do not think that the general moratorium on approvals necessarily resulted in the European Communities not communicating the anticipated processing periods to applicants upon request. The European Communities could apply the general moratorium on approvals and at the same communicate to applicants the anticipated processing periods upon request.

7.1590 In the light of this, we conclude that the United States has failed to establish its claim under the first obligation contained in Annex C(1)(b), insofar as that claim is based on the requirement to communicate to applicants anticipated processing periods.

(b) Second obligation in Annex C(1)(b) (completeness of documentation)

7.1591 Concerning the second obligation contained in Annex C(1)(b), the United States argues that because of the general moratorium on approvals the European Communities did not promptly examine the completeness of documentation and inform applicants of any deficiencies.

7.1592 We note that the United States has identified no concrete evidence to support this assertion.[1323] Moreover, we do not think that the general moratorium on approvals necessarily resulted in the European Communities not examining promptly the completeness of documentation and not informing applicants of any deficiencies. The European Communities could apply the general moratorium on approvals and at the same time examine the completeness of documentation and inform applicants of deficiencies in the documentation submitted.[1324]

7.1593 In the light of this, we conclude that the United States has failed to establish its claim under the second obligation contained in Annex C(1)(b).

(c) Third obligation in Annex C(1)(b) (transmission of results)

7.1594 With regard to the third obligation contained in Annex C(1)(b), the United States argues that under the general moratorium results of procedures were not promptly communicated to applicants so that corrective action could be taken.

7.1595 We note that the United States has not identified any results of procedures which were not transmitted to an applicant as soon as possible and in a precise and complete manner. Moreover, we do not think that the general moratorium on approvals necessarily resulted in the European Communities not transmitting as soon as possible, and in a precise and complete manner, the results of approval procedures. Furthermore, it should be recalled that under the general moratorium, the European Communities prevented final results from being achieved. Thus, there were no final results which could have been communicated to applicants.

7.1596 In the light of this, we conclude that the United States has failed to establish its claim under the third obligation contained in Annex C(1)(b).

(d) Fourth obligation in Annex C(1)(b) (processing of deficient applications)

7.1597 In relation to the fourth obligation contained in Annex C(1)(b), the United States argues that under the general moratorium the European Communities did not proceed as far as practicable in the approval process.

[1323] It is well to recall in this context that it is not incumbent on us to search the record for evidence which would assist the United States in establishing a prima facie case of inconsistency with one or more of the obligations contained in Annex C(1)(b).

[1324] It is well to recall that the United States itself has stated that "the moratorium was a decision by the EC not to move products to a *final* decision in the approval process. Certain progress in the process, short of final decision, is not the least bit inconsistent with a moratorium on final approvals". US second written submission, para. 51 (emphasis in original).

7.1598 We note that pursuant to Annex C(1)(b) the competent body is to proceed as far as practicable with the procedure "if the applicant so requests". The United States has provided no evidence of an applicant making such a request and of a relevant EC entity denying that request because of the general moratorium. Moreover, we do not think that the general moratorium on approvals necessarily resulted in the European Communities not proceeding as far as practicable with procedures if applicants so requested. The European Communities could apply the general moratorium on approvals and at the same time proceed as far as practicable with procedures upon request.[1325]

7.1599 In the light of this, we conclude that the United States has failed to establish its claim under the fourth obligation contained in Annex C(1)(b).

(e) Fifth obligation in Annex C(1)(b) (explanation of delay)

7.1600 Regarding the fifth obligation contained in Annex C(1)(b), the United States argues that under the general moratorium delays were not explained.

7.1601 The fifth obligation states that "upon request" the applicant is to be informed of the stage of the procedure, with any delay being explained. The United States has provided no evidence of an applicant making such a request and of a relevant EC entity denying an explanation of any delay because of the general moratorium. Moreover, we do not think that the general moratorium on approvals necessarily resulted in the European Communities not informing applicants of the stage of procedures and not explaining any delays, if applicants so requested. The European Communities could apply the general moratorium on approvals and at the same time inform applicants of the stage of procedures and explain any delays.

7.1602 In the light of this, we conclude that the United States has failed to establish its claim under the fifth obligation contained in Annex C(1)(b).

(f) Article 8

7.1603 Turning now to the United States' claim under Article 8, we recall that the United States seeks to establish an inconsistency with Article 8 on the basis of an alleged inconsistency with Annex C(1)(b). We have determined that the United States has failed to establish its claims under Annex C(1)(b). Under the approach followed by the United States, this means that the consequential claim under Article 8 has not been established either.

(g) Overall conclusion

7.1604 In the light of the above, the Panel reaches the following conclusion:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence submitted by the United States and the European Communities, the Panel concludes that the United States has not established that the European Communities has acted inconsistently with its obligations under Annex C(1)(b) of the *SPS Agreement* and,

[1325] Here again, it is useful to recall that the United States itself has stated that "the moratorium was a decision by the EC not to move products to a *final* decision in the approval process. Certain progress in the process, short of final decision, is not the least bit inconsistent with a moratorium on final approvals". US second written submission, para. 51 (emphasis in original).

consequently, with its obligations under Article 8 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

13. Consistency of the general *de facto* moratorium on approvals with Article 10.1 of the *SPS Agreement*

7.1605 Argentina claims that the general *de facto* moratorium on approvals applied by the European Communities has failed to take account of Argentina's special needs as a developing country Member and thus is inconsistent with Article 10.1 of the *SPS Agreement*.

7.1606 Article 10.1 provides:

> "In the preparation and application of sanitary or phytosanitary measures, Members shall take account of the special needs of developing country Members, and in particular of the least-developed country Members."

7.1607 **Argentina** argues that Article 10.1 required the European Communities to take positive action in favour of developing countries. According to Argentina, in preparing and applying a general *de facto* moratorium on approvals, the European Communities should have provided preferential market access for developing country products or implemented its obligations in a manner beneficial, or less detrimental, to the interests of developing country Members. Argentina argues that the general moratorium on approvals had the effect of preventing Argentina's biotech products from having access to the EC market. According to Argentina, this had implications particularly for Argentina's economic development as Argentina is: (i) highly dependent on agricultural exports, (ii) the world's second-largest producer of biotech products, (iii) the world's leading developing country producer of biotech products. Argentina further points out that the EC market is an integrated market consisting of twenty-five member State markets and that the EC market is therefore of great importance for Argentina. Argentina considers that the fact that the general moratorium on approvals prevented its biotech products from having access to the EC market demonstrates that the European Communities has not taken account of the special needs of Argentina.

7.1608 The **European Communities** states that it bears in mind the provisions concerning special and differential treatment of developing country Members when developing and applying its legislation, including, where relevant, its approval legislation for biotech products. The European Communities notes that Argentina's argument seems to be that since the European Communities, in Argentina's view, has violated other WTO provisions and this affects Argentina as a developing country, the European Communities has consequently also failed to comply with Article 10.1. Furthermore, the European Communities does not accept the factual assertion of Argentina that the measure it is complaining about restricts exports of developing country Members to the European Communities. Trade statistics show that imports from developing countries that produce agricultural biotech products have not decreased. On the contrary, imports into the European Communities from Argentina or Brazil of commodities likely to contain genetically modified organisms have steadily increased since 1995/96.

7.1609 **Argentina** does not agree that Article 10.1 needs to be observed only "where relevant". It does not give Members the discretion to take account of the needs of developing country Members or not. Argentina further argues that the European Communities has not provided any evidence proving that it has taken into account Argentina's special needs as a developing country Member when preparing and applying its legislation. The legislation does not contain any reference to the special needs of developing country Members. Moreover, for the entire period of application of the general *de facto* moratorium on approvals, Argentina cannot identify any evidence which would permit the

conclusion that the European Communities has taken account of Argentina's special needs in the context of the approval procedures of interest to Argentina. In addition, the European Communities is incorrect when it suggests that Argentina is making a consequential claim under Article 10.1. Finally, Argentina notes that the trade statistics referred to by the European Communities have not been submitted to the Panel. In any event, those statistics cannot relate to trade in agricultural biotech products after 1998 as no such products have been approved since that date. Argentina further submits that WTO rules protect competitive expectations, not volumes of trade.

7.1610 The **Panel** notes that it is less than clear precisely what Argentina's claim is. We must, therefore, address this issue before we analyse whether the European Communities has breached Article 10.1.

(a) Argentina's claim

7.1611 Article 10.1 applies to the "preparation and application of [SPS] measures". Argentina's submissions do not indicate clearly what, in Argentina's view, is the SPS measure at issue. On the one hand, Argentina argues that the European Communities has failed to comply with Article 10.1 because of the way it has prepared and applied the general *de facto* moratorium on approvals.[1326] This suggests that, as far as Argentina is concerned, the SPS measure at issue is the general *de facto* moratorium on approvals. On the other hand, Argentina appears to argue that the European Communities has failed to comply with Article 10.1 because of the way it has applied the relevant EC approval legislation.[1327] This suggests that the SPS measure at issue is the relevant EC approval legislation.[1328] We think that both ways of framing a claim under Article 10.1 are possible.

7.1612 Judging by the entirety of Argentina's submissions, we think that Argentina intended to claim that the general *de facto* moratorium on approvals constitutes the relevant "SPS measure". We will examine that claim below. In view of the fact that Argentina's submissions on this issue are less than fully clear and that Article 10.1 is a provision on differential and more favourable treatment for

[1326] Argentina's first written submission, paras. 182 (referring to the "ordering and applying a general moratorium") and 189 (referring to "the decision and subsequent application of the 'de facto' moratorium"); Argentina's first oral statement, para. 77 (referring to the "deciding on and applying the 'de facto' moratorium"); Argentina's second written submission, para. 123 (referring to "the application of the 'de facto' moratorium").

[1327] Argentina's second written submission, paras. 116 (referring to the time of "elaborating and applying its legislation related to agricultural biotech products") and 125 (asserting that there is no evidence that "during the proceedings [*i.e.*, individual approval procedures] the EC has effectively taken into account Argentina's special needs").

[1328] It is pertinent to note that in the context of its challenge to various product-specific measures Argentina makes similar claims under Article 12.3 of the *TBT Agreement.* Article 12.3 provides:

> Members shall, in the preparation and application of technical regulations, standards and conformity assessment procedures, take account of the special development, financial and trade needs of developing country Members, with a view to ensuring that such technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to exports from developing country Members.

It is clear from Argentina's submissions that Argentina's claims under Article 12.3 are in respect of the application by the European Communities of its approval legislation, which Argentina says may be considered as laying down "conformity assessment procedures" within the meaning of Article 12.3. Argentina's first written submission, p. 144 (heading) and paras. 445 and 450. However, as indicated, Argentina's claims under Article 12.3 relate to the product-specific measures, whereas we are concerned here with a claim concerning the general *de facto* moratorium on approvals.

developing country Members, we will, however, offer alternative findings. For the purposes of these alternative findings, we will assume that Argentina intended to make the additional claim that the EC approval legislation also constitutes a relevant "SPS measure".

(b) General *de facto* moratorium on approvals as "SPS measure"

7.1613 As indicated, we first examine Argentina's claim that the European Communities has acted inconsistently with Article 10.1 because of the way it has prepared and applied the general *de facto* moratorium on approvals. Under this claim, the general *de facto* moratorium on approvals is considered as an "SPS measure".

7.1614 We have found earlier that the European Communities' decision to apply a general *de facto* moratorium on approvals was a decision relating to the application, or operation, of the existing EC approval procedures and that, as such, it did not constitute an "SPS measure" within the meaning of Annex A(1).[1329] However, as we have done in other cases, we also consider the specific provisions of Article 10.1 before reaching a definitive conclusion on whether the general *de facto* moratorium on approvals was an "SPS measure".

7.1615 Article 10.1 provides that in the "preparation and application of [SPS] measures" Members must take account of the special needs of developing country Members. According to Annex A(1), the term "SPS measures" includes "requirements and procedures". It makes sense to say that in the "preparation and application" of "requirements and procedures" Members must take account of developing country Members' needs. In contrast, if the application, or operation, of approval procedures were considered to be an "SPS measure" within the meaning of Article 10.1, Article 10.1 would impose an obligation on Members with regard to the "application" of the "application of an approval procedure". Clearly, such a reading of Article 10.1 would be unreasonable and contrary to logic.[1330] It is no answer to say that in cases where the measure is the "application of an approval procedure", the separate reference in Article 10.1 to the "application" of SPS measures is unnecessary. It is well established in WTO jurisprudence that a treaty interpreter must give meaning and effect to all the terms used in a treaty provision and must avoid interpretations which render treaty terms redundant.[1331]

7.1616 In view of the above considerations, we find our earlier conclusion that the general *de facto* moratorium on approvals was not an "SPS measure" within the meaning of Annex A(1) appropriate in the specific context of Article 10.1. We thus determine that the general *de facto* moratorium on approvals was not an "SPS measure" within the meaning of Article 10.1. Since the claim we are considering is based on the premise that the general *de facto* moratorium was an "SPS measure", it is clear that this claim cannot succeed.

7.1617 Accordingly, we find that Argentina has failed to establish its claim that the European Communities has acted inconsistently with Article 10.1 because of the way it has prepared and applied the general *de facto* moratorium on approvals.

[1329] We recall that in accordance with Article 1.1 of the *SPS Agreement* the definitions provided in Annex A are applicable to Article 10.1.

[1330] It is instructive to note in this regard that the equivalent provision of the *TBT Agreement*, Article 12.3, refers to the "preparation and application" of "conformity assessment procedures". This supports our reading of Article 10.1 of the *SPS Agreement*.

[1331] Appellate Body Report, *US – Gasoline*, p. 23.

(c) EC approval legislation as "SPS measure"

7.1618 As indicated above, we will offer alternative findings on the assumption that Argentina intended to make the additional claim that the EC approval legislation also constitutes a relevant "SPS measure". Thus, for the purposes of our alternative inquiry, we understand Argentina to claim, in addition, that by adopting and applying a general *de facto* moratorium on approvals, the European Communities has failed to apply its approval legislation in a manner which takes account of developing country Members' needs.

7.1619 Argentina argues that some of the products affected by the European Communities' general moratorium on approvals are of particular export interest to Argentina as a major developing country exporter of those products. Argentina considers that the European Communities should have provided preferential market access for its and other developing countries' products, or implemented its approval legislation in a manner beneficial, or less detrimental, to the trade interests of developing country Members.

7.1620 Argentina's argument implies that when an importing Member applies a measure which (i) treats exports originating in the territory of developing country Members in the same way as exports originating in the territory of developed country Members and (ii) has a significant adverse effect on the developing countries' exports, the importing Member is acting inconsistently with its obligation under Article 10.1. Argentina suggests that in such situations the exports of developing country Members are entitled under Article 10.1 to special and differential treatment *vis-à-vis* the exports of developed country Members. However, the obligation laid down in Article 10.1 is for the importing Member to "take account" of developing country Members' needs. The dictionary defines the expression "take account of" as "consider along with other factors before reaching a decision".[1332] Consistent with this, Article 10.1 does not prescribe a specific result to be achieved. Notably, Article 10.1 does not provide that the importing Member must invariably accord special and differential treatment in a case where a measure has lead, or may lead, to a decrease, or a slower increase, in developing country exports.

7.1621 The fact that there is no indication that between June 1999 and August 2003 the European Communities accorded Argentina special and differential treatment – *e.g.*, by approving the marketing of biotech products exported from Argentina – does not in and of itself constitute prima facie evidence that the European Communities has failed to "take account" of Argentina's needs. While the European Communities must take account of the interests of developing country Members in applying its approval legislation, the European Communities may at the same time take account of other legitimate interests, including those of its own consumers, its environment, etc. There is nothing in Article 10.1 to suggest that in weighing and balancing the various interests at stake, the European Communities must necessarily give priority to the needs of Argentina as a developing country. We therefore think it is conceivable that the European Communities "took account" of Argentina's needs when adopting and applying its general *de facto* moratorium on approvals, but ultimately determined that applications concerning products of export interest to Argentina warranted no special and differential treatment.[1333] Accordingly, we consider that the fact that the European Communities did not accord Argentina special and differential treatment *vis-à-vis* other developed country exporters does not demonstrate, by itself, an inconsistency with Article 10.1.

[1332] *The Concise Oxford Dictionary*, 10th edn., J. Pearsall (ed.) (Clarendon Press, 1999), p. 8.

[1333] We recall Argentina's statement that its claim under Article 10.1 is not a consequential claim, but an autonomous claim. Thus, for the purposes of our analysis of Argentina's claim under Article 10.1, we must assume that, but for a possible inconsistency with Article 10.1, the general de facto moratorium on approvals is WTO-consistent.

7.1622 Argentina argues that the European Communities has not provided any evidence which would prove that it has taken into account Argentina's special needs as a developing country Member. This argument lacks merit, for it is incumbent on Argentina as the Complaining Party to adduce evidence and argument sufficient to raise a presumption that the European Communities has failed to take into account Argentina's special needs as a developing country Member.[1334]

7.1623 Argentina also contends that there is no reference in the EC approval legislation to the special needs of developing country Members. However, the absence of a reference to developing country needs in the text of the EC approval legislation does not demonstrate that that legislation itself fails to take account of these needs[1335], or that the European Communities is precluded from taking account, or has not taken account, of these needs when applying that legislation. We therefore consider that it is not sufficient, for the purposes of establishing a claim under Article 10.1, to point to the absence in the EC approval legislation of a reference to the needs of developing country Members.

7.1624 Argentina further argues that for the entire period of application of the general *de facto* moratorium on approvals it could not identify any evidence supporting the conclusion that the European Communities has taken account of Argentina's special needs. We note that Argentina has merely asserted the absence of relevant evidence, without specifying what efforts it has undertaken to collect such evidence. Moreover, we note that Article 10.1 does not specifically require the importing Member to document how it has complied with Article 10.1. In these circumstances, we do not consider that Argentina's argument provides a sufficient basis for us to find that Argentina has met its burden of establishing an inconsistency with Article 10.1.

7.1625 Even considering all of Argentina's arguments together, we are not satisfied that Argentina has met its burden. We recognize that Argentina may not have ready access to information about whether and to what extent the European Communities "took account" of Argentina's needs as a developing country Member. However, there is no evidence on record to show that Argentina ever approached the European Communities and sought information on how the European Communities complied with its obligation under Article 10.1 when applying its approval legislation to applications concerning biotech products of export interest to Argentina. We do not mean to suggest that it is Argentina's duty specifically to request the European Communities to take account of Argentina's needs as a developing country Member. But under well-established rules on burden of proof it is for Argentina to prove its claim that the European Communities did not take account of developing country Members' needs.

7.1626 In the light of the above considerations, we find, in the alternative, that Argentina has failed to establish its claim that the European Communities has acted inconsistently with Article 10.1 because of the way it has applied its approval legislation between October 1998 and August 2003.

[1334] It is worth noting in this context that Argentina has not explained how the European Communities would in the present case have known that a particular application concerned a biotech product of export interest to Argentina. As far as we are able to determine, in none of the many approval procedures affected by the general moratorium was the applicant an Argentinean company or individual. Typically, the applicant was a biotech company of a developed country nationality. While such applicants may have provided information on actual or potential exporting countries as part of the information submitted with their applications, neither Argentina nor the European Communities has confirmed that they were required to do so, or if not, that they have consistently done so.

[1335] We note, however, that Directive 2001/18 in its 13th preambular paragraph states that the content of the Directive "duly takes into account" the European Communities' "international trade commitments". Argentina did not acknowledge this paragraph.

(d) Overall conclusion

7.1627 In the light of the above, the Panel reaches the following conclusion:

(i) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that Argentina has not established that the European Communities has acted inconsistently with its obligations under Article 10.1 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

E. PRODUCT-SPECIFIC MEASURES

1. Measures at issue

7.1628 In addition to the general *de facto* moratorium on approvals, the Complaining Parties are also challenging a number of product-specific measures. The Panel begins its analysis by setting out the Complaining Parties' general descriptions of the measures at issue and the European Communities' comments in response.

(a) General

7.1629 The **United States** notes that it is challenging the failure by the Commission and the member States to consider for approval certain applications specified in its request for the establishment of a panel. The United States refers to these product-specific measures as "product-specific moratoria". According to the United States, these product-specific moratoria are separate measures from the general moratorium affecting all applications. The United States also notes, however, that they are similar measures in that both refer to the European Communities' failure to consider applications for approval. Also, since the general moratorium applied to all applications, a necessary corollary is that the European Communities also adopted product-specific moratoria on each of the relevant applications specified in the United States' panel request. Accordingly, the evidence and arguments the United States adduced in support of the existence of a general moratorium also establish the existence of the product-specific moratoria, and that the European Communities did not undertake and complete its approval procedures for each individual application without undue delay.

7.1630 **Canada** states that it is challenging the failure by the European Communities to consider or approve, without undue delay, certain applications specified in its request for the establishment of a panel. Canada refers to the failure by the European Communities in this regard as the product-specific marketing bans. Canada contends that the general moratorium and the product-specific marketing bans are closely related, though distinct, measures. The product-specific marketing bans are a direct consequence of the moratorium as applied to individual applications. They are the manifestation of the moratorium in the context of the approval procedures of the four specific products of concern to Canada. Canada's arguments in relation to product-specific marketing bans are intended to focus on the direct and detrimental impact of the moratorium on specific applications.

7.1631 **Argentina** states that it is challenging (i) the suspension by the European Communities of consideration of specified applications for approval, or the failure to consider specified applications for approval as well as (ii) the undue delays in completing the consideration and processing of specified applications. Argentina argues that the product-specific suspension of processing or failure

to consider as well as the undue delay are effects of the application of the *de facto* moratorium to specific applications for approval.

7.1632 The **European Communities** notes that it has considerable difficulty in understanding the difference between the first group of claims by the Complaining Parties relating to the alleged moratorium on approvals and the second group of claims relating to alleged failures to consider for approval specific applications. According to the European Communities, the Complaining Parties' assertions about a "suspension of procedures" or any "failure to consider applications" are assertions about delay.

7.1633 The **Panel** notes that, according to the Complaining Parties, the product-specific measures they are challenging are distinct from the general *de facto* moratorium on approvals. At the same time all three Complaining Parties point out that the product-specific measures are related to the general moratorium on approvals. Based on these statements and the Complaining Parties' arguments, it is our understanding that the product-specific measures are, or arise from:

- specified acts and/or omissions through which the relevant EC entities were giving effect, in the context of particular approval procedures, to their decisions to impose a general moratorium on approvals, or
- specified acts and/or omissions through which relevant EC entities chose to respond, again in the context of particular approval procedures, to the circumstance that other EC entities were imposing a general moratorium on approvals.

7.1634 It should be noted, however, that in their requests for the establishment of a panel, the Complaining Parties have described the product-specific measures in more general terms. Moreover, each Complaining Party has used a somewhat different description. It is therefore useful to address these different descriptions one by one.

7.1635 The United States in its panel request says that the measure at issue is the failure by the European Communities to consider particular applications for approval. It is clear to us that the United States does not contend that the European Communities has not considered the relevant applications at all. In our view, the United States contends that the European Communities has failed to consider the relevant applications for *final* approval. We understand this to be essentially a contention that the consideration of these applications was affected by the general moratorium on final approvals, in the sense that their consideration was either effectively suspended at some point in the approval process or continued at a delayed pace. This understanding would appear to be supported by the fact that when referring to the product-specific measures, the United States speaks of the "product-specific moratoria".

7.1636 Canada in its panel request says that the measure at issue is the failure by the European Communities to consider or approve, without undue delay, the applications mentioned in its request. Thus, unlike the United States, Canada explicitly includes an allegation of undue delays in the consideration and approval of the relevant applications in the definition of the measures being challenged. At the same time, Canada refers to the alleged failure to consider or approve the relevant applications without undue delay as the product-specific marketing bans. Canada claims in this regard that at some point in the approval process each of the relevant applications was subjected by the European Communities to an effective marketing ban. The validity of this claim will be discussed further below. At this stage, it is sufficient to note that we will conduct our examination based on the description of the product-specific measures set out in Canada's panel request.

7.1637 Argentina distinguishes two types of product-specific measures. The first type of product-specific measure is described in Argentina's panel request as the suspension of consideration of, or the failure to consider, particular applications for approval. In our understanding, this type of measure is conceptually the same as the product-specific measures referred to in the United States' panel request. The second type of product-specific measure identified in Argentina's panel request concerns undue delays in finalizing consideration of particular applications for approval. Accordingly, like Canada, Argentina explicitly includes an allegation of undue delays in the consideration of the relevant applications in the definition of the measures being challenged.

(b) Relevant applications

7.1638 As noted above, each of the product-specific measures challenged by a particular Complaining Party relates to a particular application. Below it is indicated (i) how many applications were specified by each Complaining Party and (ii) on how many of these applications the Panel has been requested to offer product-specific findings.

(i) DS291 (United States)

7.1639 The United States in its request for the establishment of a panel stated that the relevant applications are mentioned in Annexes I and II to its request. These two Annexes list a total of forty-one applications. As all forty-one applications are within the terms of reference of this Panel, there are, in principle, forty-one product-specific measures which the United States could seek to challenge. However, in its first written submission, the United States indicated that it is making claims in respect of only twenty-seven applications.[1336] We conclude from this that the United States has abandoned its product-specific claims in respect of the remaining fourteen applications.[1337]

7.1640 According to the United States' first written submission, the twenty-seven applications in respect of which it is pursuing product-specific claims include eighteen which were submitted under Directive 90/220 and were pending under Directive 2001/18 on the date of establishment of this Panel as well as nine applications pending under Regulation 258/97.[1338] Among the nine applications the United States claims were pending under Regulation 258/97, there are two applications which were withdrawn before the Panel was established. They are Transgenic red-hearted chicory (food) and Transgenic green-hearted chicory (food). Evidence provided by the European Communities shows that both were withdrawn by the applicant in May 2003.[1339] We note in this respect that, in a submission made subsequent to its first written submission, the United States stated that it is not requesting findings on applications that were withdrawn prior to the establishment of the Panel.[1340] In the light of this categorical statement, we consider we need not, and hence do not, make findings in respect of the two aforementioned applications concerning transgenic chicory. This means that there are in total twenty-five applications on which the Panel is expected to offer product-specific findings

[1336] US first written submission, paras. 67, 131, 137-138.

[1337] It should be noted that the United States discussed the applications concerning MS1/RF2 oilseed rape and MS1/RF1 oilseed rape (EC-89) under the heading "product-specific moratoria". US second written submission, para. 53. However, the United States also presented arguments relating to its general moratorium claim under that heading. US second written submission, paras. 52-53. Accordingly, we do not understand the United States to have increased the number of measures in respect of which it is making product-specific claims.

[1338] The eighteen applications pending under Directive 2001/18 are identified at paras. 49-51 of the US first written submission; the nine applications pending under Regulation 258/97 are identified at paras. 54-55 of the US first written submission.

[1339] Exhibits EC-97/At. 32 and EC-98/At. 42. The United States also acknowledges this fact. US second written submission, footnote 76.

[1340] US reply to Panel question No. 197, footnote 26.

– eighteen which were pending under Directive 2001/18 and seven which were pending under Regulation 258/97.

7.1641 The eighteen applications which were pending under Directive 2001/18 as of August 2003 comprise those concerning:

- Bt-531 cotton
- RR-1445 cotton
- Falcon oilseed rape
- MS8/RF3 oilseed rape
- RR fodder beet
- Transgenic potato
- Liberator oilseed rape
- Bt-11 maize (EC-69)
- GA21 maize (EC-78) (withdrawn in September 2003)
- MON810 x GA21 maize (withdrawn in September 2003)
- LL soybeans (EC-71) (withdrawn in June 2004)
- LL oilseed rape
- BXN cotton[1341]
- Bt-1507 maize (EC-74)
- Bt-1507 maize (EC-75)
- NK603 maize (approved by Commission in July 2004)
- RR oilseed rape (EC-70) (approved by Commission in August 2005[1342])
- RR sugar beet (withdrawn in April 2004)

7.1642 The seven applications which were pending under Regulation 258/97 as of August 2003 are those concerning:

- GA21 maize (food)
- Bt-11 sweet maize (food) (approved by Commission in May 2004)
- NK603 maize (food) (approved by Commission in October 2004)
- LL soybeans (food) (withdrawn in July 2004)
- Bt-1507 maize (food)
- RR sugar beet (food) (withdrawn in April 2004)
- MON810 x GA21 maize (food)

(ii) DS292 (Canada)

7.1643 Canada's request for the establishment of a panel identifies four applications. They were all submitted under Directive 90/220. As of August 2003, they were either pending under Directive 2001/18 or awaiting the lead CA's written consent to the placing on the market. Canada requests product-specific findings on all four applications. The applications at issue are those concerning:

[1341] According to the European Communities, the application concerning BXN cotton was withdrawn by the applicant after the establishment of the Panel. However, the European Communities has provided no support for this assertion.

[1342] We recall that after the second substantive meeting, on 1 September 2005, the Panel received a letter from the European Communities stating that the Commission had approved the application concerning RR oilseed rape (EC-70) under Directive 2001/18.

- MS1/RF1 oilseed rape (EC-89) (awaiting the lead CA's written consent)
- MS1/RF2 oilseed rape (awaiting the lead CA's written consent)
- MS8/RF3 oilseed rape
- RR oilseed rape (EC-70) (approved by Commission in September 2005[1343])

(iii) DS293 (Argentina)

7.1644 Argentina's request for the establishment of a panel contains an attachment, Annex I, which identifies seventeen applications. It appears that Annex I is intended to illustrate the impact of the general *de facto* moratorium on specific applications as well as to specify the applications in respect of which Argentina is making product-specific claims. Among the seventeen applications referred to in Annex I, there are two which are mentioned twice.[1344] There are four additional applications in respect of which Argentina makes no claims in its submissions.[1345] The eleven remaining applications are the applications on which we think we are requested to make product-specific findings. Of these eleven applications, six were submitted under Directive 90/220. With one exception[1346], they were pending under Directive 2001/18 on the date of establishment of this Panel. Argentina claims that the other five applications were all submitted under Regulation 258/97.

7.1645 The six applications submitted under Directive 90/220 comprise those concerning:

- Bt-531 cotton
- RR-1445 cotton
- GA21 maize (EC-78) (withdrawn in September 2003)
- GA21 maize (EC-85) (withdrawn in June 2001)
- NK603 maize (approved by Commission in July 2004)
- LL soybeans (EC-71) (withdrawn in June 2004)

7.1646 The five applications which Argentina says were submitted under Regulation 258/97 are those concerning:

- Bt-531 cotton
- RR-1445 cotton
- GA21 maize (food)

[1343] We recall that after the second substantive meeting, on 1 September 2005 the Panel received a letter from the European Communities stating that the application concerning RR oilseed rape (EC-70) was approved by the Commission in September 2005. We further note that in the context of presenting its product-specific claims in respect of the application concerning RR oilseed rape (EC-70), Canada also presented arguments on RR oilseed rape (EC-79). *E.g.*, Canada's first written submission, paras. 86-87 and 295. *See also* Canada's reply to Panel question No. 60. The application concerning RR oilseed rape (EC-79) was submitted to France. However, Annex I to Canada's panel request refers only to the application submitted to the Netherlands, which is that concerning RR oilseed rape (EC-70). Accordingly, we will not entertain Canada's product-specific claims in respect of the application concerning RR oilseed rape (EC-79) submitted to France. We consequently offer no product-specific findings on that application.

[1344] This is the case of the applications concerning GA21 maize (food) and LL soybeans (EC-71). Argentina in its submissions to the Panel does not argue that the applications which we consider are mentioned twice are in fact different applications.

[1345] This is the case of the applications concerning GA21 maize (EC-78) (alleged procedure under Regulation 258/97), T14 maize (procedure under Directive 90/220 and alleged procedure under Regulation 258/97) and LL soybeans (EC-81). T14 maize is mentioned in footnote 188 of Argentina's first written submission, but no claim is raised there.

[1346] The application concerning GA21 maize (EC-85) was withdrawn in June 2001.

– NK603 maize (food) (approved by Commission in October 2004)
– LL soybeans (food) (withdrawn in July 2004)

(c) Withdrawn and approved applications

7.1647 The above analysis shows that among the applications in respect of which the Panel is requested to make product-specific findings are applications which were withdrawn either before or after the Panel was established. There also are applications which were approved by the Commission in the course of the Panel proceedings. The European Communities argues that the Panel should not make findings with regard to withdrawn or approved applications. Accordingly, we must decide whether it is appropriate to assess the WTO-consistency of the relevant product-specific measures.

(i) Applications withdrawn before the establishment of the Panel

7.1648 We note at the outset that if an application is withdrawn, this means that the product-specific measure complained of no longer exists. In the case of the application concerning GA21 maize (EC-85), the product-specific measure complained of by Argentina is the alleged "undue delay in finalizing consideration of that application". Once that application was withdrawn, this meant that there no longer was an undue delay in finalizing consideration of that application.

7.1649 As we pointed out earlier, the product-specific measure which relates to the application concerning GA21 maize (EC-85) is within the terms of reference of DS293 (Argentina). Notwithstanding this, the European Communities submits that claims concerning applications withdrawn before the Panel was established are without object and, hence, inadmissible ab initio. In our view, the mere fact that the product-specific measure concerning GA21 maize (EC-85) no longer existed as of the date of establishment of the Panel does not, *ipso facto*, deprive us of our authority to make findings on a measure that is within our terms of reference.[1347]

7.1650 This is also clear from the Appellate Body report in *US – Certain EC Products*. That dispute concerned a measure which was withdrawn almost two months before a panel was established.[1348] The panel considered the measure, offered findings on it and recommended that it be brought into conformity with WTO rules.[1349] The Appellate Body found that the panel should not have made a recommendation regarding a measure that no longer existed.[1350] But the Appellate Body nowhere suggested that the panel erred in making findings regarding that measure.[1351] We recognize that in our case the application concerning GA21 maize (EC-85) was withdrawn more than two years before the Panel was established. However, there is nothing in the DSU to suggest that our jurisdiction, which is established by our terms of reference[1352], is affected by such considerations of time.

7.1651 Having said this, past jurisprudence shows that a panel is not necessarily required to make use of its authority to make findings in respect of measures which were no longer in existence on the date of establishment of a panel. In *Argentina – Textiles and Apparel*, the panel decided not to make

[1347] A different issue (which we do not reach) is whether we have the authority to make recommendations in relation to the product-specific measure in question.

[1348] The panel in that case was established on 16 June 1999, while the measure at issue (the "3 March Measure") ceased to exist on 19 April 1999 when a new measure (the "19 April Action") was adopted.

[1349] Panel Report, *US – Certain EC Products*, para. 7.3.

[1350] Appellate Body Report, *US – Certain EC Products*, para. 81. The Appellate Body in *US – Upland Cotton*, referring to its report on *US – Certain EC Products*, stated that "the fact that a measure has expired may affect what recommendation a panel may make". Appellate Body Report, *US – Upland Cotton*, para. 272.

[1351] *Ibid*., para. 271.

[1352] Appellate Body Report, *Brazil – Desiccated Coconut*, p. 22.

findings on the WTO-consistency of a measure which had been revoked eleven days before the panel was established.[1353] Moreover, as noted by the panel in *US – Gasoline*, "it had not been the usual practice of a panel established under the General Agreement [on Tariffs and Trade 1947] to rule on measures that, at the time the panel's terms of reference were fixed, were not and would not become effective".[1354]

7.1652 We consider that in determining whether to make findings on a measure no longer in existence on the date of establishment of a panel, panels should notably take account of the object and purpose of the dispute settlement system.[1355] Pursuant to Article 3.7 of the DSU, "[t]he aim of the dispute settlement mechanism is to secure a positive solution to a dispute".

7.1653 In the case of the application concerning GA21 maize (EC-85), we are not persuaded that making product-specific findings with regard to that application is necessary to "secure a positive solution to [the] dispute" between Argentina and the European Communities. We note in this regard that there is no agreement between the Parties that it would be useful for us to make findings on the product-specific measure concerning the application in question. Moreover, the application was withdrawn more than two years prior to the establishment of the Panel. Thus, unlike in the *US – Certain EC Products* case where the measure at issue was in force for just over a month, this is a case where Argentina could have presented its claims while the application was still pending.[1356] Finally, we note that the applicant resubmitted the application to another member State and that the resubmitted application – the application concerning GA21 maize (EC-78) – was still pending on the date of establishment of this Panel. We will make findings on the resubmitted application. As a result, we are resolving the dispute between Argentina and the European Communities insofar as it relates to GA21 maize.

7.1654 In the light of these considerations, we will neither examine nor make product-specific findings on the application concerning GA21 maize (EC-85).

(ii) Applications withdrawn after the establishment of the Panel

7.1655 In relation to applications which were withdrawn after the Panel was established, we note that only the United States and Argentina are seeking product-specific findings on applications falling within this category.

7.1656 The **European Communities** argues that the Panel should not address product-specific measures concerning applications which were withdrawn after the Panel was established. According to the European Communities, the issue has become moot and the relevant claims must be considered inadmissible. The European Communities bases its argument on three provisions of the DSU. *First*, Article 3.3 of the DSU states that the basic aim of the dispute settlement system is "the prompt settlement of situations in which a Member considers that any benefits accruing to it directly or indirectly under the covered agreements *are being* impaired by measures taken by another Member" (emphasis added). This shows that the purpose of dispute settlement is to address and redress situations that are in actual existence. *Secondly*, Article 3.4 of the DSU provides that

[1353] Panel Report, *Argentina – Textiles and Apparel*, para. 6.15.
[1354] Panel Report, *US – Gasoline*, para. 6.19.
[1355] This approach is consistent with that of the panel in *Chile – Price Band System*, which stated that "[a]lthough we do not consider that the termination of a measure before the commencement of panel proceedings deprives a panel of the authority to make findings in respect of that measure, we would only make findings regarding the provisional safeguard measures in this case if we were to consider this necessary in order to 'secure a positive solution' to the dispute." Panel Report, *Chile – Price Band System*, para. 7.115.
[1356] We note that the application was first submitted in December 1997.

"recommendations or rulings by the DSB shall be aimed at achieving a satisfactory settlement of the matter". This cannot be the case if there is no matter to settle (i.e., if no measure is being applied). *Thirdly*, Article 3.7 of the DSU provides that "before bringing a case a Member shall exercise its judgment as to whether action under these procedures would be fruitful. The aim of the dispute settlement mechanism is to secure a positive solution to a dispute". A case on a measure that is not in existence any longer would be devoid of any purpose and not fruitful. The European Communities also points out that it is a legal principle recognized in jurisdictions around the world and commonly applied by international tribunals, including the International Court of Justice (the "ICJ"), that a tribunal should not rule on a measure no longer in existence.[1357]

7.1657 The **United States** argues that the concept of mootness is of no relevance, since the product-specific measures existed in August 2003, when the terms of reference were set. The United States refers to the panel report on *India – Autos*, which states that "[a] WTO Panel is generally competent to consider measures in existence at the time of its establishment. This power is not necessarily adversely affected simply because a measure under review may have been subsequently removed or rendered less effective".[1358] Regarding the European Communities' argument with regard to a "legal principle" concerning mootness, the United States notes that the European Communities failed to mention that GATT and WTO panels in the past considered terminated measures, and that the European Communities failed to explain how such a principle would be consistent with the text of the DSU.

7.1658 **Argentina** argues that the European Communities' statement on mootness is not supported by WTO jurisprudence. Argentina refers to the panel report on *Chile – Price Band System*, wherein the panel stated that "Article 19.1 of DSU does not prevent us from making findings regarding the consistency of an expired provisional safeguard measure".[1359] Argentina also refers to the above-quoted passage from the panel report on *India – Autos*.

7.1659 Subsequently, the **European Communities** clarified its position. It notes that it is not its position that the Panel may not consider product-specific measures concerning applications which were withdrawn after the Panel was established.[1360] But the European Communities remains of the view that such measures are "*sans objet*", and that there is no longer any utility in considering such measures because there does not exist, in respect of such measures, a dispute between the Parties.

7.1660 The **Panel** notes that there is no disagreement among the Parties that the product-specific measures which relate to applications withdrawn after the establishment of the Panel are within the Panel's terms of reference. There also is no disagreement among the Parties that the Panel in principle has the authority to consider measures which ceased to exist after the establishment of the Panel. We agree with both points. In relation to the second point – the authority of panels to consider measures which ceased to exist after the establishment of a panel – we note that the panel in *India – Autos* observed that:

[1357] The European Communities refers to the following ICJ judgments: *Questions of Interpretation and Application of the 1971 Montreal Convention raising from the Aerial Incident at Lockerbie* (Libyan Arab Jamahiriya v. United States of America), Judgment, ICJ Reports 1998, at 131, para 45; *Nuclear Tests* (Australia v. France), Judgment, ICJ Reports 1974, p.272, para 62; and *Border and Transborder Armed Actions* (Nicaragua v. Honduras), Jurisdiction and Admissibility, Judgment, ICJ Reports 1988, p.95, para. 66.

[1358] Panel Report, *India – Autos*, para. 7.26.

[1359] Panel Report, *Chile – Price Band System*, para. 7.124.

[1360] The European Communities nonetheless notes that the Panel should not issue recommendations in respect of such measures.

> "A WTO Panel is generally competent to consider measures in existence at the time of its establishment. This power is not necessarily adversely affected simply because a measure under review may have been subsequently removed or rendered less effective."[1361]

7.1661 The Parties disagree on whether the Panel should make use of its authority to make findings on the product-specific measures concerning the withdrawn applications. The European Communities argues that it is no longer useful for the Panel to consider the relevant product-specific measures, and that the Panel should therefore refrain from ruling on these measures. According to the European Communities, this would be consistent with international practice, including that of the International Court of Justice.

7.1662 In considering this issue, we note that previous panels have addressed measures which ceased to exist after the establishment of the panel. The panel in *Indonesia – Autos* stated in this regard that:

> "[I]n previous GATT/WTO cases, where a measure included in the terms of reference was otherwise terminated or amended after the commencement of the panel proceedings, panels have nevertheless made findings in respect of such a measure."[1362]

7.1663 We would agree with the European Communities that it may be appropriate for panels to look to the practice of international tribunals for inspiration, particularly in situations where the WTO agreements, GATT/WTO jurisprudence or practice provide no useful guidance. But we do not find ourselves in a situation of this kind. As is clear from the above remarks, there is specific GATT/WTO jurisprudence and practice to guide us. In these circumstances, we see no need to draw on the jurisprudence of the International Court of Justice.

7.1664 We do not consider that Articles 3.3 or 3.4 of the DSU support the view that we should refrain from making findings on the relevant product-specific measures. In relation to Article 3.3, the European Communities appears to argue that if benefits are no longer "being" impaired by a measure, because the measure has ceased to exist, the Panel should not make findings on it. However, the main objective of Article 3.3 is to emphasise the importance of the *prompt* settlement of situations in which benefits are being impaired by a measure. In our view, it cannot be deduced from this that in situations where benefits are no longer being impaired by a measure, a panel should refrain from making findings on it. We note that pursuant to Article 3.2 of the DSU the dispute settlement system also serves "to preserve the rights and obligations of Members under the covered agreements". We think that it is consistent with this function of the dispute settlement system for a panel to make findings on the WTO-consistency of a measure which has ceased to exist, especially if so requested by one of the parties.

7.1665 Turning to Article 3.4, we note that that provision states that recommendations or rulings by the DSB must be aimed at achieving a satisfactory settlement of the "matter". The European Communities suggests that if a measure has ceased to exist, there is no longer a "matter" to be settled. However, the "matter" to be settled is the matter referred to the DSB for settlement. As is clear from Article 7.1 of the DSU and the Appellate Body report in *Guatemala – Cement I*[1363], the matter referred to the DSB is the matter described by a Complaining Party in its request for the establishment of a panel. Pursuant to Article 6.2 of the DSU, the request for establishment of a panel must identify the

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[1361] Panel Report, *India – Autos*, para. 7.26.
[1362] Panel Report, *Indonesia – Autos*, para. 14.9.
[1363] Appellate Body Report, *Guatemala – Cement I*, para. 72.

specific measures at issue. Applying these considerations to the present case, it is clear that the "matter" to be settled by the DSB in a satisfactory manner includes the product-specific measures identified by the United States and Argentina in their respective panel requests. Therefore, we do not agree that once the relevant product-specific measures ceased to exist, there was, to that extent, no longer a "matter" which could be settled by the DSB.

7.1666 Regarding whether it is useful for the Panel to address the product-specific measures concerning the withdrawn applications, we recall our view that in making that determination, account should notably be taken of the object and purpose of the dispute settlement system, which is to secure a positive solution to a dispute. We note in this regard that there is no agreement between the Parties that it would be useful for us to make findings on the product-specific measures concerning the applications in question. However, the United States and Argentina as Complaining Parties did not say that in view of the withdrawal of the applications in question, they were no longer seeking findings on the product-specific measures concerning these applications. On the contrary, Argentina, for instance, explicitly requested the Panel to offer such findings. Moreover, unlike in the case of the application concerning GA21 maize (EC-85), our findings on other product-specific measures do not resolve the dispute relating to the relevant biotech products. Finally, we note that the applications were withdrawn by the applicants. It is clear, therefore, that this is not a case where the relevant measures were terminated by the responding party in the course of panel proceedings in a good faith effort to resolve the underlying dispute. Thus, we do not consider that if we make findings on the product-specific measures at issue, we would be frustrating efforts undertaken to reach a positive solution to the dispute. In these circumstances, we are unable to agree with the European Communities that it is no longer useful for us to offer findings on the product-specific measures at issue.

7.1667 In the light of the above, the Panel will make findings on the product-specific measures concerning those applications which were withdrawn after the Panel was established.

(iii) Applications approved after the establishment of the Panel

7.1668 The last category of applications to be addressed concerns applications which were approved by the Commission in the course of the Panel proceedings. All three Complaining Parties are seeking product-specific findings on such applications. In our view, applications which were *definitively* approved[1364] in the course of the Panel proceedings may be assimilated, for the purposes of the present inquiry, to applications which were withdrawn in the course of the Panel proceedings. Both categories of applications have in common the fact that the underlying approval procedures were pending on the date of establishment of the Panel, but were subsequently discontinued. The only difference is that in the case of a definitively approved application, the relevant approval procedure was discontinued as a result of action directly attributable to the European Communities. We do not consider that this difference, by itself, warrants a different approach by the Panel. We note in this regard that the European Communities does not argue that the Commission approved applications in order to resolve its dispute with the Complaining Parties in relation to the relevant applications.[1365]

[1364] We use the phrase "definitively approved" to refer to a situation where according to information on our record the applicant may proceed with the placing on the market of the biotech product which is the subject of the approved application.

[1365] The European Communities argues that the approvals of the relevant applications are simply the consequence of these applications having reached the final decision-making stage after being assessed at member State and Community level. EC comments on the Complaining Parties' replies to Panel questions, paras. 62-63.

7.1669 In the light of this, the Panel will make findings also with regard to those product-specific measures that concern applications which were definitively approved in the course of the Panel proceedings. The evidence on record supports the conclusion that two applications – namely, the application concerning Bt-11 sweet maize (food) and the application concerning NK603 maize (food) – were definitively approved in the course of the Panel proceedings. For the other relevant applications approved by the Commission in the course of the Panel proceedings, the record does not allow us to determine whether these applications have been definitively approved, such that they may be placed on the market.[1366] In any event, it is clear from the foregoing that we would offer findings on product-specific measures concerning such applications even if they had been definitively approved after the date of the establishment of the Panel.

(iv) Conclusion

7.1670 In the light of the foregoing considerations, we will offer no findings on the product-specific measure concerning GA21 maize (EC-85) (DS293), but we will make findings on product-specific measures concerning applications which were withdrawn after the Panel was established as well as on the product-specific measure concerning Bt-11 sweet maize (food) (DS291), an application which was definitively approved in the course of the Panel proceedings. However, we will not make any recommendations in the event that we find that the product-specific measures concerning applications which were withdrawn after the Panel was established, or the product-specific measure concerning Bt-11 sweet maize (food) (DS291), are WTO-inconsistent.

2. Claims of inconsistency raised by the Complaining Parties

7.1671 The Complaining Parties have each presented a series of claims of inconsistency in relation to the European Communities' product-specific EC measures they are challenging

7.1672 The **United States** claims that the product-specific EC measures it is challenging are inconsistent with, or have given rise to inconsistencies with, the following WTO provisions:[1367]

(a) Annex C(1)(a) and, consequently, Article 8 of the *SPS Agreement*;

(b) Annex B(1) and, consequently, Article 7 of the *SPS Agreement*;

(c) Annex C(1)(b) and, consequently, Article 8 of the *SPS Agreement*;

(d) Article 5.1 and, consequently, Article 2.2 of the *SPS Agreement*;

(e) Article 5.5 of the *SPS Agreement*.

7.1673 **Canada** claims that the product-specific EC measures it is challenging are inconsistent with, or have given rise to inconsistencies with, the following WTO provisions:[1368]

[1366] We note in this regard that in relation to the applications concerning NK603 maize (for animal feed use) and RR oilseed rape (EC-70) the record contains no evidence that the relevant lead CA has given its written consent for the placing on the market of these products after they were approved by the Commission under Directive 2001/18.

[1367] The claims are listed in the order in which they were developed in the first written submission of the United States.

[1368] The claims are listed in the order in which they were developed in the first written submission of Canada.

(a) Article 5.1 and, consequently, Article 2.2 of the *SPS Agreement*;

(b) Article 5.6 and, consequently, Article 2.2 of the *SPS Agreement*;

(c) Article 5.5 and, consequently, Article 2.3 of the *SPS Agreement*;[1369]

(d) Annex C(1)(a) and, consequently, Article 8 of the *SPS Agreement*;

(e) Article III:4 of the GATT 1994;

(f) Articles 2.1, 2.2, 5.1.2 and 5.2.1, first part, of the *TBT Agreement*.

7.1674 With regard to Canada's claims under the *TBT Agreement*, Canada explained that, if the Panel determines that parts of the relevant product-specific measures are covered by the *TBT Agreement* in addition to the *SPS Agreement*, its claims under the *TBT Agreement* are to be considered cumulative rather than alternative.

7.1675 **Argentina** claims that the product-specific EC measures are inconsistent with, or have given rise to inconsistencies with, the following WTO provisions:[1370]

(a) Article 5.1 and, consequently, Article 2.2 of the *SPS Agreement*;

(b) Articles 5.5 and 5.6 of the *SPS Agreement*;

(c) Annex C(1)(a), (b), (c) and (e) and, consequently, Article 8 of the *SPS Agreement*;

(d) Article III:4 of the GATT 1994;

(e) Articles 2.1, 2.2, 5.1.1, 5.1.2, 5.2.1, 5.2.2 and 12 of the *TBT Agreement*.

7.1676 As previously indicated, the Panel will make findings in relation to ten product-specific EC measures challenged by Argentina. However, Argentina's claims under Article 8 and Annex C(1) of the *SPS Agreement* and those under Article 5.2 of the *TBT Agreement* concern only eight of the ten "relevant product-specific measures". The two measures which are not the subject of a claim under these provisions are the measures affecting the approval of Bt-531 cotton and RR-1445 cotton under Regulation 258/97.

7.1677 We further note that Argentina's claims under the *TBT Agreement* are put forth as alternatives to its claims under the *SPS Agreement*.

7.1678 The **European Communities** argues that none of the product-specific claims presented by the three Complaining Parties is founded, and that it has not acted inconsistently with any of the WTO provisions which are being invoked by the Complaining Parties in respect of any of the product-specific measures.

7.1679 In view of the European Communities' view that all of the Complaining Parties' product-specific claims should be dismissed in their entirety, it is clear that the **Panel** needs to assess the merits of those claims. We will first examine the Complaining Parties' substantive claims under

[1369] Canada's claim under Article 5.5 is put forth as an alternative to its claim under Article 5.6.

[1370] The claims are listed in the order in which they were developed in the first written submission of Argentina.

Articles 5 and 2 of the *SPS Agreement*, and, if appropriate, will go on to examine the transparency claim under Annex B of the *SPS Agreement* and the procedural claims under Annex C of the *SPS Agreement*. Finally, to the extent it is necessary to do so, we will also examine Canada's and Argentina's claims under the GATT 1994 and under the *TBT Agreement*.

3. Consistency of the product-specific measures with Article 5.1 of the *SPS Agreement*

7.1680 All three Complaining Parties claim that the European Communities has acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* in respect of the product-specific measures they are challenging.

7.1681 Article 5.1 of the *SPS Agreement* provides:

> "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations."

7.1682 The **United States** argues that like the general moratorium, to the extent the product-specific measures – the product-specific moratoria – are preventing the sale or marketing of biotech products, each failure by the European Communities to consider for approval a pending application of a biotech product is an "SPS measure" that is not "based on a risk assessment" as required by Article 5.1. The United States considers that the product-specific moratoria, which, in effect, ban the relevant biotech products from the EC market, are "SPS measures" as defined in Annex A(1) of the *SPS Agreement*. The EC approval regime, including that part of the regime modified by the product-specific moratoria, are plainly "sanitary or phytosanitary" measures. Similarly, the product-specific moratoria, although unwritten, are "measures" under the *SPS Agreement*, just as the general moratorium affecting all products is a "measure" under the *SPS Agreement*. Regarding the requirement that SPS measures be based on a risk assessment, the United States submits that with respect to fourteen of the pending applications, the European Communities has not put forth any risk assessment whatsoever. As for the remaining thirteen applications, the European Communities has undertaken risk assessments but the product-specific moratoria are not based on these assessments.

7.1683 **Canada** argues that the failure of the European Communities to consider or approve, without undue delay, the four applications of specific interest to Canada is an SPS measure as defined in Annex A(1). According to Canada, the failure to consider and approve these applications, which Canada refers to as the "product-specific marketing bans", is not "based on" risk assessments contrary to Article 5.1. While the European Communities has completed risk assessments for each of the four applications, it has failed to base its failure to consider, and approve, these applications on these assessments.

7.1684 **Argentina** argues that the suspension of consideration of, or the failure to consider, the particular applications of interest to Argentina constitutes an SPS measure and is contrary to the requirements of Article 5.1 because it is not based on any risk assessments. Argentina points out that there are applications that have not been approved in spite of the fact that member States or the EC scientific committees have conducted risk assessments and the assessments were favourable. In these cases, the requirements of Article 5.1 have not been met because the favourable risk assessment has not been taken into consideration. Other applications have had their processing suspended without any risk assessment having been conducted either by member States or EC scientific committees. In these cases, the requirements of Article 5.1 have not been met because no risk assessment was

performed on account of the suspension of consideration of, or failure to consider, the relevant applications.

7.1685 The **European Communities** argues that the delays (or failure to act within a specific timeframe) in the approval process alleged by the Complaining Parties can be reviewed under the *SPS Agreement* as an issue of *application* of an SPS measure and more specifically, of the approval system set up under the EC GMO legislation, and that the delays of the kind alleged by the Complaining Parties here thus cannot constitute an SPS measure in the sense of Annex A(1). As a matter of logic, it is clear that alleged behaviour by a Member cannot be an SPS measure itself as well as the application of another SPS measure. As the delays of the kind alleged by the Complaining Parties do not fall within the definition of an SPS measure defined by Annex A(1), the European Communities considers that Article 5.1 is not applicable to these delays.

7.1686 The **Panel** notes that, by its clear terms, Article 5.1 applies to SPS measures. Accordingly, for a particular product-specific measure to be subject to Article 5.1, it must be an SPS measure. The European Communities contests that the product-specific measures constitute SPS measures within the meaning of Article 5.1. It is therefore necessary to consider this issue.

7.1687 We recall that the Complaining Parties have stated that the product-specific measures they are challenging are related to the general moratorium on approvals. We have observed that based on these statements we understand that the product-specific measures are, or arise from:

- specified acts and/or omissions through which the relevant EC entities were giving effect, in the context of particular approval procedures, to their decisions to impose a general moratorium on approvals, or
- specified acts and/or omissions through which relevant EC entities chose to respond, again in the context of particular approval procedures, to the circumstance that other EC entities were imposing a general moratorium on approvals.

7.1688 In relation to the general moratorium on approvals, we have found earlier that the European Communities' decision to apply a general moratorium on approvals was not a decision effectively imposing an across-the-board definitive marketing ban, but a decision concerning the application, or operation, of approval procedures. We also found that the decision in question was not, itself, a measure applied to achieve the European Communities' appropriate level of protection. These findings led us to conclude that the European Communities' decision to apply a general moratorium on approvals was not an "SPS measure" within the meaning of Annex A(1) and Article 5.1.

7.1689 If, as we believe, the European Communities' decision to apply a general moratorium on approvals was not an "SPS measure", logic suggests that the same should be true for the product-specific measures, considering that, in our understanding, they essentially are acts and/or omissions through which relevant EC entities were giving effect to the decision to apply a general moratorium on approvals, or through which they were reacting to the circumstance that other EC entities were imposing a general moratorium.[1371] Notwithstanding the fact that there is a logical link between the general moratorium and the product-specific measures, it is appropriate to examine in more detail whether the latter measures constitute SPS measures within the meaning of Annex A(1) and Article 5.1. As the Complaining Parties have provided slightly different descriptions of the product-

[1371] We recall that in relation to the second category of acts and/or omissions, the Complaining Parties essentially allege that applications were processed at a delayed pace in view of the existence of a general moratorium on final approvals until certain conditions were met.

specific measures of which they are complaining, we examine this issue separately for each Complaining Party.[1372]

(a) DS291 (United States)

7.1690 As we have previously noted, the United States is challenging the alleged failure by the European Communities to consider particular applications for final approval. We recall that for a particular measure to be subject to Article 5.1 it must be an "SPS measure". To determine whether the European Communities' alleged failure to consider a particular application for final approval constitutes an "SPS measure", we first look to the definition of that term set out in Annex A(1) of the *SPS Agreement*. According to Annex A(1), SPS measures include "requirements and procedures".

7.1691 Regarding "requirements", we note that failure to consider a particular application for final approval, even if intentional, is not the same thing as a negative final approval decision on that application. Nor does failure to consider for final approval necessarily lead to, or predetermine, a negative final approval decision. Consequently, we are of the view that the European Communities' alleged failure to consider a particular application for final approval would not have imposed a substantive SPS "requirement" within the meaning of the Annex A(1) definition of the term "SPS measure".

7.1692 The United States argues, however, that, in effect, the European Communities' alleged failure to consider particular applications for final approval banned the relevant biotech products from the EC market. We would agree that failure to consider a particular application for final approval would ordinarily result in delays in the completion of the relevant approval procedure. In turn, these delays would have the effect of extending the time-period during which the biotech product in question was subject to the provisional marketing ban flowing from the EC pre-marketing approval requirement. But a failure to consider a particular application for final approval would not have imposed a new ban; a ban was already in place, as a consequence of the pre-marketing approval requirement. In other words, the origin of the provisional marketing ban, including of the effectively extended ban, would not have been the failure to consider the relevant application for final approval, but the EC pre-marketing approval requirement, *i.e.*, the European Communities' substantive decision to ban biotech products until they have been approved.

7.1693 Consistent with the foregoing, we agree that failure to consider a particular application for final approval would have had an impact on how long the provisional marketing ban was in place for the relevant biotech product. Yet we are unable to agree that a failure to consider an application for final approval effectively would have imposed a new marketing ban, and, hence, a negative "requirement", on the biotech product concerned. If the United States had been of the view that the aforementioned impact on the provisional marketing ban resulted in that ban being applied inconsistently with Article 5.1, it was open to it to challenge that ban (*i.e.*, the pre-marketing approval requirement) as the source of the provisional marketing ban. The United States chose not to do so in this case.

7.1694 Regarding "procedures", we note the United States' argument that the European Communities' alleged failure to consider particular applications for final approval "modified" part of the EC approval regime. Since the alleged product-specific measures in question would not, in our view, have imposed any new substantive requirement, we do not think that they would have modified any substantive requirement which is part of the EC approval regime. What remains to be examined, then,

[1372] *See also* our discussion of the Complaining Parties' Article 5.1 claim in Section VII.D.5 above.

is whether the product-specific measures would have modified the relevant EC approval procedures.[1373]

7.1695 Clearly, the European Communities' alleged failure to consider a particular application for final approval would not itself have constituted, or established, a procedure for approving the relevant biotech product or, more to the point, for preventing the final approval of this biotech product. The failure to consider a particular application for final approval also would not have effectively amended the relevant EC approval procedure for the specific biotech product in question. As we have explained in earlier findings on the general moratorium on approvals, the European Communities did not apply a different type of approval procedure. The applications in question continued to be assessed in accordance with the procedure set out in Directives 90/220 and 2001/18, as well as Regulation 258/97. Therefore, we are not persuaded that the alleged failure to consider a particular application for final approval would have "modified" the relevant EC approval procedure. In our assessment, the foregoing also leads to the conclusion that the alleged failure to consider a particular application for final approval cannot be considered a "procedure" within the meaning of Annex A(1).

7.1696 Thus far, we have found that the European Communities' alleged failure to consider a particular application for final approval qualifies neither as a "requirement" nor as a "procedure" within the meaning of Annex A(1). But we have not yet determined in positive terms what is the legal nature of the failure in question. We think the United States' reference to the failure by the European Communities to consider a particular application for final approval should be understood, and makes sense, as a reference to the application by the European Communities of a particular way of operating the relevant EC approval procedure – a way which reflected the intention, or the anticipation, that there would be no final approval decision on the application in question until certain conditions were met. In other words, we think that, in essence, the United States is complaining of a particular manner of operating the EC approval procedures in specific cases.

7.1697 In terms of Annex A(1), this means that we are concerned with the application, or operation, of "procedures". As we have said in our earlier findings, while "procedures" as such may according to the Annex A(1) definition constitute SPS measures, the application, or operation, of such procedures does not, itself, constitute an SPS measure within the meaning of Annex A(1). Accordingly, we come to the conclusion that the European Communities' alleged failure to consider a particular application for final approval does not meet all of the constituent elements of the definition of the term "SPS measure" as provided in Annex A(1).

7.1698 Turning now to Article 5.1, we recall our earlier finding that the term "SPS measure" in Article 5.1 should be interpreted to refer to a measure applied for achieving the relevant Member's appropriate level of sanitary or phytosanitary protection. In our view, the European Communities' alleged failure to consider a particular application for final approval would not, itself, have been a measure applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection. Rather, as we have said, it would have been the application of a particular way of operating the relevant EC approval procedure. As we explained above, the practical effect of the alleged failure to consider a particular application for final approval would have been to extend the time-period during which the relevant biotech product was subject to the provisional marketing ban flowing from the pre-marketing approval requirement. The pre-marketing approval requirement which imposes the provisional marketing ban is a measure applied to achieve the European Communities' level of protection, but that requirement is a separate measure from the European Communities' alleged failure to consider a particular application for final approval. By itself, the

[1373] The relevant approval procedures are set out in Directive 90/220 and its successor, Directive 2001/18, as well as Regulation 258/97.

alleged failure to consider a particular application for final approval would not have achieved or implied a particular level of protection.

7.1699 As the European Communities' alleged failure to consider a particular application for final approval would not, itself, have been a measure applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection, it cannot, in our view, be considered an "SPS measure" within the meaning of Article 5.1.

7.1700 Based on the above considerations, we thus determine that the European Communities' alleged failure to consider a particular application for final approval cannot be considered an "SPS measure" within the meaning of Article 5.1 and Annex A(1). As only "SPS measures" are subject to the provisions of Article 5.1, it follows that the provisions of Article 5.1 are not applicable to the European Communities' alleged failure to consider particular applications for final approval. In view of this conclusion, we need not continue our analysis of the United States' claim under Article 5.1.

(b) DS292 (Canada)

7.1701 In relation to DS292, we have noted above that Canada is challenging the alleged failure by the European Communities to consider or approve, without undue delay, particular applications of specific interest to Canada. Canada also refers to this failure to consider or approve applications as an effective "product-specific marketing ban".

7.1702 Regarding Canada's reference to an effective product-specific marketing ban, we note that we have already addressed a similar argument of the United States. Thus, we need only recall that we agree that the alleged failure by the European Communities to consider or approve a particular application would have had an impact on how long the provisional marketing ban resulting from the EC pre-marketing approval requirement was in place for the relevant biotech product. But we are unable to agree that the alleged failure to consider or approve an application effectively would have imposed a new marketing ban, and, hence, a negative "requirement", on the biotech product concerned.

7.1703 Instead, similar to what we have said of the measures challenged by the United States, we consider that Canada's reference to the failure by the European Communities to consider or approve a particular application should be understood, and makes sense, as a reference to the application by the European Communities of a particular way of operating the relevant EC approval procedure – a way which reflected the intention, or the anticipation, that there would be no final approval decision on the application in question until certain conditions were met. Thus, we think that, in essence, Canada is complaining of a particular manner of operating the EC approval procedures in specific cases.

7.1704 For the same reasons as those we have given in the context of our analysis of the measures challenged by the United States, the type of measure Canada is challenging in our view (i) does not itself constitute an SPS measure within the meaning of Annex A(1) and (ii) is not a measure applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection and hence cannot be considered an "SPS measure" within the meaning of Article 5.1.

7.1705 As only "SPS measures" are subject to the provisions of Article 5.1, it follows that the provisions of Article 5.1 are not applicable to the European Communities' alleged failure to consider or approve particular applications. In view of this conclusion, we need not continue our analysis of Canada's claim under Article 5.1.

(c) DS293 (Argentina)

7.1706 In relation to DS293, we note that Argentina makes claims under Article 5 of the *SPS Agreement* regarding all ten applications in respect of which the Panel has decided to offer product-specific findings. We first address the applications concerning Bt-531 cotton and RR-1445 cotton which Argentina says have yet to be approved under Regulation 258/97.

(i) Product-specific measures affecting the approval of Bt-531 cotton and RR-1445 cotton under Regulation 258/97

7.1707 Argentina challenges under Article 5.1 the suspension of consideration of, or failure to consider, applications concerning Bt-531 cotton and RR-1445 cotton which were allegedly submitted for "approval"[1374] under Regulation 258/97.

7.1708 Argentina has provided no evidence of the existence of applications concerning Bt-531 cotton and RR-1445 cotton which were submitted for "approval" under Regulation 258/97. The only evidence provided by Argentina in support of its claim relates to cottonseed oil derived from Bt-531 cottonseed or RR-1445 cottonseed. These products were subject to the simplified procedure set out in Article 5 of Regulation 258/97. As indicated by us earlier, under the simplified procedure, there are no "applications" for the placing on the market of subject products which are then "approved" by member State assessment bodies. Moreover, in its request for the establishment of a panel, Argentina identifies Bt-531 cotton and RR-1445 cotton as a relevant biotech product, but not cottonseed oil derived from Bt-531 cottonseed or RR-1445 cottonseed. Thus, cottonseed oil derived from Bt-531 cottonseed or RR-1445 cottonseed is outside the terms of reference of DS293 (Argentina).

7.1709 In view of the fact that we have seen no evidence that applications concerning Bt-531 cotton and RR-1445 cotton were submitted for approval under Regulation 258/97, we find that Argentina has failed to meet its burden of demonstrating the existence of a suspension of consideration of, or failure to consider, Bt-531 cotton and RR-1445 cotton for approval under Regulation 258/97. As the existence of these product-specific measures has not been demonstrated, we cannot but reject Argentina's claim that the European Communities has acted inconsistently with its obligations under Article 5.1 in relation to these alleged measures.

(ii) Other product-specific measures challenged by Argentina

7.1710 We now turn to address the remaining eight product-specific measures in respect of which the Panel has decided to make findings. As noted, Argentina describes the product-specific measures it is challenging under Article 5.1 as the suspension by the European Communities of consideration of, or the failure to consider, particular applications of interest to Argentina.

7.1711 As with the measures challenged by the United States, we are of the view that the measures challenged by Argentina qualify neither as "requirements" nor as "procedures" within the meaning of Annex A(1). Instead, we think Argentina's reference to the suspension of consideration of, or failure to consider, a particular application should be understood, and makes sense, as a reference to the application by the European Communities of a particular way of operating the relevant EC approval procedure – a way which reflected the intention, or the anticipation, that there would be no final approval decision on the application in question until certain conditions were met. In other words, we think that, in essence, Argentina is complaining of a particular manner of operating the EC approval procedures in specific cases.

[1374] Argentina's first written submission, paras. 201-202.

7.1712 For the same reasons as those we have given in the context of our analysis of the measures challenged by the United States, the type of measure Argentina is challenging in our view (i) does not itself constitute an SPS measure within the meaning of Annex A(1) and (ii) is not a measure applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection and hence cannot be considered an "SPS measure" within the meaning of Article 5.1.

7.1713 As only "SPS measures" are subject to the provisions of Article 5.1, it follows that the provisions of Article 5.1 are not applicable to the European Communities' alleged suspension of consideration of, or failure to consider, particular applications. In view of this conclusion, we need not continue our analysis of Argentina's claim under Article 5.1.

(d) Conclusions

7.1714 In the light of the above, the Panel reaches the following conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence submitted by the United States and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* in respect of any of the product-specific measures on which the Panel is offering findings.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence submitted by Canada and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* in respect of any of the product-specific measures on which the Panel is offering findings.

4. Consistency of the product-specific measures with Article 5.6 of the *SPS Agreement*

7.1715 Canada and Argentina claim that the European Communities has acted inconsistently with its obligations under Article 5.6 of the *SPS Agreement* in respect of the product-specific measures they are challenging.

7.1716 Article 5.6 of the *SPS Agreement* provides:

> "Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or

> phytosanitary protection, taking into account technical and economic feasibility." (footnote omitted)

7.1717 **Canada** argues that the failure of the European Communities to consider or approve, without undue delay, the four applications of specific interest to Canada is an SPS measure as defined in Annex A(1). The failure to consider and approve these applications, which Canada refers to as the "product-specific marketing bans", is "more trade restrictive than required", contrary to Article 5.6. This is because there is another SPS measure that is reasonably available, taking into account technical or economic feasibility; achieves the European Communities' appropriate level of sanitary and phytosanitary protection; and is significantly less restrictive to trade than the contested SPS measure.

7.1718 **Argentina** argues that the suspension of consideration of, or the failure to consider, the particular applications of interest to Argentina constitutes an SPS measure and is contrary to the requirements of Article 5.6. This violation of Article 5.6 results from the fact that there exists another SPS measure that: (1) is reasonably available taking into account technical and economic feasibility; (2) achieves the European Communities' appropriate level of sanitary and phytosanitary protection; and (3) is significantly less restrictive to trade than the contested SPS measure.

7.1719 The **European Communities** argues that the delays (or failure to act within a specific timeframe) in the approval process alleged by the Complaining Parties can be reviewed under the *SPS Agreement* as an issue of *application* of an SPS measure and more specifically, of the approval system set up under the EC GMO legislation, and that the delays of the kind alleged by the Complaining Parties thus cannot constitute an SPS measure in the sense of Annex A(1). As a matter of logic, it is clear that alleged behaviour by a Member cannot be an SPS measure itself as well as the application of another SPS measure. As the delays of the kind alleged by the Complaining Parties do not fall within the definition of an SPS measure defined by Annex A(1), the European Communities considers that Article 5.6 is not applicable to these delays.

7.1720 The **Panel** will analyse Canada's and Argentina's claim separately.[1375]

(a) DS292 (Canada)

7.1721 In relation to DS292, we note that for a particular measure to be subject to Article 5.6 it must be an SPS measure. We also note that Article 5.6 explicitly refers to "[SPS] measures to achieve the appropriate level of sanitary or phytosanitary protection". Furthermore, we recall that in the context of our earlier analysis of Canada's claim under Article 5.1 we found that the type of measure Canada is challenging in our view (i) does not itself constitute an SPS measure within the meaning of Annex A(1) and (ii) is not a measure applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection. It follows from these elements that the alleged failure by the European Communities to consider or approve a particular application cannot be considered an "SPS measure" within the meaning of Article 5.6.

7.1722 As only "SPS measures" are subject to the provisions of Article 5.6, the provisions of Article 5.6 are not applicable to the European Communities' alleged failure to consider or approve particular applications. In view of this conclusion, we need not continue our analysis of Canada's claim under Article 5.6.

[1375] *See also* our discussion of Canada's and Argentina's Article 5.6 claim in Section VII.D.6 above.

(b) DS293 (Argentina)

7.1723 In relation to DS293, we begin our analysis with the applications concerning Bt-531 cotton and RR-1445 cotton which Argentina says have yet to be approved under Regulation 258/97.

(i) Product-specific measures affecting the approval of Bt-531 cotton and RR-1445 cotton under Regulation 258/97

7.1724 Argentina challenges under Article 5.6 the suspension of consideration of, or failure to consider, applications concerning Bt-531 cotton and RR-1445 cotton which were allegedly submitted for "approval"[1376] under Regulation 258/97.

7.1725 We recall that in respect of the same alleged product-specific measures Argentina presented a claim under Article 5.1 of the *SPS Agreement*. In the context of our analysis of that claim, we have pointed out that we have seen no evidence that applications concerning Bt-531 cotton and RR-1445 cotton were submitted for approval under Regulation 258/97, and we therefore found that Argentina has failed to meet its burden of demonstrating the existence of a suspension of consideration of, or failure to consider, Bt-531 cotton and RR-1445 cotton for approval under Regulation 258/97. As the existence of these product-specific measures has not been demonstrated, we cannot but reject Argentina's claim that the European Communities has acted inconsistently with its obligations under Article 5.6 in relation to these alleged measures.

(ii) Other product-specific measures challenged by Argentina

7.1726 We now turn to address the remaining eight product-specific measures in respect of which the Panel has decided to make findings.

7.1727 We recall that for a particular measure to be subject to Article 5.6 it must be an SPS measure. We also recall that Article 5.6 explicitly refers to "[SPS] measures to achieve the appropriate level of sanitary or phytosanitary protection". Furthermore, we recall that in the context of our earlier analysis of Argentina's claim under Article 5.1 we found that the type of measure Argentina is challenging in our view (i) does not itself constitute an SPS measure within the meaning of Annex A(1) and (ii) is not a measure applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection. It follows from these elements that the European Communities' alleged suspension of consideration of, or failure to consider, a particular application cannot be considered an "SPS measure" within the meaning of Article 5.6.

7.1728 As only "SPS measures" are subject to the provisions of Article 5.6, the provisions of Article 5.6 are not applicable to the European Communities' alleged suspension of consideration of, or failure to consider, particular applications. In view of this conclusion, we need not continue our analysis of Argentina's claim under Article 5.6.

[1376] Argentina's first written submission, paras. 201-202

(c) Conclusions

7.1729 In the light of the above, the Panel reaches the following conclusions:

(i) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence submitted by Canada and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.6 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.6 of the *SPS Agreement* in respect of any of the product-specific measures on which the Panel is offering findings.

5. Consistency of the product-specific measures with Article 5.5 of the *SPS Agreement*

7.1730 All three Complaining Parties claim that the European Communities has acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* in respect of the product-specific measures they are challenging.

7.1731 Article 5.5 of the *SPS Agreement* provides:

> "With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.[....]"

7.1732 The **United States** argues that the product-specific moratoria, which, in effect, ban the relevant biotech products from the EC market, are "SPS measures" as defined in Annex A(1) of the *SPS Agreement*. The United States argues that like the general moratorium, the product-specific moratoria meet all three elements that are required to establish a violation of Article 5.5. *First*, the European Communities has set forth distinct levels of sanitary protection in "different situations": products produced with biotech processing aids and other biotech products. *Second*, those levels of protection exhibit differences that are "arbitrary or unjustifiable." *Third*, the product-specific moratoria result in "discrimination or a disguised restriction on international trade."

7.1733 **Canada** puts forth its claim under Article 5.5 as an alternative to its claim under Article 5.6. In putting forth the Article 5.6 claim, Canada assumed that the European Communities' appropriate level of protection is a "high level of protection", but not a zero-risk level. However, if this assumption is not correct and the European Communities' appropriate level of protection for the four applications of specific interest to Canada at issue is that reflected by the product-specific marketing bans, namely a zero-risk level, then Canada is of the view that the European Communities has violated Article 5.5 of the *SPS Agreement*.

7.1734 Canada argues that the failure of the European Communities to consider or approve, without undue delay, the four applications of specific interest to Canada is an SPS measure as defined in Annex A(1). Canada claims that the failure to consider and approve these applications, which Canada refers to as the "product-specific marketing bans" meet all three elements that are required to establish a violation of Article 5.5. *First*, the European Communities has adopted different appropriate levels of sanitary and phytosanitary protection in "different situations" that are comparable. *Second*, those different appropriate levels of protection are "arbitrary or unjustifiable." *Third*, the measures embodying those differences, the product-specific marketing bans, result in "discrimination or a disguised restriction on international trade".

7.1735 According to Canada, the "comparable" situations above are of the following two kinds: (i) the biotech products whose applications have been stalled as a result of the product-specific marketing bans on the one hand and the biotech products that were approved for commercialization prior to the imposition of the moratorium on the other; (ii) the biotech products whose applications have been stalled as a result of the product-specific marketing bans on the one hand and novel non-biotech products such as those produced by conventional plant breeding techniques on the other.

7.1736 **Argentina** argues that the suspension of consideration of, or the failure to consider, the particular applications of interest to Argentina constitutes an SPS measure and is contrary to the requirements of Article 5.5. This is because the suspension of consideration of, or the failure to consider, the particular applications of interest to Argentina meets the three distinct and cumulative elements which are required to be demonstrated in support of a claim under Article 5.5: (i) The Member that imposes the measure that is the subject of the complaint must have adopted its own levels of sanitary protection against risks to human, animal or plant life or health in various different situations, which are comparable; (ii) these levels of protection exhibit arbitrary or unjustifiable differences in the treatment of different situations; and (iii) these arbitrary or unjustifiable differences must result in discrimination or a restriction of international trade.

7.1737 According to Argentina, the "comparable" situations are of the following two kinds: (1) biotech products introduced before and after the moratorium; (2) new "non-biotech" products and new biotech products.

7.1738 The **European Communities** argues that the delays (or failure to act within a specific timeframe) in the approval process alleged by the Complaining Parties can be reviewed under the *SPS Agreement* as an issue of *application* of an SPS measure and more specifically, of the approval system set up under the EC GMO legislation, and that the delays of the kind alleged by the Complaining Parties thus cannot constitute an SPS measure in the sense of Annex A(1). As a matter of logic, it is clear that alleged behaviour by a Member cannot be an SPS measure itself as well as the application of another SPS measure. As the delays of the kind alleged by the Complaining Parties do not fall within the definition of an SPS measure defined by Annex A(1), the European Communities considers that Article 5.6 is not applicable to these delays.

7.1739 The **Panel** will analyse separately the claim presented by each Complaining Party.[1377]

(a) DS291 (United States)

7.1740 In relation to DS291, we recall that we have determined in the context of our analysis of the challenge to the general EC moratorium that Article 5.5 implies a reference to "SPS measures" and that the SPS measures at issue in Article 5.5 are those which are applied for achieving a particular

[1377] *See also* our discussion of the Complaining Parties' Article 5.5 claim in Section VII.D.7 above.

level of sanitary or phytosanitary protection (*i.e.*, measures implementing a particular level of protection). Accordingly, Article 5.5 implies that the measure complained of is an implementing "SPS measure". We recall that in the context of our earlier analysis of the United States' product-specific claim under Article 5.1 we found that the type of measure the United States is challenging in our view (i) does not itself constitute an SPS measure within the meaning of Annex A(1) and (ii) is not a measure applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection. It follows from these elements that the alleged failure by the European Communities to consider a particular application for final approval cannot be considered an "SPS measure" within the meaning of Annex A(1) and Article 5.5 as interpreted by the Appellate Body.

7.1741 As Article 5.5 in our view implies that the measures complained of are implementing "SPS measures", we consider that the provisions of Article 5.5 are not applicable to the European Communities' alleged failure to consider particular applications for final approval. In view of this conclusion, we need not continue our analysis of the United States' claim under Article 5.5.

(b) DS292 (Canada)

7.1742 In relation to DS292, we recall that we have determined in the context of our analysis of the challenge to the general EC moratorium that Article 5.5 implies a reference to "SPS measures" and that the SPS measures at issue in Article 5.5 are those which are applied for achieving a particular level of sanitary or phytosanitary protection (*i.e.*, measures implementing a particular level of protection). Accordingly, Article 5.5 implies that the measure complained of is an implementing "SPS measure". We recall that in the context of our earlier analysis of Canada's product-specific claim under Article 5.1 we found that the type of measure Canada is challenging in our view (i) does not itself constitute an SPS measure within the meaning of Annex A(1) and (ii) is not a measure applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection. It follows from these elements that the alleged failure by the European Communities to consider or approve a particular application cannot be considered an "SPS measure" within the meaning of Annex A(1) and Article 5.5 as interpreted by the Appellate Body.

7.1743 As Article 5.5 in our view implies that the measure complained of is an implementing "SPS measure", we consider that the provisions of Article 5.5 are not applicable to the European Communities' alleged failure to consider or approve particular applications. In view of this conclusion, we need not continue our analysis of Canada's claim under Article 5.5.

(c) DS293 (Argentina)

7.1744 In relation to DS293, we begin our analysis with the applications concerning Bt-531 cotton and RR-1445 cotton which Argentina says have yet to be approved under Regulation 258/97.

(i) Product-specific measures affecting the approval of Bt-531 cotton and RR-1445 cotton under Regulation 258/97

7.1745 Argentina challenges under Article 5.5 the suspension of consideration of, or failure to consider, applications concerning Bt-531 cotton and RR-1445 cotton which were allegedly submitted for "approval"[1378] under Regulation 258/97.

7.1746 We recall that in respect of the same alleged product-specific measures Argentina presented a claim under Article 5.1 of the *SPS Agreement*. In the context of our analysis of that claim, we have

[1378] Argentina's first written submission, paras. 201-202.

pointed out that we have seen no evidence that applications concerning Bt-531 cotton and RR-1445 cotton were submitted for approval under Regulation 258/97, and we therefore found that Argentina has failed to meet its burden of demonstrating the existence of a suspension of consideration of, or failure to consider, Bt-531 cotton and RR-1445 cotton for approval under Regulation 258/97. As the existence of these product-specific measures has not been demonstrated, we cannot but reject Argentina's claim that the European Communities has acted inconsistently with its obligations under Article 5.5 in relation to these alleged measures.

(ii) Other product-specific measures challenged by Argentina

7.1747 We now turn to address the remaining eight product-specific measures in respect of which the Panel has decided to make findings.

7.1748 We recall that we have determined in the context of our analysis of the challenge to the general EC moratorium that Article 5.5 implies a reference to "SPS measures" and that the SPS measures at issue in Article 5.5 are those which are applied for achieving a particular level of sanitary or phytosanitary protection (*i.e.*, measures implementing a particular level of protection). Accordingly, Article 5.5 implies that the measure complained of is an implementing "SPS measure". We recall that in the context of our earlier analysis of Argentina's product-specific claim under Article 5.1 we found that the type of measure Argentina is challenging in our view (i) does not itself constitute an SPS measure within the meaning of Annex A(1) and (ii) is not a measure applied for achieving the European Communities' appropriate level of sanitary or phytosanitary protection. It follows from these elements that the alleged suspension by the European Communities of consideration of, or the failure to consider, a particular application cannot be considered an "SPS measure" within the meaning of Annex A(1) and Article 5.5 as interpreted by the Appellate Body.

7.1749 As Article 5.5 in our view implies that the measures complained of are implementing "SPS measures", we consider that the provisions of Article 5.5 are not applicable to the European Communities' alleged suspension of consideration of, or the failure to consider, particular applications. In view of this conclusion, we need not continue our analysis of Argentina's claim under Article 5.5.

(d) Conclusions

7.1750 In the light of the above, the Panel reaches the following conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence submitted by the United States and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* in respect of any of the product-specific measures on which the Panel is offering findings.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence submitted by Canada and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* in respect of any of the product-specific measures on which the Panel is offering findings.

6. Consistency of the product-specific measures with Article 2.2 of the *SPS Agreement*

7.1751 All three Complaining Parties claim that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* in respect of the product-specific measures they are challenging.

7.1752 Article 2.2 of the *SPS Agreement* provides:

> "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5."

7.1753 **The United States** claims that, as the basic obligations provided in Article 2.2 have been viewed as being specifically applied in Article 5.1, the product-specific measures – the product-specific moratoria – are also inconsistent with Article 2.2, because they are not based on risk assessments as required by Article 5.1 and Annex A, paragraph 4.

7.1754 **Canada** argues that Articles 5.1 and 5.6 can be viewed as a specific application of the basic obligation contained in Article 2.2, and a violation of Articles 5.1 and 5.6 can be thus presumed to imply a violation of the more general provision of Article 2.2. Canada is of the view that, as it has already demonstrated that the product-specific marketing bans are not "based on" risk assessments and are therefore inconsistent with Articles 5.1 and 5.6, it can therefore be presumed that the product-specific marketing bans also violate the requirements of Article 2.2.

7.1755 **Argentina** argues that since it has demonstrated that the suspension of consideration of, or the failure to consider, the particular applications of interest to Argentina is not "based on a risk assessment", it has duly proven that the said suspension does not meet the requirements of Article 2.2.

7.1756 The **European Communities** argues that the delays (or failure to act within a specific timeframe) in the approval process alleged by the Complaining Parties can be reviewed under the *SPS Agreement* as an issue of *application* of an SPS measure and more specifically, of the approval system set up under the EC GMO legislation, and that the delays of the kind alleged by the Complaining Parties here thus cannot constitute an SPS measure in the sense of Annex A(1). As a matter of logic, it is clear that alleged behaviour by a Member cannot be an SPS measure itself as well as the application of another SPS measure. As the delays of the kind alleged by the Complaining Parties do not fall within the definition of an SPS measure defined by Annex A(1), the European Communities considers that Article 2.2 is not applicable to these delays.

(a) Evaluation

7.1757 The **Panel** notes that the Complaining Parties' claim under Article 2.2[1379] is in the nature of a consequential claim. The Complaining Parties submit that an inconsistency with Article 2.2 follows by implication from a demonstrated inconsistency with Article 5.1. However, we have determined above that Article 5.1 is not applicable to the product-specific measures as defined by the Complaining Parties and that, consequently, the European Communities has not acted inconsistently with its obligations under Article 5.1 in respect of the relevant product-specific measures. Since the European Communities has not acted inconsistently with Article 5.1, and since the Complaining Parties' claim under Article 2.2 is premised on the existence of a breach of Article 5.1 by the European Communities, the Complaining Parties' claim under Article 2.2 in our view cannot succeed.

7.1758 In relation to DS292, we note that Canada argues in addition that an inconsistency with Article 2.2 also follows by implication from a demonstrated inconsistency with Article 5.6. However, we have reached the same conclusion on Canada's claim under Article 5.6 as we have on Canada's claim under Article 5.1. Accordingly, our reasoning in the preceding paragraph *mutatis mutandis* also applies to Canada's argument based on the alleged inconsistency of the relevant product-specific measures with Article 5.6.

7.1759 In relation to DS293, we recall, in addition, our earlier finding that Argentina has failed to meet its burden of demonstrating the existence of a suspension of consideration of, or failure to consider, Bt-531 cotton and RR-1445 cotton for approval under Regulation 258/97. As the existence of these product-specific measures has not been demonstrated, we cannot but reject Argentina's claim that the European Communities has acted inconsistently with its obligations under Article 2.2 in relation to these alleged measures.

(b) Conclusions

7.1760 In the light of the above, the Panel reaches the following conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence submitted by the United States and the European Communities, the Panel concludes that the United States has failed to establish that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* in respect of any of the product-specific measures on which the Panel is offering findings.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence submitted by Canada and the European Communities, the Panel concludes that Canada has failed to establish that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

[1379] *See also* our discussion of the Complaining Parties' Article 2.2 claim in Section VII.D.8 above.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that Argentina has failed to establish that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* in respect of any of the product-specific measures on which the Panel is offering findings.

7. Consistency of the product-specific measures with Article 2.3 of the *SPS Agreement*

7.1761 Canada claims that the European Communities has acted inconsistently with its obligations under Article 2.3 of the *SPS Agreement* in respect of the product-specific measures it is challenging.

7.1762 Article 2.3 of the *SPS Agreement* provides:

> "Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade."

7.1763 **Canada** argues that, as the product-specific marketing bans are inconsistent with the European Communities' obligations under Article 5.5, they are, by implication, also inconsistent with the European Communities' obligations under Article 2.3, in accordance with the jurisprudence established by the Appellate Body.

7.1764 The **European Communities** argues that the delays (or failure to act within a specific timeframe) in the approval process alleged by the Complaining Parties can be reviewed under the *SPS Agreement* as an issue of *application* of an SPS measure and more specifically, of the approval system set up under the EC GMO legislation, and that the delays of the kind alleged by the Complaining Parties thus cannot constitute an SPS measure in the sense of Annex A(1). As a matter of logic, it is clear that alleged behaviour by a Member cannot be an SPS measure itself as well as the application of another SPS measure. As the delays of the kind alleged by the Complaining Parties do not fall within the definition of an SPS measure defined by Annex A(1), the European Communities considers that Article 2.3 is not applicable to these delays.

(a) DS292 (Canada)

7.1765 The **Panel** notes that Canada's claim under Article 2.3[1380] is in the nature of a consequential claim. Canada submits that an inconsistency with Article 2.3 follows by implication from a demonstrated inconsistency with Article 5.5. However, we have determined above that Article 5.5 is not applicable to the product-specific measures as defined by Canada and that, consequently, the European Communities has not acted inconsistently with its obligations under Article 5.5 in respect of the relevant product-specific measures. Since the European Communities has not acted inconsistently with Article 5.1, and since Canada's claim under Article 2.3 is premised on the existence of a breach of Article 5.5 by the European Communities, Canada's claim under Article 2.3 in our view cannot succeed.

[1380] *See also* our discussion of Canada's Article 2.3 claim in Section VII.D.9 above.

(b) Conclusion

7.1766 In the light of the above, the Panel reaches the following conclusion:

(i) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence submitted by Canada and the European Communities, the Panel concludes that Canada has failed to establish that the European Communities has acted inconsistently with its obligations under Article 2.3 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

8. Consistency of the product-specific measures with Article 7 and Annex B(1) of the *SPS Agreement*

7.1767 The United States claims that the European Communities has failed to publish promptly the existence of the product-specific measures the United States is challenging and that the European Communities has thereby acted inconsistently with its obligations under Article 7 and Annex B(1) of the *SPS Agreement*.

7.1768 Article 7 of the *SPS Agreement* provides:

> "Members shall notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B."

7.1769 Annex B(1) of the *SPS Agreement* provides:

> "Members shall ensure that all sanitary and phytosanitary regulations[1381] which have been adopted are published promptly in such a manner as to enable interested Members to become acquainted with them."

7.1770 The **United States** submits that the product-specific measures it is challenging – the product-specific moratoria – are subject to the publication requirement in Annex B(1). The United States argues that this is for the same reasons which it has provided to establish the applicability of Annex B(1) to the general moratorium. The United States considers that because the European Communities has failed to publish, and, therefore, to publish promptly, the existence of the product-specific moratoria, the European Communities has acted inconsistently with its obligations under Annex B(1) and Article 7.

7.1771 The **European Communities** argues that Article 7 contains procedural obligations (publication) regarding an SPS measure. Thus, the applicability of Article 7 is premised on the existence of an SPS measure. SPS measures as defined in Annex A(1) of the *SPS Agreement* presuppose the existence of an act. The European Communities submits that the measures challenged by the United States are alleged failures to act within a particular timeframe. Thus, the United States is in reality complaining about delay in the completion of specified individual approval procedures. In the European Communities' view, delay of this kind cannot constitute an SPS measure within the

[1381] Sanitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally.

meaning of Annex A(1). Delay is a failure to act in a timely manner. The European Communities deduces from these considerations that the alleged measures are not subject to Article 7.

7.1772 The **Panel** notes that the United States alleges an inconsistency of the product-specific measures identified by it with Annex B(1). The United States uses the alleged inconsistency with Annex B(1) as a basis for a consequential claim of inconsistency under Article 7. Accordingly, we will begin our analysis with the United States' claim under Annex B(1).

(a) "Sanitary and phytosanitary regulations"

7.1773 As we have stated earlier, Annex B(1) applies to "sanitary and phytosanitary regulations" (hereafter "SPS regulations") which have been "adopted". An explanatory footnote to Annex B(1) indicates that the term "SPS regulations" should be understood as meaning "[s]anitary and phytosanitary measures such as laws, decrees or ordinances which are applicable generally".

7.1774 It follows from the foregoing that a threshold issue before us is whether the product-specific measures challenged by the United States constitute generally applicable SPS measures which have been adopted. We first examine whether the relevant product-specific measures are "generally applicable".

7.1775 We recall that what the United States is challenging in the case of each of the product-specific measures is an alleged failure by the European Communities to consider a specified application for final approval. As is already clear from our own description of these measures, these measures are product-specific. In other words, each of these measures affects an application concerning a specific biotech product. None of these measures is applicable to all biotech products generally, or at least to all biotech products which fall within the scope of the relevant EC approval procedures and require approval. To that extent, there is thus a clear difference between the product-specific measures identified by the United States and the general moratorium on approvals, which we found was generally applicable inasmuch as it was applicable to all applications which were pending between June 1999 and August 2003.

7.1776 In the light of this, we are unable to agree with the United States that each of the product-specific measures it is challenging is a measure which is "applicable generally". As general applicability is a necessary definitional element of the term "SPS regulations", it is not necessary for us to examine whether the relevant product-specific measures are "SPS measures" and whether they have been "adopted". We therefore find that none of the product-specific measures challenged by the United States is an "SPS regulation" within the meaning of Annex B(1). It follows that the provisions of Annex B(1) are not applicable to these measures.

7.1777 We recall that the United States seeks to establish an inconsistency with Article 7 on the basis of an alleged inconsistency with Annex B(1). As we have found that the provisions of Annex B(1) are not applicable to the product-specific measures challenged by the United States, these measures cannot be inconsistent with these provisions. Under the approach followed by the United States, there can then logically be no inconsistency with Article 7 either, even assuming that Article 7 is applicable to these measures.

(b) Conclusion

7.1778 In the light of the above, the Panel reaches the following conclusion:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence submitted by the United States and the European Communities, the Panel concludes that the European Communities has not acted inconsistently with its obligations under Annex B(1) and Article 7 of the *SPS Agreement* in respect of any of the product-specific measures on which the Panel is offering findings.

9. Consistency of the product-specific measures with Article 8 and Annex C(1)(a), first clause, of the *SPS Agreement*

(a) General

7.1779 All three Complaining Parties claim that the European Communities has acted inconsistently with its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement* in respect of the product-specific measures they are challenging.

7.1780 Article 8 of the *SPS Agreement* provides:

> "Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement."

7.1781 Annex C(1)(a), first clause, of the *SPS Agreement* provides:

> "1. Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:
>
> (a) such procedures are undertaken and completed without undue delay [...]."

7.1782 The Complaining Parties seek to establish an inconsistency with Article 8 on the basis of an inconsistency with Annex C(1)(a), first clause. Article 8 requires, *inter alia*, that Members observe the provisions of Annex C in the operation of their approval procedures. It follows that a failure to observe the provisions of Annex C(1)(a) implies a breach of Article 8. Accordingly, should we conclude that the European Communities has failed to observe the provisions of Annex C(1)(a), first clause, in respect of any of the product-specific measures on which we make findings, we will also conclude that the European Communities has, by implication, also acted inconsistently with the provisions of Article 8.

7.1783 In relation to Annex C(1)(a), first clause, we note that we have addressed the interpretation of this provision in Section VII.D.11 above.[1382] We further note that in accordance with the lead-in to

[1382] We note that like the other Parties, Argentina has addressed the meaning of Annex C(1)(a), first clause. However, Argentina's relevant arguments do not lead us to an interpretation of Annex C(1)(a), first clause, which is different from the one we set out earlier.

Annex C(1) the provisions of Annex C(1)(a) apply "with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures". We have previously found that the procedures set out in Directives 90/220 and 2001/18 as well as Regulation 258/97 (to the extent it is an SPS measure) constitute procedures "to check and ensure the fulfilment of sanitary or phytosanitary measures" within the meaning of Annex C(1) and, as such, are subject to the provisions of Annex C(1), which include those of Annex C(1)(a). Therefore, the European Communities was and is required under the provisions of Annex C(1)(a) to "undertake and complete" the approval procedures set out in Directives 90/220 and 2001/18 as well as Regulation 258/97 (to the extent it is an SPS measure) "without undue delay".

7.1784 We recall that the United States is challenging the alleged failure by the European Communities to consider particular applications for final approval, while Canada is challenging the alleged failure by the European Communities to consider or approve, without undue delay, particular applications. We have observed in this regard that these are essentially challenges to the application by the European Communities of a particular way of operating the relevant EC approval procedures. We also recall that Argentina is challenging alleged undue delays in completing the consideration and processing of specified applications.

7.1785 It is clear to us, therefore, that the type of measure challenged by each of the Complaining Parties could in principle constitute, or lead to, a breach of the European Communities' obligations under Annex C(1)(a), first clause, and that this type of measure can therefore be examined in the light of the provisions of Annex C(1)(a), first clause. Since the Complaining Parties seek to establish an inconsistency with Article 8 on the basis of an alleged inconsistency with Annex C(1)(a), first clause, this conclusion applies also to Article 8.

(b) Deliberate Release – Applications submitted under Directive 90/220 and/or Directive 2001/18

7.1786 We now begin our examination of the approval procedures which were conducted under Directives 90/220 and 2001/18 for the applications identified by the Complaining Parties. Before going further, however, we should briefly address certain issues presented by the application of Annex C(1)(a), first clause, to approval procedures conducted under the aforementioned Directives.

(i) Application of Annex C(1)(a), first clause, to approval procedures begun under Directives 90/220 and continued under 2001/18

7.1787 Each of the relevant approval procedures on which the Panel is making findings was begun under Directive 90/220 but not completed by the date of repeal of Directive 90/220 (17 October 2002). Pursuant to the provisions of Directive 2001/18, applications which were pending on the date of repeal of Directive 90/220 (17 October 2002) became subject to Directive 2001/18 and therefore had to be "complemented" by the applicant in the light of the provisions of Directive 2001/18. If the applicant did so by a specified deadline (17 January 2003), approval procedures were to be undertaken in accordance with the provisions of Directive 2001/18.[1383] For each of the approval procedures here at issue, approval procedures were undertaken under Directive 2001/18 after the applicant had complemented its application.

7.1788 This presents the question whether approval procedures undertaken under Directive 2001/18 in respect of applications which had previously been assessed under Directive 90/220 should be viewed as new approval procedures or as a continuation of the approval procedures which were not

[1383] Article 35 of Directive 2001/18. None of the Complaining Parties questioned the WTO-consistency of Article 35.

completed under Directive 90/220. We have already examined this question in the context of our analysis of the general EC moratorium on approvals.[1384] It is therefore sufficient at this juncture to recall our conclusion that (i) approval procedures undertaken under Directive 2001/18 in respect of applications which had previously been assessed under Directive 90/220 were a continuation of the approval procedures previously conducted under Directive 90/220, and that (ii) an approval procedure begun under Directive 90/220 and continued under Directive 2001/18 constitutes one single approval procedure for the purposes of Annex C(1)(a), first clause.

7.1789 It follows from this conclusion that there is no need, in the context of our inquiry under Annex C(1)(a), first clause, to distinguish between undue delays which may have occurred in the processing of an application under Directive 90/220 and undue delays which may have occurred when the procedure for the same application was continued under Directive 2001/18. Notably, our conclusion means that a failure to observe the provisions of Annex C(1)(a), first clause, can be established on the basis of undue delays which occurred while Directive 90/220 was in force. Likewise, a failure to observe the provisions of Annex C(1)(a), first clause, can also be established on the basis of undue delays which occurred after the entry into force of Directive 2001/18. In either case, the relevant approval procedure would have been unduly delayed, contrary to the requirements of Annex C(1)(a), first clause.

7.1790 Finally, we recall that in Section VII.D we have addressed whether the reason for the general EC moratorium on final approvals could have provided a justification for delays which might have occurred as a result of that moratorium. We have also addressed whether the adoption of Directive 2001/18 could have justified delaying the completion of approval procedures conducted under Directive 90/220 so that as of October 2002 they would become subject to the new provisions of Directive 2001/18. These earlier observations are relevant and applicable also to our examination of the Directive 90/220 (and 2001/18) approval procedures identified by the Complaining Parties.

7.1791 With these general observations in mind, we now proceed with the examination of the individual product-specific measures complained against.

(ii) Falcon oilseed rape (EC-62)

7.1792 One Complaining Party, the United States, claims that the completion of the approval procedure concerning Falcon oilseed rape has been unduly delayed.

7.1793 The **United States** initially argued that the Commission in this procedure did not submit a draft measure to the Regulatory Committee. Later, the United States argued that the Regulatory Committee twice failed to vote on a draft measure and that after the second attempt, the Commission never submitted a draft measure to the Regulatory Committee again. The United States also submits that under the applicable EC legislation, in the absence of action by the Regulatory Committee, the Commission was required to submit a draft measure, whether favourable or negative, to the Council. The United States recalls in this respect that the *SPS Agreement* requires that the European Communities make a decision without undue delay. In this case, the Commission failed to forward a decision to the Council.

7.1794 The United States submits, in addition, that the application concerning Falcon oilseed rape is one of nine applications identified by the United States which were stalled at the Commission level at the time Directive 90/220 expired and which, as of the date of establishment of the Panel, have been pending for an average of six and one half years. The United States contends in this respect that

[1384] *See supra*, paras. 7.1535-7.1536.

although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning Falcon oilseed rape is undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.1795 The **European Communities** argues that the United States is mistaken in saying that the Commission failed to submit a draft measure to the Regulatory Committee. The Commission launched a voting procedure in June 1999, and the Regulatory Committee met twice on the matter. The Regulatory Committee did not vote on 9 March 2000 because it came to the conclusion that further information was needed on the assessment of the effect of the newly expressed protein on the biogeochemical cycle and the food chain as well as the likelihood of spreading. The European Communities also states that in May 2001, the applicant modified the scope of its application, and that after that, the application proceeded with further submissions by the applicant of additional information.

7.1796 The **United States** responds that the only information that could have been requested at the March 2000 Regulatory Committee meeting was the information requested by Italy concerning the effect of the transgenic product on the biogeochemical cycles and on the food chain and on the spreading of the gene due to the possibility of crossing between the PGM and wild species. The United States points out in this respect that the applicant responded to Italy's request on 30 November 2000 even though, in the Untied States' view, Italy's request was not scientifically justified.

7.1797 The **Panel** begins its analysis by addressing the US argument concerning the Commission's failure to re-convene the Regulatory Committee for a vote on the Commission's draft measure.

> Failure by the Commission to re-convene the Regulatory Committee for a vote on a draft measure

7.1798 The Panel recalls that the Regulatory Committee met twice, on 29 October 1999 and on 9 March 2000, to consider a draft measure submitted by the Commission. At neither meeting was there a vote on the draft measure, and the Regulatory Committee did not meet again for another attempt at taking a vote on the application.

7.1799 The Panel also recalls that in November 2000 the applicant provided the additional information which had been requested by Italy. In late May 2001, following a request by the lead CA of April 2000, the applicant clarified certain aspects of its application. According to the lead CA, uncertainty as to these aspects had prevented the Regulatory Committee from voting on the application in March 2000.

7.1800 When the applicant clarified certain aspects of its application in late May 2001, it also submitted additional and updated information to the lead CA. The applicant apparently did so of its own motion. It stated that this information confirmed that the application was already "in line with the main provisions" of Directive 2001/18, which had been adopted in March 2001. The applicant requested the lead CA to inform the other member States about the new set of documents at the next Regulatory Committee meeting.[1385] However, the lead CA did not forward the documents to the other member States and the Commission because it considered that further clarification was necessary.[1386]

[1385] Exhibit EC-62/At. 98.
[1386] Exhibit EC-62/At. 101.

The applicant provided the requested clarification on 30 October 2001.[1387] Towards the end of November 2001, the applicant wrote to the Commission, drawing attention to the additional information and indicating its desire to present the information to the other member States at a meeting of the "working group on herbicide-tolerant crops" scheduled for early December 2001.[1388] The record does not indicate whether this meeting took place.

7.1801 The Panel has previously stated its view that after the March 2000 meeting of the Regulatory Committee, it was incumbent on the Commission to convene another meeting with a view to obtaining a vote on its draft measure. The question thus arises whether the Commission was justified in not convening another meeting at any point prior to the repeal of Directive 90/220 in October 2002.

7.1802 In approaching this question, the Panel takes note of the following elements. To begin with, by the end of May 2001 the applicant had met all requests for information and clarification conveyed to it in the wake of the March 2000 Regulatory Committee meeting. As noted, however, at the end of May 2001 the applicant also provided additional and updated information to the lead CA. That information was apparently never forwarded by the lead CA to the other member States and the Commission. Nevertheless, the record indicates that the Commission was made aware of its existence in June 2001[1389], inquired about it in September 2001[1390], and also in September 2001 was told by the lead CA that it would be informed about when the applicant would provide the clarification sought by the lead CA[1391]. In November 2001, the Commission was told directly by the applicant that the applicant had provided the clarification requested by the lead CA at the end of October 2001.

7.1803 Furthermore, it is important to remember that the applicant provided the additional information, not pursuant to a requirement flowing from the provisions of Directive 90/220, but in an effort to convince member States to vote in favour of approving its application. Also, the lead CA had not been requested to offer an assessment of the additional information before transmitting it to the other member States and the Commission. Indeed, the lead CA did not purport to undertake an assessment, for it merely asked the applicant for clarification and made suggestions for modifications, to avoid questions from other member States or to "further acceptance" by other member States.[1392]

7.1804 In view of these elements, the Panel considers that at the latest at the end of November 2001, after the applicant had clarified and revised the additional information first submitted in May 2001 and directly approached the Commission in this regard, the Commission could have stepped in and requested the lead CA to forward the additional information to other member States and itself.[1393] At least, the Commission could have done so if, as is likely, it wanted member States to have access to the additional information before re-convening the Regulatory Committee.

7.1805 The Panel notes that in its November 2001 letter to the Commission, the applicant made known its desire to present the additional information to the other member States at a meeting of the

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[1387] Exhibit EC-62/At. 105.
[1388] *Ibid*.
[1389] Exhibit EC-62/At. 101.
[1390] Exhibit EC-62/At. 102 (e-mail from lead CA to applicant).
[1391] Exhibit EC-62/At. 101.
[1392] Exhibit EC-62/At. 98.
[1393] It should be noted that more than five months after the applicant had provided the clarification requested by the lead CA, the latter sought further modifications and additional information. Exhibit EC-62/At. 106. However, as the lead CA was not required to make an assessment of the clarification provided by the applicant before transmitting the new documents to other member States and the Commission, there is no reason to consider that the Commission could not have sought the transmission of these documents to itself and other member States in November 2001.

"working group on herbicide-tolerant crops" scheduled for early December 2001. The European Communities has not explained the mandate of the "working group on herbicide-tolerant crops". There is no indication that this working group played a part in the lead-up to the October 1999 and March 2000 meetings of the Regulatory Committee. At any rate, the fact that the applicant wished to "present" the additional information to the working group does not imply that the applicant did not want the information to be distributed to the other member States until after its presentation.

7.1806 Had the Commission requested the lead CA to forward the additional information towards the end of November 2001, it could have scheduled a meeting of the Regulatory Committee for early 2002, thus giving other member States and itself time to review the additional information. As well, since Directive 90/220 was not repealed until mid-October 2002, there was enough time for the Commission to adopt its draft measure in the event of a favourable vote in the Regulatory Committee and for the lead CA to give its written consent.[1394]

7.1807 In earlier findings, we observed that the Commission could have considered that some member States simply did not wish to see the Commission call another vote on its draft measure, or that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority, with the consequence that the Commission would have to complete the procedure by adopting its own draft measure. In our view, neither consideration would provide a justification for the Commission's failure to re-convene a Regulatory Committee meeting in early 2002.

7.1808 Anticipated member State opposition might well have been a concern for the Commission in view of the consequences it could have had for the legitimacy and acceptability of an eventual decision by the Commission to approve its own draft measure. However, this would not have justified the Commission in suspending the approval process until it was confident that its draft measure would achieve a qualified majority in the Regulatory Committee.[1395] Were it otherwise, the obligation to complete approval procedures without undue delay would impose no real discipline as the Commission could then suspend approval procedures every time it anticipates significant member State opposition and regardless of whether there are valid reasons for such opposition.

7.1809 Regarding the possibility that certain member States might have been reluctant to proceed to a vote on the Commission's draft measure, it may also be noted that the applicant strengthened the Commission's position by supplying new information which it said confirmed that its application was

[1394] In earlier findings on the application concerning Falcon oilseed rape, we noted that the Commission could have considered that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority and that the Commission would then have to complete the procedure by adopting its draft measure. Even assuming that in this scenario there was not enough time for the Commission to complete the procedure in question while Directive 90/220 was still in force, the Panel does not consider that this would have justified the Commission's failure to re-convene the Regulatory Committee for a vote. The Commission would have anticipated a "blocking minority" on the basis of the June 1999 declaration by the Group of Five countries. As pointed out above, there is no indication that the June 1999 declaration was intended to bind the Governments of the Group of Five countries vis-à-vis other member States or the Commission. In other words, the Group of Five countries retained the freedom under EC law to vote in favour of applications in the Regulatory Committee and Council. In the light of this, the Commission could not have legitimately invoked the June 1999 declaration as a justification for not re-convening the Regulatory Committee in early 2002.

[1395] To recall, the record does not indicate, and the European Communities did not argue, that the Commission after the March 2000 meeting of the Regulatory Committee launched inter-service consultations to reconsider the relevant draft measure.

already in accordance with the main provisions of the new Directive 2001/18.[1396] Certainly as of the end of November 2001, after the applicant had clarified and revised the additional information first submitted in May 2001, the Commission therefore had additional arguments for seeking a vote on its draft measure in the Regulatory Committee.

7.1810 Based on the above considerations, the Panel is of the view that at the latest in early 2002 the Commission should have re-convened the Regulatory Committee meeting for a vote on the application concerning Falcon oilseed rape. Accordingly, the Panel concludes that the time actually taken by the Commission to convene a further Regulatory Committee meeting – no meeting was convened between March 2000 and October 2002 – was unjustifiably long.

7.1811 In addition, we recall that the United States claims that the approval procedure concerning Falcon oilseed rape was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to re-convene the Regulatory Committee for a vote on the application concerning Falcon oilseed rape after May 2001 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Commission's inaction was a consequence of the general moratorium on approvals.

7.1812 In view of our conclusion with regard to the Commission's failure to re-convene the Regulatory Committee for a vote on a draft measure, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.1813 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to convene a further Regulatory Committee meeting – no meeting was convened between March 2000 and October 2002 – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's inaction was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning Falcon oilseed rape for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning Falcon oilseed rape, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

[1396] It should also be recalled that in November 2000 the applicant provided the additional information which had been requested by Italy. In addition, in late May 2001, following a request by the lead CA of April 2000, the applicant clarified certain aspects of its application.

(iii) MS8/RF3 oilseed rape (EC-63)

7.1814 Two Complaining Parties, the United States and Canada, claim that the completion of the approval procedure concerning MS8/RF3 oilseed rape has been unduly delayed.

7.1815 The **United States** initially argued that the progress of the application concerning MS8/RF3 oilseed rape stalled when the Commission refused to submit a draft measure to the Regulatory Committee as required by the approval process. Later, the United States argued that the Regulatory Committee twice failed to vote on a draft measure, and that after the second attempt the Commission never submitted a draft measure to the Regulatory Committee again. The United States submits that the resulting delay was undue.

7.1816 The United States submits, in addition, that the application concerning MS8/RF3 oilseed rape is one of nine applications identified by the United States which were stalled at the Commission level at the time Directive 90/220 expired and which, as of the date of establishment of the Panel, have been pending for an average of six and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning MS8/RF3 oilseed rape is undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.1817 **Canada** submits that the applicant proposed and continuously revised its risk management measures in response to concerns expressed by member States, the SCP and the Commission. Regardless of these attempts by the applicant, the processing of the application has been delayed, which Canada believes demonstrates that the European Communities was and is intent on blocking the approval of this product for cultivation and is intent on imposing such onerous and unnecessary conditions as to make the importation of the product for processing uneconomical.

7.1818 Canada argues that since the application went to the Community level, member States took approximately 12 months to put forth their objections to the application, and after the SCP issued its positive opinion on the application, the European Communities took another 12 months to address recommendations contained in the SCP opinion, including a monitoring plan. Although the application was discussed at the Regulatory Committee in the summer of 1999, no vote was taken. Canada notes that in August 1999 the applicant proposed to voluntarily agree to meet the requirements of the Council's June 1999 Common Position. On the basis of these commitments, the Commission invited the applicant to present its proposal to the Regulatory Committee in October 1999. However, while the Regulatory Committee again considered the proposal, it failed to hold a vote. Subsequently, the applicant made further proposals as a further attempt to address concerns expressed by member States. However, although the matter went yet again before the Regulatory Committee in March 2000, it failed to hold a vote.

7.1819 Canada also claims that any delay in the completion of the approval procedure following the failure of the Regulatory Committee to adopt the draft measure approving MS8/RF3 oilseed rape in March 2000 should be considered "undue". Canada notes in this regard the efforts made by the applicant to respond to further requests by the lead CA. Canada observes that while the lead CA finally accepted the applicant's proposed post-marketing monitoring plan and agricultural guidelines in May 2002, the European Communities provided no information to explain the delay between May 2002 and early January 2003, when the applicant submitted a further updated dossier under Article 35 of Directive 2001/18.

7.1820 Finally, Canada observes that more than eight years after the application was initially submitted for approval to the lead CA in 1996 and more than six years after the SCP issued its opinion in May 1998, MS8/RF3 oilseed rape remains unapproved either for import and processing or cultivation, despite reasonably available risk management measures. Canada submits that by any reasonable standard, the extraordinary length of time to process this application constitutes "undue delay".

7.1821 The **European Communities** argues that the United States is mistaken in saying that the Commission failed to submit a draft measure to the Regulatory Committee. The Commission launched a voting procedure in the Regulatory Committee in June 1999, and the Regulatory Committee met twice on the matter. According to the European Communities, the Regulatory Committee did not vote on 9 March 2000 because Italy raised scientific issues regarding the effects of the product in question on biogeochemical cycles and on food chains and the likelihood of spreading. The European Communities also states that in May 2001, the applicant modified the scope of its application, and that after that, the application proceeded with further submissions by the applicant of additional information.

7.1822 **Canada** notes that Italy's questions had already been addressed in the application dossier and by the SCP. Further, the attempts to raise concerns about impacts of herbicide use on farmland biodiversity inappropriately linked concerns related to herbicide use to approval of a seed variety. Canada notes that: 1) for all other seed varieties, seed approval legislation is distinct from the pesticide approval legislation; 2) herbicide use is one of many factors that may have an impact on farmland biodiversity; and 3) EC member States have actually authorized the use of glufosinate-ammonium for general use as well as for specific use on genetically modified herbicide-tolerant crops. Canada also counters that the European Communities fails to point out that the submission of further information by the applicant was necessary because the information requirements were either unclear or changing.

7.1823 The **Panel** begins its analysis by addressing the United States' and Canada's arguments concerning the Commission's failure to re-convene the Regulatory Committee for a further meeting.

> Failure by the Commission to re-convene the Regulatory Committee for a vote on a draft measure

7.1824 The Panel recalls that the Regulatory Committee met twice, on 29 October 1999 and on 9 March 2000, to consider a draft measure submitted by the Commission. No vote was taken on the draft measure at either meeting and the Regulatory Committee did not meet again for another attempt at taking a vote on the application.

7.1825 The record does not indicate why the Regulatory Committee did not proceed to a vote on MS8/RF3 oilseed rape at the March 2000 meeting.[1397] One reason may have been a request for information from the Italian CA. Italy transmitted its request to the lead CA on 14 March 2000, and the lead CA then forwarded it to the applicant.[1398] In November 2000 the applicant provided the lead CA with answers to the questions raised by Italy indicating that all the issues raised had been

[1397] The record contains a summary of the conclusions for the October 1999 Regulatory Committee meeting, but not for the March 2000 meeting.

[1398] Exhibit EC-63/At. 87. This fax of 14 March 2000 from the Italian CA to the lead CA specifically "refer[s] to the conclusion of the last meeting of the Regulatory Committee meeting".

previously addressed by the SCP as well as the update of the application provided by the applicant in November 1999. This communication was also circulated to the other CAs and the Commission.[1399]

7.1826 It should further be noted that in June 2001 the applicant sent a letter to the lead CA which clarified certain aspects of the application, including its scope. There is no indication that this clarification had been requested. However, the applicant's letter noted that following the March 2000 meeting of the Regulatory Committee the clarification appeared necessary.[1400] In a separate letter of the same date, "following the revision of Directive 90/220/EEC", the applicant also submitted updated information to the lead CA, including an updated environmental risk assessment, a post-market monitoring plan, agricultural guidelines, additional information regarding identification and labelling and information for the public concerning the product in question.[1401] The letter stated that this information confirmed that the application was already "in line with the main provisions" of Directive 2001/18, which had been adopted in March 2001. The letter requested the lead CA to inform the other member States about the new set of documents at the next Regulatory Committee meeting.[1402] There is no indication that the lead CA ever forwarded the new documents to the other member States and the Commission. A meeting of CAs was held two weeks after the applicant submitted the additional information, but the Panel has no information about what was discussed at that meeting. It is clear from the record, however, that the lead CA confirmed receipt of the new documents only in July 2001. The lead CA informed the applicant that it had forwarded the documents to the relevant scientific committee of the Belgian Biosafety Council (hereafter the "BBC") for an opinion.[1403] No reason was given for why an opinion had been requested.

7.1827 The Panel has previously stated its view that after the March 2000 meeting of the Regulatory Committee, it was incumbent on the Commission to convene another meeting with a view to obtaining a vote on its draft measure. The question thus arises whether the Commission was justified in not convening another meeting at any point prior to the repeal of Directive 90/220 in October 2002.

7.1828 In approaching this question, the Panel takes note of the following elements. In November 2000 the applicant had met all requests for information conveyed to it following the March 2000 Regulatory Committee. The additional information was circulated to all CAs and the Commission in December 2000. As noted, however, in June 2001 the applicant provided additional clarification and updated information to the lead CA. The record does not indicate that the Commission was made aware of the existence of the June 2001 information. At the same time, there is nothing in the record to suggest that the Commission was "waiting" for the June 2001 information.

7.1829 Regarding the clarification provided by the applicant in June 2001, we note that if the Commission was not waiting for that clarification, then that clarification could not provide a justification for the Commission's failure to re-convene the Regulatory Committee sometime between December 2000 and June 2001. On the other hand, if the Commission had been waiting for clarification from the applicant, it should have inquired with the lead CA whether the applicant had provided clarification. There is no evidence that the Commission did so.

7.1830 Regarding the updated information also provided by the applicant in June 2001, it is important to remember that the applicant provided that information, not pursuant to a requirement flowing form the provisions of Directive 90/220, but in an effort to convince member States to vote in

[1399] Exhibit EC-63/At. 89 and 90.
[1400] Exhibit EC-63/At. 92.
[1401] Exhibit EC-63/At. 91.
[1402] *Ibid*.
[1403] Exhibit EC-63/At. 93.

favour of approving its application. Also, the lead CA had not been requested to offer an assessment of that additional information before transmitting it to the other member States and the Commission. Notwithstanding this, the lead CA requested an opinion of the BBC. However, it seems that for the BBC, it was not obvious that an opinion was needed. In November 2001, the BBC discussed the information in question. According to the minutes of the internal discussion, "no opinion on the part of the Biosafety Advisory Council was necessary prior to the forwarding of these documents to the European Commission; and in the past such additional information had already been sent straight to the Commission on several occasions."[1404] However, as this was the first time a company had submitted a monitoring plan, agricultural guidelines and public dossier, the BBC "thought it advisable to ask the Biosafety Advisory Council to discuss these documents before forwarding them to the European Commission."[1405] It was noted that in this way the relevant experts would have an opportunity to gain experience in the evaluation of such documents.[1406]

7.1831 We are not convinced that a lead CA assessment of the updated information was required before that information could be transmitted to the Commission and the other CAs, and that the Commission therefore needed to wait for the lead CA's assessment before re-convening the Regulatory Committee. Indeed, we note that in a parallel situation, a different lead CA did not find it necessary to make an assessment of additional information submitted by an applicant to demonstrate that its application was already in line with the main provisions of Directive 2001/18.[1407]

7.1832 In any event, in the approval procedure concerning MS8/RF3 oilseed rape, the applicant replied to the last pending question of the BBC in early May 2002.[1408] The record shows no further developments in this approval procedure until October 2002, when Directive 90/220 was repealed. Thus, there is no indication that the BBC ever provided its opinion on the June 2001 information to the lead CA. Even assuming that the Commission knew about the updated information of June 2001, and even assuming that it was justifiable in principle for the Commission to let the lead CA undertake some assessment of the information, it remained the Commission's responsibility to seek a vote by the Regulatory Committee on its draft measure. Yet even as the date of repeal of Directive 90/220 was approaching, the Commission apparently did not request the lead CA promptly to finish its assessment of the updated information and to circulate it together with that information so that a further attempt at completing the approval procedure under Directive 90/220 could be made.[1409]

7.1833 In view of these elements, we consider that if the Commission had sought the circulation of the additional information once the applicant had replied to the last pending question in May 2002, it should have been possible for the information to be circulated promptly and for a Regulatory Committee meeting to be held in the summer of 2002 at the latest. As Directive 90/220 was not repealed until mid-October 2002, we think this would have left enough time for the Commission to adopt its draft measure in the event of a favourable vote in the Regulatory Committee and for the lead CA to give its written consent.[1410]

[1404] Exhibit EC-63/At. 102.

[1405] *Ibid*.

[1406] *Ibid*.

[1407] *See* our earlier analysis of the approval procedure concerning Falcon oilseed rape.

[1408] Exhibit EC-63/At. 108. The applicant also indicated readiness to follow a suggestion by the BBC regarding information to the public, subject to further clarification by the BBC. *Ibid*.

[1409] If the Commission did not know about the updated information submitted by the applicant in June 2001, then the existence of that information could not provide a justification for the Commission's failure to re-convene the Regulatory Committee after December 2000.

[1410] The Commission might have considered that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the

7.1834 In earlier findings, the Panel observed that the Commission could have considered that some member States simply did not wish to see the Commission call another vote on its draft measure, or that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not have achieved the required qualified majority, with the consequence that the Commission would have to complete the procedure by adopting its own draft measure. In the Panel's view, neither consideration would provide a justification for the Commission's failure to re-convene the Regulatory Committee for a third meeting.

7.1835 Anticipated member State opposition might well have been a concern for the Commission in view of the consequences it could have had for the legitimacy and acceptability of an eventual decision by the Commission to approve its own draft measure. However, this would not have justified the Commission in suspending the approval process until it was confident that its draft measure would achieve a qualified majority in the Regulatory Committee.[1411] Were it otherwise, the obligation to complete approval procedures without undue delay would impose no real discipline as the Commission could then suspend approval procedures every time it anticipates significant member State opposition and regardless of whether there are valid reasons for such opposition.

7.1836 Regarding the possibility that certain member States might have been reluctant to proceed to a vote on the Commission's draft measure, it should also be noted that if the Commission was aware of the existence of the updated information of June 2001, then that information would have provided it with additional arguments for seeking a vote on its draft measure in the Regulatory Committee. To recall, the applicant submitted the June 2001 information to demonstrate that the application concerning MS8/RF3 was already in accordance with the main provisions of the new Directive 2001/18.

7.1837 Based on the above considerations, the Panel is of the view that at the very latest in the summer of 2002 the Commission should have re-convened the Regulatory Committee for a vote on the application concerning MS8/RF3 oilseed rape. Accordingly, the Panel concludes that the time actually taken by the Commission to convene the Regulatory Committee for a further meeting – no meeting was held between March 2000 and October 2002 – was unjustifiably long.

7.1838 In relation to DS291, we recall that the United States claims that the approval procedure concerning MS8/RF3 oilseed rape was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to re-convene the Regulatory Committee for a vote on the application concerning MS8/RF3 oilseed rape after November 2001 is consistent with the application of such a measure. In the light of this, and in

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required qualified majority and that the Commission would then have to complete the procedure by adopting its draft measure. Even assuming that in this scenario there was not enough time for the Commission to complete the procedure in question while Directive 90/220 was still in force, the Panel does not consider that this would have justified the Commission's failure to re-convene the Regulatory Committee for a vote. The Commission would have anticipated a "blocking minority" on the basis of the June 1999 declaration by the Group of Five countries. As pointed out above, there is no indication that the June 1999 declaration was intended to bind the Governments of the Group of Five countries *vis-à-vis* other member States or the Commission. In other words, the Group of Five countries retained the freedom under EC law to vote in favour of applications in the Regulatory Committee and Council. In the light of this, the Commission could not have legitimately invoked the June 1999 declaration as a justification for not re-convening the Regulatory Committee.

[1411] The record does not indicate, and the European Communities did not argue, that the Commission after the March 2000 meeting of the Regulatory Committee launched inter-service consultations to reconsider the relevant draft measure.

the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Commission's inaction was a consequence of the general moratorium on approvals.

7.1839 In view of our conclusion with regard to the Commission's failure to re-convene the Regulatory Committee for a vote on a draft measure, we do not go on to examine other arguments put forward by the United States and Canada in support of their claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.1840 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to convene the Regulatory Committee for a further meeting – no meeting was convened between March 2000 and October 2002 – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's inaction was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning MS8/RF3 oilseed rape for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning MS8/RF3 oilseed rape, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ii) DS292 (Canada)

With reference to DS292, the Panel recalls its finding that the time taken by the Commission to convene the Regulatory Committee for a further meeting – no meeting was convened between March 2000 and October 2002 – was unjustifiably long. Based on this finding, the Panel accepts Canada's contention that the European Communities failed to "consider or approve, without undue delay", the application concerning MS8/RF3 oilseed rape, and that it consequently did not complete the relevant approval procedure without "undue delay". Accordingly, the Panel concludes that in respect of the approval procedure concerning MS8/RF3 oilseed rape, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(iv) RR fodder beet (EC-64)

7.1841 One Complaining Party, the United States, claims that the completion of the approval procedure concerning the RR fodder beet has been unduly delayed.

7.1842 The **United States** initially argued that the Commission in this procedure did not submit a draft measure to the Regulatory Committee. Later, the United States argued that the Regulatory Committee twice failed to vote on a draft measure and that after the second attempt, the Commission never submitted a draft measure to the Regulatory Committee again. The United States also submits that under the applicable EC legislation, in the absence of action by the Regulatory Committee, the

Commission was required to submit a draft measure, whether favourable or negative, to the Council. The United States recalls in this respect that the *SPS Agreement* requires that the European Communities make a decision without undue delay. In this case, the Commission failed to forward a decision to the Council.

7.1843 The United States submits, in addition, that the application concerning RR fodder beet is one of nine applications identified by the United States which were stalled at the Commission level at the time Directive 90/220 expired and which, as of the date of establishment of the Panel, have been pending for an average of six and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning RR fodder beet is undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.1844 The **European Communities** argues that contrary to the US argument, the Commission launched a voting procedure in June 1999, and the Regulatory Committee met twice on the matter – first on 29 October 1999 and then on 9 March 2000. The Regulatory Committee did not vote on 29 October 1999 due to outstanding requests for information.

7.1845 The **United States** responds that contrary to the European Communities' assertion that there were outstanding requests for information, the applicants had voluntarily provided additional information in an attempt to remove any possible remaining obstacle to a Regulatory Committee vote during the one and a half years between when the SCP issued its opinion and when the Regulatory Committee finally met. The United States also notes that when the applicants attempted to get a resolution of this matter on 12 July 2000, stating that they had fully addressed all objections raised by member States and requesting the lead CA "to inform all member States that the application was complete and subject to a Community decision"[1412], the European Communities ignored, for six months, the applicant's request.

7.1846 The **Panel** begins its analysis by addressing the US argument concerning the Commission's failure to re-convene the Regulatory Committee for a vote on the Commission's draft measure.

> Failure by the Commission to re-convene the Regulatory Committee for a vote on a draft measure

7.1847 The Panel recalls that, after the SCP issued its favourable opinion with regard to this application on 23 June 1998, the Regulatory Committee met twice, on 29 October 1999 and on 9 March 2000, to consider a draft measure submitted by the Commission. No vote was taken on the draft measure at either meeting, and the Regulatory Committee did not meet again for another attempt at taking a vote on the application.

7.1848 We also recall that in July 2000 the applicant provided the additional information requested by the Italian CA, as well as data on molecular characterization which were apparently generated at the request of the United Kingdom's CA. The conclusion of the July 2000 letter states that, in the applicant's view, all objections raised by the CAs within the 60-day period provided for in Directive 90/220 had now been fully addressed. We further recall that the lead CA did not forward the new documents to the other CAs. As also noted earlier, the Commission received a copy of the applicant's July 2000 letter.

[1412] Exhibit EC-64/At. 119.

7.1849 The Panel has previously stated its view that after the March 2000 meeting of the Regulatory Committee, it was incumbent on the Commission to convene another meeting with a view to obtaining a vote on its draft measure. The question thus arises whether the Commission was justified in not convening another meeting at any point prior to the repeal of Directive 90/220 in October 2002.

7.1850 In approaching this question, the Panel takes note of the following elements. To begin with, by mid-July 2000 the applicant had apparently addressed all objections raised by the CAs within the 60-day period provided for in Directive 90/220 and conveyed to the applicant. That information was never forwarded by the lead CA to the other CAs. However, it should be recalled in this respect that in February 2001 the applicant suggested to the lead CA, in view of the "very volatile" EC regulatory context, that it forward the documents after the adoption of Directive 2001/18 (which came in March 2001) and the circulation of a Commission proposal on new EC rules concerning labelling and traceability (which came in July 2001).[1413] The lead CA did not follow the applicant's suggestion.

7.1851 Furthermore, as noted, the Commission received a copy of the applicant's July 2000 letter. It is likely that the Commission wanted the other CAs to have access to the additional information provided in July 2000 before re-convening the Regulatory Committee. Yet even as the date of repeal of Directive 90/220 was approaching, the Commission apparently did not request the lead CA promptly to circulate the additional information provided by the applicant in July 2000 so that a further attempt at completing the approval procedure under Directive 90/220 could be made.

7.1852 In view of these elements, we consider that after July 2000, once the applicant had provided the additional information sought by the Italian CA, or at the latest in the summer of 2001, when the Commission circulated its proposal for new EC rules on labelling and traceability, the Commission could have re-convened the Regulatory Committee for a vote on the application concerning RR fodder beet. Directive 90/220 was not repealed until 17 October 2002. In our view, there was thus enough time for the Commission to adopt its draft measure in the event of a favourable vote in the Regulatory Committee and for the lead CA to give its written consent.

7.1853 In earlier findings, we observed that the Commission could have considered that some member States simply did not wish to see the Commission call another vote on its draft measure, or that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority, with the consequence that the Commission would have to complete the procedure by adopting its own draft measure. In our view, neither consideration would provide a justification for the Commission's failure to re-convene the Regulatory Committee for a vote prior to the repeal of Directive 90/220.

7.1854 Anticipated member State opposition might well have been a concern for the Commission in view of the consequences it could have had for the legitimacy and acceptability of an eventual decision by the Commission to approve its own draft measure. However, this would not have justified the Commission's suspension of the approval process until it was confident that its draft measure would achieve a qualified majority in the Regulatory Committee.[1414] Were it otherwise, the obligation to complete approval procedures without undue delay would impose no real discipline as the Commission could then suspend approval procedures every time it anticipated significant member State opposition and regardless of whether there were valid reasons for such opposition.

[1413] *Ibid*.

[1414] To recall, the record does not indicate, and the European Communities did not argue, that the Commission after the March 2000 meeting of the Regulatory Committee launched inter-service consultations to reconsider the relevant draft measure.

7.1855 Regarding the possibility that certain member States might have been reluctant to proceed to a vote on the Commission's draft measure, it may also be noted that the applicant strengthened the Commission's position by supplying supplementary information addressing objections raised by other CAs.

7.1856 Based on the above considerations, the Panel is of the view that at the latest in the summer of 2001 the Commission should have re-convened the Regulatory Committee for a vote on the application concerning RR fodder beet. Accordingly, the Panel concludes that the time actually taken by the Commission to convene the Regulatory Committee for a further meeting – no meeting was convened between March 2000 and October 2002 – was unjustifiably long.

7.1857 In addition, we recall that the United States claims that the approval procedure concerning RR fodder beet was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to re-convene the Regulatory Committee for a vote on the application concerning RR fodder beet after July 2000 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Commission's inaction was a consequence of the general moratorium on approvals.

7.1858 In view of our conclusion with regard to the Commission's failure to re-convene the Regulatory Committee for a vote on its draft measure, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.1859 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to convene the Regulatory Committee for a further meeting – no meeting was convened between March 2000 and October 2002 – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's inaction was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning RR fodder beet for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning RR fodder beet, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(v) Bt-531 cotton (EC-65)

7.1860 Two Complaining Parties, the United States and Argentina, claim that the completion of the approval procedure concerning Bt-531 cotton has been unduly delayed.

7.1861 The **United States** submits that the application concerning Bt-531 cotton under Directive 90/220 suffered a three-and-a-half-year period of inactivity by EC regulators. From 7 May 1999, after the launch of inter-service consultations on a draft measure to be submitted to the Council, until 12 February 2003, when the lead CA finally circulated the updated application to the Commission, the application was totally ignored by the Commission and lead CA. The United States considers this lengthy delay to be unwarranted and thus undue.

7.1862 The United States points out in this respect that the application in question had received a favourable scientific assessment by the European Community's own scientific committee, the SCP. That certain member States objected in the Regulatory Committee does not justify the Commission's refusal to act on the application. The United States submits that those objections which were explained in statements, notably those by Austria and the United Kingdom, were the subject of detailed scientific consideration in the SCP's positive opinion in July 1998. The United States also notes that there is at any rate nothing to indicate that the Commission undertook any process whatsoever to resolve the member State concerns. Moreover, nothing in the record indicates that the applicant was ever requested to submit additional information to address the member State objections, nor that the basis of these objections was ever even notified to the applicant. The United States is therefore of the view that the delay in question was not caused, as the European Communities claims, by a pending request to the applicant for additional information.

7.1863 The United States notes in addition that the EC legislative framework provides a specific avenue for further action where the Regulatory Committee is unable to come to a decision: the Commission is to forward the application to the Council "without delay" for a decision. The United States considers that where the European Communities' own legislation provides timelines, a suspension of the approval procedure without any scientific justification must be considered undue delay.

7.1864 The United States submits, finally, that the application concerning Bt-531 cotton is one of nine applications identified by the United States which were stalled at the Commission level at the time Directive 90/220 expired and which, as of the date of establishment of the Panel, have been pending for an average of six and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning Bt-531 cotton is undue. The United States also argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.1865 **Argentina** argues that after the Regulatory Committee in February 1999 failed to achieve a qualified majority in favour of approving the application concerning Bt-531 cotton, the Commission refused to submit a draft measure to the Council until the application had to be resubmitted under Directive 2001/18. Argentina submits that this was not due to any action or omission on the part of the applicant. According to Argentina, there notably are no EC documents which specifically requested the applicant to provide additional information. Argentina considers that the delay which it says was caused by the Commission is undue. Argentina argues in this respect that the requirements of legislation not yet in force do not provide grounds for a prolonged failure to process an application. In particular, the application concerning Bt-531 cotton should not have been forced to start the procedure again under the new Directive 2001/18 when the procedure under the old Directive 90/220 had already been in progress for three years. Furthermore, Argentina asserts that there is no scientific evidence to justify the delay after the Regulatory Committee vote. Those member States which in the Regulatory Committee voted against approving Bt-531 cotton ignored the positive scientific opinion of the SCP of July 1998. Moreover, Argentina contests the scientific validity of the statements

offered by some member States in support of their votes inasmuch as these statements do not refute the positive opinion of the SCP.[1415]

7.1866 Argentina singles out another instance of delay which it considers undue. Argentina asserts that although the applicant in January 2003 submitted an updated application in accordance with the requirements of Directive 2001/18, the application did not progress. Argentina submits that, as a result, as of the date of its first written submission – April 2004 – the application concerning Bt-531 cotton had been inactive for an additional period of 1 year and 3 months.

7.1867 Finally, Argentina submits that the total time consumed by the procedures under Directives 90/220 and 2001/18, from the time the application was first submitted until April 2004, the date of Argentina's first written submission, has been 7 years and 4 months. In Argentina's view, this delay can in no way be justified in the light of the deadlines stipulated in the relevant EC legislation. Argentina contends that the procedure under Directive 90/220 should normally have been completed within 240 days, which does not include the time during which a CA or the Commission may be awaiting additional information it may have requested or the time needed by an EC scientific committee to issue an opinion ("clock-stop"). Similarly, Argentina contends that under Directive 2001/18, a procedure should be completed within 285 days if no objections to the lead CA's initial assessment are made, and 450 days if objections are made. Again, this does not include the time spent waiting for additional information or for a scientific committee opinion. Argentina asserts that the delay affecting the approval procedure concerning Bt-531 cotton cannot be justified by such "clock-stops".

7.1868 The **European Communities** argues that the Regulatory Committee in February 1999 failed to reach a qualified majority because a number of member States raised scientific concerns which had not been addressed in any of the applicant's previous submissions. The European Communities submits that long after the vote in the Regulatory Committee, on 25 July 2001, the applicant provided the requested additional information, and that the translation of this material was not made available until February 2002. According to the European Communities, if there was a three-year delay after the Regulatory Committee vote, it was because of the time taken by the applicant to provide the requested additional information.

7.1869 Regarding the requirement contained in Article 21 of Directive 90/220 that the Commission "shall, without delay, submit to the Council a proposal relating to the measures to be taken", the European Communities points out that in the *Pharos* case[1416], the European Court of Justice examined an identical requirement to submit a proposal to the Council "without delay" in the context of legislation on the setting of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (Regulation 2377/90). The Court stated that nothing in the wording of the relevant provision "suggests any conclusion regarding the length of time indicated by the expression 'without delay', other than that, while a certain degree of rapidity is required, the Commission is not required to act within a precise period of time nor at once, contrary to the appellant's submission".[1417] The Court then went on to point out that the Commission was free to modify its proposal before submitting it to the Council and found that "if the Commission has the right to amend the proposal relating to the measures to be taken which it submits to the Council, it must have sufficient time to consider the various courses of action open to it".[1418] On that basis, the Court found that the Commission, which had taken over eleven months before forwarding a proposal to the Council, had not breached its

[1415] Exhibit ARG-54, p. 3.
[1416] European Court of Justice, Case C-151/98, *Pharos against Commission [1999]* ECR I-8157.
[1417] *Ibid.*, para. 20.
[1418] *Ibid.*, para. 24.

obligation to act "without delay".[1419] The Court pointed to the fact that the matter with which the Commission was confronted was "highly complex and sensitive".[1420] The Court also made it clear that the Commission could not be criticised for having sought additional advice from an EC scientific committee in an effort to prevent its proposal from being rejected by the Council.[1421]

7.1870 Concerning the case at hand, the European Communities argues that the concerns raised by certain member States were all legitimate and scientifically sound. They could not be ignored or brushed off by the Commission without detailed consideration. Moreover, according to the European Communities, in the light of the impending legislative changes, further reflection was necessary before proceeding further. The European Communities submits that this is in line with the jurisprudence of the European Court of Justice.

7.1871 In relation to the delay which occurred after the application was resubmitted under Directive 2001/18, the European Communities submits that the application contained an incomplete monitoring plan. According to the European Communities, the lead CA is awaiting additional information on the post-marketing monitoring plan that it has requested with letters of August and October 2003. The European Communities argues that it cannot be responsible for the lack of diligence or failings of an individual applicant.

7.1872 The **Panel** begins its analysis by addressing the delay allegedly caused by the Commission.

Failure by the Commission to submit a draft measure to the Council

7.1873 The Panel begins its analysis by addressing the delay allegedly caused by the Commission. The Panel recalls that on 7 May 1999, the Commission launched inter-service consultations on a draft measure to be submitted to the Council. But at no point prior to 17 October 2002, the date of repeal of Directive 90/220, did the Commission submit a draft measure to the Council. The United States and Argentina argue that the Commission should have completed its inter-service consultations and submitted a draft measure to the Council before October 2002.

7.1874 It is clear that the preparation by the Commission of a draft measure and its submission to the Council is not a process which necessarily takes more than three years. To begin with, in other approval procedures, the Commission was able to prepare and submit draft measures to the Council within a few months, despite the fact that in those procedures some member States also voted against the Commission's draft measure in the Regulatory Committee, and that some made written statements.[1422] Moreover, as the Panel understands it, the preparation by the Commission of a draft measure to be submitted to the Council is not a process that is fundamentally different from the preparation by the Commission of a draft measure to be submitted to the Regulatory Committee. In the approval procedure here at issue, the Commission prepared a draft measure and launched a vote in

[1419] The Panel notes that the judgement indicates that during the eleven-month period, the Commission initially reconsidered the file for six months and then sought a second scientific opinion. *Ibid.*, para. 32.

[1420] *Ibid.*, para. 26.

[1421] *Ibid.*, para. 27.

[1422] In the approval procedure concerning NK603 maize (Exhibit EC-76) and conducted under Directive 2001/18, the Commission submitted a draft measure to the Council little over one month after the Regulatory Committee had failed to reach a qualified majority. At that meeting, Austria made a statement in support of its negative vote. Exhibit EC-76/At. 72. In the approval procedure concerning Bt-11 sweet maize (food) and conducted under Regulation 258/97, the Commission adopted a draft measure and referred it to the Council less than two months after the Regulatory Committee had failed to reach a qualified majority. At that meeting, several member States made statements in support of their votes. Exhibit EC-92/At. 70.

the Regulatory Committee in less than three months.[1423] It may be inferred from these examples that the Commission could in principle have completed its task well before October 2002.

7.1875 The issue thus becomes whether in the specific circumstances of this case the Commission could in fact have completed its task before October 2002. The European Communities argues that the Commission did not need to forward a draft measure to the Council because the applicant took too long to provide information which had been requested of it. The European Communities notes that the applicant did not provide that information until 25 July 2001, and that the translation of this material was made available only in February 2002. However, in its earlier analysis of the approval procedure in question, the Panel found that there is no evidence to suggest that the Commission was waiting for the additional information provided by the applicant in July 2001. The Panel pointed out that even after the applicant had provided the information, the Commission did not forward a draft measure to the Council, although Directive 90/220 remained in force for another seventeen months, until October 2002. Accordingly, the information provided by the applicant in July 2001 does not justify the Commission's failure to forward a draft measure to the Council.

7.1876 Another argument put forward by the European Communities to justify the Commission's failure to forward a draft measure to the Council relates to the fact that the Regulatory Committee failed to achieve the necessary qualified majority to approve the application concerning Bt-531 cotton and that Austria, Sweden and the United Kingdom, in written statements supporting their votes, expressed certain concerns. The European Communities submits that these concerns were scientifically sound and had not been previously addressed by the applicant, and that they could not, therefore, be ignored or brushed off by the Commission without detailed consideration.

7.1877 As no qualified majority was reached in the Regulatory Committee, the Panel considers that, as a general matter, it was justifiable for the Commission to take some time, as part of its inter-service consultations, to analyse the reasons for the outcome of the vote in the Regulatory Committee and to determine, in the light of the results of such an analysis, whether it would be appropriate to modify the Commission's draft measure before it was sent on to the Council, and if so, how.

7.1878 The Panel recognizes that, as a matter of EC law, the Commission's draft measure did not need to obtain a qualified majority in the Council to complete the approval procedure. If the Council had failed to reach a favourable qualified majority, the Commission would have had to adopt its draft measure and hence approve the application concerning Bt-531 cotton.[1424] However, it must be borne in mind that an EC decision to approve the application concerning Bt-531 cotton would have authorized the applicant to market its product in all EC member States. In the light of this, the Commission had good reasons, in the Panel's view, to seek a qualified majority in the Council as this would have enhanced the legitimacy and acceptability of an EC decision to approve the application concerning Bt-531 cotton.[1425] This means that the Commission could take a reasonable period of time to explore ways of modifying its draft measure with a view to increasing the measure's chances of

[1423] Exhibit EC-65/Ats. 48 and 51. The Panel does not express a view as to whether this three-month period was necessary in the circumstances to complete the relevant procedural stage.

[1424] Article 21 of Directive 90/220. If the Council had reached a qualified majority against approving the application, then the application would, however, have had to be rejected.

[1425] It should also be recalled that the Complaining Parties did not question the design of the approval procedure set out in Directive 90/220 (or its successor, Directive 2001/18), and in particular the fact that member States vote on applications. If the Commission were obliged to press on immediately, preventing it from taking into account the votes and views expressed by member States, it would undermine the European Communities' ability to operate its approval procedure as designed.

being accepted by the Council by a qualified majority.[1426] It does not mean that the Commission could simply wait for the majorities in the Council to change enough to allow the Commission's original draft measure to be accepted by a qualified majority. The obligation imposed on the European Communities is to complete its approval procedures without undue delay. This obligation may at times require the Commission to complete an approval procedure even if it does not have the (qualified) majority support of the Council.

7.1879 How much time is to be accorded to the Commission for the purpose of reconsidering a draft measure which did not obtain a qualified majority in the Regulatory Committee can only be determined in the light of the circumstances of each case.

7.1880 Turning, then, to the circumstances of this case, the European Communities asserts that the concerns identified in the written statements by Austria, Sweden and the United Kingdom had not been addressed by the applicant before. The Panel is unable to agree with this assertion. As pointed out by the United States, the concerns referred to in the statements by the three member States were addressed in the SCP opinion of July 1998.[1427] At any rate, the record does not indicate that after the Regulatory Committee vote, the Commission or the lead CA sought additional information from the applicant in an effort to allay these concerns.

7.1881 Even if it were assumed that during its inter-service consultations the Commission was undertaking its own assessment of the scientific validity of the specific concerns expressed with a view to supporting its draft measure with scientific arguments[1428], it is well to recall that the SCP was able to undertake a comprehensive scientific assessment of the application concerning Bt-531 cotton in little over three months' time.[1429] The Panel also notes that the European Communities does not assert that the concerns raised by the member States in question presented either new or particularly complex scientific problems.

7.1882 Another circumstance invoked by the European Communities is the fact that Directive 90/220 was being revised at the time. According to the European Communities, a period of time for reflection was therefore needed before proceeding further. To recall, the Commission in this case launched its inter-service consultations on a draft measure to be submitted to the Council in May 1999. At the end of June 1999, the Council reached a political agreement – the Common Position – on the proposal to amend Directive 90/220, but Directive 2001/18, the Directive amending Directive 90/220, was not adopted until March 2001 and did not enter into force until October 2002. Thus, the Commission started its inter-service consultations almost three-and-a-half years before the entry into force of Directive 2001/18. In the light of this, even accepting that the Commission could take some time to reconsider its draft measure, the Commission's failure to forward a draft measure to the Council cannot be excused on the grounds that there was not enough time to complete the approval procedure while Directive 90/220 was still in force.[1430]

[1426] The Panel recalls once more that in other approval procedures the Commission was able to prepare and submit draft measures to the Council within a few months, despite the fact that in those procedures some member States also voted against the Commission's draft measure in the Regulatory Committee.

[1427] Exhibit EC-65/At. 47, paras. 6.2.1 and 6.3.3-6.3.4. The Panel notes that Sweden voted in favour of the Commission's draft measure and that Sweden's statement suggests that its concerns were met.

[1428] The European Communities did not specifically assert that it was undertaking a scientific assessment of the concerns in question; it merely implied that the Commission embarked on a "detailed consideration" of these concerns.

[1429] Exhibit EC-65/Ats. 43 and 47.

[1430] In its earlier findings on the application concerning Bt-531 cotton, the Panel noted that the Commission had reason to believe that due to the "blocking minority" of the Group of Five countries in the

7.1883 Furthermore, the fact that some member States and segments of public opinion may have considered that Directive 90/220 was no longer adequate and may have voiced opposition to further approvals under that Directive 90/220 did not, in the Panel's view, provide a justification for the Commission to delay the approval procedure in question until new legislation had been put in place. The EC legislator allowed Directive 90/220 to remain in force and hence applicable until October 2002. Moreover, if the Commission saw a need to respond to concerns about perceived inadequacies inherent in Directive 90/220, there were other courses of action open to it. Thus, the Commission could in the first instance have sought voluntary commitments from the applicant. Alternatively, it could have proposed that the application be approved subject to conditions. In this respect, it is worth noting that Directive 90/220 provided additional safeguards if new information on risks of Bt-531 cotton had become available after its EC-wide approval.[1431] In such an event, a member State could, pursuant to Article 16, provisionally restrict or prohibit the marketing of Bt-531 cotton. Finally, if in fact the Commission had been of the view that the risks arising from the marketing of Bt-531 cotton could not be adequately assessed or managed under Directive 90/220, it could arguably have sought the rejection of the application, subject to the right of the applicant to submit the application for reconsideration under the revised Directive, once it entered into force.[1432]

7.1884 Based on the above considerations, the Panel is of the view that in the specific circumstances of this procedure, the time actually taken by the Commission to prepare and forward a draft measure to the Council – no draft measure was forwarded between June 1999 and October 2002 – was unjustifiably long.

7.1885 Regarding DS291, we recall that the United States claims that the approval procedure concerning Bt-531 cotton was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to submit a draft measure concerning Bt-531 cotton to the Council is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Commission's inaction was a consequence of the general moratorium on approvals.

7.1886 In view of our conclusion with regard to the Commission's failure to submit a draft measure to the Council, we do not go on to examine other arguments put forward by the United States and Argentina in support of their claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Council, it would have to adopt the draft measure it submitted to the Council. In the Panel's view, even in this scenario, there was enough time for the Commission to complete the procedure in question while Directive 90/220 was still in force.

[1431] The Commission usually made this point in its decisions approving applications. *See, e.g.*, Exhibit ARG-35 ("[w]hereas Article 11(6) and Article 16(1) of Directive 90/220/EEC provide additional safeguards if new information on risks of the product becomes available").

[1432] The fact that such a final decision might possibly have been challenged by the applicant before an EC court would obviously not have been a legitimate reason for not completing the approval procedure.

Conclusions

7.1887 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to forward a draft measure to the Council – no draft measure was forwarded between June 1999 and October 2002 – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's inaction was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning Bt-531 cotton for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning Bt-531 cotton, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, the Panel recalls its finding that the time taken by the Commission to forward a draft measure to the Council – no draft measure was forwarded between June 1999 and October 2002 – was unjustifiably long. In the light of this finding, the Panel concludes that the European Communities failed to complete the approval procedure concerning Bt-531 cotton without "undue delay", thus breaching its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(vi) RR-1445 Cotton (EC-66)

7.1888 Two Complaining Parties, the United States and Argentina, claim that the completion of the approval procedure concerning RR-1445 cotton has been unduly delayed.

7.1889 The **United States** submits that the application concerning RR-1445 cotton was delayed for nearly four years under Directive 90/220 by EC regulators. The United States submits that from 22 February 1999, after the failure of the Regulatory Committee to reach a decision, and despite the launch of inter-service consultations on a draft measure to be submitted to the Council starting 7 May 1999, the application was totally ignored by the Commission and lead CA until is was re-submitted under Directive 2001/18 on 16 January 2003. The United States considers this lengthy delay to be unwarranted and thus undue.

7.1890 The United States points out in this respect that the application in question had received a favourable scientific assessment by the SCP. In the United States' view, the fact that certain member States objected in the Regulatory Committee does not justify the Commission's refusal to act on the application. The United States submits that those objections which were explained in statements, notably those by Austria, Sweden and the United Kingdom, were the subject of detailed scientific consideration in the SCP's positive opinion in July 1998. None of the member States objecting at the Regulatory Committee stage offered any competing risk assessment or scientific evidence for their objections, nor did they identify any specific inadequacies in the SCP review. The United States also notes that there is at any rate nothing to indicate that the Commission undertook any process

whatsoever to resolve the member State concerns. Moreover, nothing in the record indicates that the applicant was ever requested to submit additional information to address the member State objections, nor that the basis of these objections was ever even notified to the applicant. The United States is therefore of the view that the delay in question was not caused, as the European Communities claims, by a pending request to the applicant for additional information.

7.1891 The United States notes in addition that the EC legislative framework provides a specific avenue for further action where the Regulatory Committee is unable to come to a decision: the Commission is to forward the application to the Council "without delay" for a decision. The United States considers that where the European Communities' own legislation provides timelines, a suspension of the approval procedure without any scientific justification must be considered undue delay.

7.1892 The United States submits, finally, that the application concerning RR-1445 cotton is one of nine applications identified by the United States which were stalled at the Commission level at the time Directive 90/220 expired and which, as of the date of establishment of the Panel, have been pending for an average of six and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning RR-1445 cotton is undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years

7.1893 **Argentina** argues that after the Regulatory Committee in February 1999 failed to achieve a qualified majority in favour of approving the application concerning RR-1445 cotton, the Commission refused to submit a draft measure to the Council until the application had to be resubmitted under Directive 2001/18. Argentina submits that this was not due to any action or omission on the part of the applicant. According to Argentina, there notably are no EC documents which specifically requested the applicant to provide additional information. Argentina considers that the delay which it says was caused by the Commission is undue. Argentina argues in this respect that the requirements of legislation not yet in force do not provide grounds for a prolonged failure to process an application. In particular, the application concerning RR-1445 cotton should not have been forced to start the procedure again under the new Directive 2001/18 when the procedure under the old Directive 90/220 had already been in progress for three years. Furthermore, Argentina asserts that there is no scientific evidence to justify the delay after the Regulatory Committee vote. Those member States which in the Regulatory Committee voted against approving RR-1445 cotton ignored the positive scientific opinion of the SCP of July 1998. Moreover, Argentina contests the scientific validity of the statements offered by some member States in support of their votes inasmuch as these statements do not refute the positive opinion of the SCP.

7.1894 Argentina identified another instance of delay which it considers undue. Argentina asserts that although the applicant in January 2003 submitted an updated application in accordance with the requirements of Directive 2001/18, the application did not progress. Argentina submits that, as a result, as of the date of its first written submission – April 2004 – the application concerning RR-1445 cotton had been inactive for an additional period of 1 year and 3 months.

7.1895 Finally, Argentina submits that the total time consumed by the procedures under Directives 90/220 and 2001/18, from the time the application was first submitted until April 2004, the date of Argentina's first written submission, has been 6 years and 9 months. In Argentina's view, this delay can in no way be justified in the light of the deadlines stipulated in the relevant EC legislation. Argentina contends that the procedure under Directive 90/220 should normally have been completed

within 240 days, which does not include the time during which a lead CA or the Commission may be awaiting additional information it may have requested or the time needed by an EC scientific committee to issue an opinion. Similarly, Argentina contends that under Directive 2001/18, a procedure should be completed within 285 days if no objections to the lead CA's initial assessment are made, and 450 days if objections are made. Again, this does not include the time spent waiting for additional information or for a scientific committee opinion. Argentina asserts that the delay affecting the approval procedure concerning RR-1445 cotton cannot be justified by such "clock-stops".

7.1896 The **European Communities** argues that the Regulatory Committee in February 1999 failed to reach a qualified majority because a number of member States raised scientific concerns which had not been addressed in any of the applicant's previous submissions. These related in particular to the long-term effects of herbicide tolerant crops on the environment, to the presence of an antibiotic resistance marker gene, residue-limit levels and to the effects on biodiversity of changes in crop management.

7.1897 Regarding the requirement contained in Article 21 of Directive 90/220 that the Commission "shall, without delay, submit to the Council a proposal relating to the measures to be taken", the European Communities points out that in the *Pharos* case[1433], the European Court of Justice examined an identical requirement to submit a proposal to the Council "without delay" in the context of legislation on the setting of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (Regulation 2377/90). The Court stated that nothing in the wording of the relevant provision "suggests any conclusion regarding the length of time indicated by the expression 'without delay', other than that, while a certain degree of rapidity is required, the Commission is not required to act within a precise period of time nor at once, contrary to the appellant's submission".[1434] The Court then went on to point out that the Commission was free to modify its proposal before submitting it to the Council and found that "if the Commission has the right to amend the proposal relating to the measures to be taken which it submits to the Council, it must have sufficient time to consider the various courses of action open to it".[1435] On that basis, the Court found that the Commission, which had taken over eleven months before forwarding a proposal to the Council, had not breached its obligation to act "without delay".[1436] The Court pointed to the fact that the matter with which the Commission was confronted was "highly complex and sensitive".[1437] The Court also made it clear that the Commission could not be criticised for having sought additional advice from an EC scientific committee in an effort to prevent its proposal from being rejected by the Council.[1438]

7.1898 Concerning the case at hand, the European Communities argues that the concerns raised by certain member States were legitimate and scientifically sound. They could not be ignored or brushed off by the Commission without detailed consideration. Moreover, according to the European Communities, in the light of the impending legislative changes, further reflection was necessary before proceeding further. The European Communities submits that this is in line with the jurisprudence of the European Court of Justice.

7.1899 In relation to the delay which occurred after the application was resubmitted under Directive 2001/18, the European Communities submits that the application contained an incomplete

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[1433] European Court of Justice, Case C-151/98, *Pharos against Commission [1999]* ECR I-8157.
[1434] *Ibid.*, para. 20.
[1435] *Ibid.*, para. 24.
[1436] The Panel notes that the judgement indicates that during the eleven-month period, the Commission initially reconsidered the file for six months and then sought a second scientific opinion. *Ibid.*, para. 32.
[1437] *Ibid.*, para. 26.
[1438] *Ibid.*, para. 27.

monitoring plan. According to the European Communities, the lead CA was awaiting additional information on the post-marketing monitoring plan that it had requested with letters of August and October 2003. The European Communities argues that it cannot be responsible for the lack of diligence or failings of an individual applicant.

7.1900 The **Panel** begins its analysis by addressing the delay allegedly caused by the Commission.

Failure by the Commission to submit a draft measure to the Council

7.1901 The Panel recalls that, following the failure of the Regulatory Committee to reach a decision, on 7 May 1999 the Commission launched inter-service consultations on a draft measure to be submitted to the Council. But at no point prior to 17 October 2002, the date of repeal of Directive 90/220, did the Commission submit a draft measure to the Council. The United States and Argentina argue that the Commission should have completed its inter-service consultations and submitted a draft measure to the Council before October 2002.

7.1902 It is clear that the preparation by the Commission of a draft measure and its submission to the Council is not a process which inherently takes more than three years. To begin with, in other approval procedures, the Commission was able to prepare and submit draft measures to the Council within a few months, despite the fact that in those procedures some member States also voted against the Commission's draft measure in the Regulatory Committee, and that some made written statements.[1439] Moreover, as the Panel understands it, the preparation by the Commission of a draft measure to be submitted to the Council is not a process that is fundamentally different from the preparation by the Commission of a draft measure to be submitted to the Regulatory Committee. In the approval procedure here at issue, the Commission prepared a draft measure and launched a vote in the Regulatory Committee in four months after receipt of the SCP opinion.[1440] It may be inferred from these examples that the Commission could in principle have completed its task well before October 2002.

7.1903 The issue thus becomes whether in the specific circumstances of this case the Commission could in fact have completed its task before October 2002. The European Communities argues that the Commission was not able to forward a draft measure to the Council because the applicant took too long to provide information which had been requested of it. The European Communities notes that the applicant did not provide that information until 25 July 2001, and that the translation of this material was made available only in February 2002. However, in our earlier analysis of the approval procedure concerning RR-1445 cotton, we found that there is no evidence to suggest that the Commission was waiting for the additional information provided by the applicant in July 2001. We pointed out that even after the applicant had provided the information, the Commission did not forward a draft measure to the Council, although Directive 90/220 remained in force for another seventeen months. Accordingly, the information provided by the applicant in July 2001 in our view does not justify the Commission's failure to forward a draft measure to the Council.

[1439] In the approval procedure concerning NK603 maize (Exhibit EC-76) and conducted under Directive 2001/18, the Commission submitted a draft measure to the Council little over one month after the Regulatory Committee had failed to reach a qualified majority. At that meeting, Austria made a statement in support of its negative vote. Exhibit EC-76/At. 72. In the approval procedure concerning Bt-11 sweet maize (food) and conducted under Regulation 258/97, the Commission adopted a draft measure and referred it to the Council less than two months after the Regulatory Committee had failed to reach a qualified majority. At that meeting, several member States made statements in support of their votes. Exhibit EC-92/At. 70.

[1440] Exhibit EC-66/Ats. 44 and 46. The Panel does not express a view as to whether this four-month period was necessary in the circumstances to complete the relevant procedural stage.

7.1904 Another argument put forward by the European Communities to justify the Commission's failure to forward a draft measure to the Council relates to the fact that the Regulatory Committee failed to achieve the necessary qualified majority to approve the application concerning RR-1445 cotton and that Austria, Italy, Sweden and the United Kingdom, in written statements supporting their votes, expressed certain concerns. The European Communities submits that these concerns were scientifically sound and had not been previously addressed by the applicant, and that they could not, therefore, be ignored or brushed off by the Commission without detailed consideration.

7.1905 As no qualified majority was reached in the Regulatory Committee, the Panel considers that, as a general matter, it was justifiable for the Commission to take some time, as part of its inter-service consultations, to analyse the reasons for the outcome of the vote in the Regulatory Committee and to determine, in the light of the results of such an analysis, whether it would be appropriate to modify the Commission's draft measure before it was sent on to the Council, and if so, how.

7.1906 The Panel recognizes that, as a matter of EC law, the Commission's draft measure did not need to obtain a qualified majority in the Council to complete the approval procedure. If the Council had failed to reach a favourable qualified majority, the Commission would have had to adopt its draft measure and hence approve the application concerning RR-1445 cotton.[1441] However, it must be borne in mind that an EC decision to approve the application concerning RR-1445 cotton would have authorized the applicant to market its product in all EC member States. In the light of this, the Commission was entitled, in the Panel's view, to try to obtain a qualified majority in the Council as this would have enhanced the legitimacy and acceptability of an EC decision to approve the application concerning RR-1445 cotton.[1442] This means that the Commission could take a reasonable period of time to explore ways of modifying its draft measure with a view to increasing the measure's chances of being accepted by the Council by a qualified majority.[1443] But the Commission could not simply wait for the majorities in the Council to change enough to allow the Commission's original draft measure to be accepted by a qualified majority. The obligation imposed on the European Communities is to complete its approval procedures without undue delay. This obligation may at times require the Commission to complete an approval procedure even if it does not have the (qualified) majority support of the Council.

7.1907 How much time is to be accorded to the Commission for the purpose of reconsidering a draft measure which did not obtain a qualified majority in the Regulatory Committee can only be determined in the light of the circumstances of each case.

7.1908 Turning, then, to the circumstances of this case, the European Communities asserts that the concerns identified in the written statements by Austria, Italy, Sweden and the United Kingdom had not been addressed by the applicant before.[1444] The Panel is unable to agree with this assertion. Austria and the United Kingdom expressed concerns arising from the antibiotic resistance marker

[1441] Article 21 of Directive 90/220. If the Council had reached a qualified majority against approving the application, then the application would, however, have had to be rejected.

[1442] It should also be recalled that the Complaining Parties did not question the design of the approval procedure set out in Directive 90/220 (or its successor, Directive 2001/18), and in particular the fact that member States vote on applications. It is arguable that if the Panel effectively were to require the Commission to press on immediately, preventing it from taking into account the votes and views expressed by member States, it would undermine the European Communities' ability to operate its approval procedure as designed.

[1443] The Panel recalls once more that in other approval procedures the Commission was able to prepare and submit draft measures to the Council within a few months, despite the fact that in those procedures some member States also voted against the Commission's draft measure in the Regulatory Committee

[1444] The statements are provided in Exhibit EC-66/At. 57. Italy voted in favour of the Commission's draft measure in the Regulatory Committee.

gene, which according to Dr. Squire had been explicitly addressed in the SCP assessment.[1445] The concern identified by Italy was to ensure that the herbicide residues were within the limits established by other EC legislation, which according to the Panel's understanding is not a concern related to the safety of RR-1445 cotton *per se*. Only the general concerns raised by Sweden and the United Kingdom regarding long-term effects of herbicide tolerant crops on the environment were not, according to Dr. Andow fully addressed by the SCP with regard to RR-1445 cotton.[1446] However, Dr. Andow indicated that the long-term experiments suggested by Sweden were not feasible and that the concerns identified could best be addressed in a monitoring plan, but that the necessity of a monitoring plan could not be determined from the objections as submitted. At any rate, the record does not indicate that after the Regulatory Committee vote, the Commission or the lead CA sought additional information from the applicant in an effort to allay these concerns.

7.1909 Even if it were assumed that during its inter-service consultations the Commission was undertaking its own assessment of the scientific validity of the specific concerns expressed with a view to supporting its draft measure with scientific arguments[1447], it is well to recall that the SCP was able to undertake a comprehensive scientific assessment of the application concerning RR-1445 cotton in little over three months' time.[1448] The Panel also notes that the European Communities does not assert that the concerns raised by the member States in question presented either new or particularly complex scientific problems.

7.1910 Another circumstance invoked by the European Communities is the fact that Directive 90/220 was being revised at the time. According to the European Communities, a period of time for reflection was therefore needed before proceeding further. To recall, the Commission in this case launched its inter-service consultations on a draft measure to be submitted to the Council in May 1999. At the end of June 1999, the Council reached a political agreement – the Common Position – on the proposal to amend Directive 90/220, but Directive 2001/18, the Directive amending Directive 90/220, was not adopted until March 2001 and did not enter into force until October 2002. Thus, the Commission started its inter-service consultations almost three-and-a-half years before the entry into force of Directive 2001/18. In the light of this, even accepting that the Commission could take some time to reconsider its draft measure, the Commission's failure to forward a draft measure to the Council cannot be excused on the grounds that there was not enough time to complete the approval procedure while Directive 90/220 was still in force.[1449]

7.1911 Furthermore, the fact that some member States and segments of public opinion may have considered that Directive 90/220 was no longer adequate and may have voiced opposition to further approvals under that Directive 90/220 did not, in the Panel's view, provide a justification for the Commission to delay the approval procedure in question until new legislation had been put in place. The EC legislator allowed Directive 90/220 to remain in force and hence applicable until October 2002. Moreover, if the Commission saw a need to respond to concerns about perceived inadequacies inherent in Directive 90/220, there were other courses of action open to it. Thus, the Commission

[1445] Annex H, para. 468.

[1446] Annex H, paras. 443-448.

[1447] The European Communities did not specifically assert that it was undertaking a scientific assessment of the concerns in question; it merely implied that the Commission embarked on a "detailed consideration" of these concerns.

[1448] Exhibit EC-66/Ats. 40 and 43.

[1449] In its earlier findings on the application concerning RR-1445 cotton, the Panel noted that the Commission had reason to believe that due to the "blocking minority" of the Group of Five countries in the Council, it would have to adopt the draft measure it submitted to the Council. In the Panel's view, even in this scenario, there was enough time for the Commission to complete the procedure in question while Directive 90/220 was still in force.

could in the first instance have sought voluntary commitments from the applicant. Alternatively, it could have proposed that the application be approved subject to conditions. In this respect, it is worth noting that Directive 90/220 provided additional safeguards if new information on risks of RR-1445 cotton had become available after its EC-wide approval.[1450] In such an event, a member State could, pursuant to Article 16 of Directive 90/220, provisionally restrict or prohibit the marketing of RR-1445 cotton. Finally, if in fact the Commission had been of the view that the risks arising from the marketing of RR-1445 cotton could not be adequately assessed or managed under Directive 90/220, it could arguably have sought the rejection of the application, subject, perhaps, to the right of the applicant to submit the application for reconsideration under the revised Directive, once it entered into force.[1451]

7.1912 Based on the above considerations, the Panel is of the view that in the specific circumstances of this procedure, the time actually taken by the Commission to prepare and forward a draft measure to the Council – no draft measure was forwarded between June 1999 and October 2002 – was unjustifiably long.

7.1913 Regarding DS291, we recall that the United States claims that the approval procedure concerning RR-1445 cotton was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to submit a draft measure concerning RR-1445 cotton to the Council is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Commission's inaction was a consequence of the general moratorium on approvals.

7.1914 In view of our conclusion with regard to the Commission's failure to submit a draft measure to the Council, we do not go on to examine other arguments put forward by the United States and Argentina in support of their claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusions

7.1915 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to forward a draft measure to the Council – no draft measure was forwarded between June 1999 and October 2002 – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's inaction was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning RR-1445 cotton for final approval, and that this resulted in "undue delay"

[1450] The Commission usually made this point in its decisions approving applications. *See, e.g.*, Exhibit ARG-35 ("[w]hereas Article 11(6) and Article 16(1) of Directive 90/220/EEC provide additional safeguards if new information on risks of the product becomes available").

[1451] The fact that such a final decision might possibly have been challenged by the applicant before an EC court would obviously not have been a legitimate reason for not completing the approval procedure.

in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning RR-1445 cotton, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, the Panel recalls its finding that the time taken by the Commission to forward a draft measure to the Council – no draft measure was forwarded between June 1999 and October 2002 – was unjustifiably long. In the light of this finding, the Panel concludes that the European Communities failed to complete the approval procedure concerning RR-1445 cotton without "undue delay", thus breaching its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(vii) Transgenic potato (EC-67)

7.1916 Only one Complaining Party, the United States, claims that the completion of the approval procedure concerning the Transgenic potato has been unduly delayed.

7.1917 The **United States** argues that after the Transgenic potato received a favourable opinion from the SCP, the Commission failed to submit a draft measure to the Regulatory Committee, with the consequence that the consideration of this application was suspended until the application was resubmitted under Directive 2001/18.

7.1918 The United States submits, in addition, that the application concerning the Transgenic potato is one of nine applications identified by the United States which were stalled at the Commission level at the time Directive 90/220 expired and which, as of the date of establishment of the Panel, have been pending for an average of six and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning the Transgenic potato is excessive and unjustified and, hence, undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.1919 The **European Communities** points out that the SCP in this procedure took more than three and a half years to assess the Transgenic potato. The European Communities submits that when the SCP issued its opinion in July 2002, Directive 2001/18 was about to enter into force and it was clear that the application had to be updated in the light of the new Directive.

7.1920 The **Panel** begins its analysis by addressing the delay allegedly caused by the Commission.

Failure by the Commission to submit a draft measure to the Regulatory Committee

7.1921 The Panel recalls that the SCP issued a favourable opinion on 18 July 2002. Following the issuance of the SCP opinion, the Commission did not submit a draft measure to the Regulatory Committee. In fact, it seems that unlike in other approval procedures[1452], the Commission in this procedure did not even launch inter-service consultations on a draft measure. In October 2002,

[1452] *See, e.g.*, Exhibits EC-62/At. 76; EC-65/At. 48.

Directive 90/220 was repealed. The United States argues that the Commission should have submitted a draft measure to the Regulatory Committee before October 2002.

7.1922 The preparation by the Commission of a draft measure and its submission to the Regulatory Committee is not a process which inherently takes very long. In some approval procedures, the Commission was able to prepare and submit draft measures to the Regulatory Committee within a matter of a few months. For example, in the procedure concerning Bt-531 cotton, the Commission prepared a draft measure and launched a vote in the Regulatory Committee in slightly less than three months.[1453] Likewise, in the procedure concerning NK603 maize, the Regulatory Committee voted on the application a little less than three months after EFSA issued its opinion.[1454]

7.1923 In the case of the approval procedure concerning the Transgenic potato, the SCP issued its opinion almost exactly three months before Directive 90/220 was repealed. The Panel understands the European Communities to argue that in these circumstances, the Commission did not need to submit a draft measure to the Regulatory Committee. This argument presents the issue whether the Commission could justifiably have reached the conclusion that three months would be insufficient to approve the application concerning the Transgenic potato.

7.1924 In its earlier findings, the Panel found that before the Transgenic potato could be approved, a number of procedural steps remained to be undertaken and completed. The Commission had to prepare a draft measure and submit it to the Regulatory Committee; the Regulatory Committee had to meet and vote on the draft measure; in the event of a favourable vote in the Regulatory Committee, the Commission had to adopt its draft measure; and finally, the lead CA had to give its written consent so that the product could be placed on the market. Directive 90/220 does not stipulate specific deadlines for any of these procedural steps.

7.1925 As pointed out above, the record shows that in one particular approval procedure, the Commission was able to obtain a Regulatory Committee vote less than three months after EFSA issued its opinion. If in the approval procedure concerning the Transgenic potato the Commission had proceeded with a sense of urgency, it might thus have succeeded in obtaining a Regulatory Committee vote in slightly less than three months.[1455] If the Commission's draft measure had achieved a qualified majority, the approval procedure would then have had to be completed within a matter of a few days.

7.1926 The record does not provide confirmation that this would have been possible. Regarding the adoption by the Commission of its own draft measure, the approval procedure concerning Bt-11 sweet maize is of interest, although that procedure was conducted under Regulation 258/97. In that procedure, the Commission took close to a month to adopt its own draft measure after the Council failed to achieve a qualified majority.[1456] Regarding the written consent to be given by the lead CA, the Panel finds informative the provisions of Article 18(2) of Directive 2001/18 according to which the lead CA must give its written consent, transmit it to the applicant and inform the other member States and the Commission thereof "within 30 days following the publication or notification of the [Commission's] decision [to adopt its draft measure]". While, as noted, Directive 90/220 stipulates no such deadline, the aforementioned steps were also to be completed under that Directive.[1457] It is

[1453] The Commission launched inter-service consultations on 4 September 1998 and launched a vote in the Regulatory Committee on 26 November 1998. Exhibit EC-65/Ats. 48 and 51.

[1454] EFSA issued its opinion on 25 November 2003 and the Regulatory Committee voted on the Commission's draft measure on 18 February 2004. Exhibit EC-76/Ats. 70 and 72.

[1455] The United States has submitted no evidence or argument to show that the Commission could have completed this task in substantially less time.

[1456] Exhibit EC-92/At. 81.

[1457] Article 13(4) of Directive 90/220.

reasonable to infer from the thirty-day deadline set out in Article 18(2) that the relevant steps could not invariably be completed in just a few days. Notwithstanding the foregoing, it may be assumed that if both the Commission and the lead CA had proceeded on an urgency basis in view of the exceptional circumstance of the imminent repeal of Directive 90/220, they might well have been able to complete their respective procedural steps in less than a month each. However, the evidence before the Panel is insufficient to support the conclusion that the procedural steps to be completed by the Commission and the lead CA should altogether have taken no more than a few days.

7.1927 In conclusion, based on the evidence on the record, the Panel is not convinced that the approval procedure concerning the Transgenic potato could have been completed in the three-month period preceding the date of repeal of Directive 90/220, and that the Commission should therefore have launched inter-service consultations on a draft measure to be submitted to the Regulatory Committee. Accordingly, the Panel finds that it has not been established that the time actually taken by the Commission to prepare and forward a draft measure – no draft measure was prepared and forwarded between July 2002 and October 2002 – was unjustifiably long.

Total amount of time taken since submission of application

7.1928 The United States also puts forward the argument that the total amount of time during which the application concerning the Transgenic potato was pending is excessive and unjustified and, hence, undue. The application concerning the Transgenic potato was first submitted for approval under Directive 90/220 in August 1996. This means that as of the end of August 2003, the approval procedure had been pending for more than seven years.

7.1929 The Panel agrees with the United States that, in absolute terms, this is a long period of time. However, the mere identification of the total amount of time during which an application has been pending does not demonstrate, in and of itself, that the time taken was unjustifiably long. Indeed, certain delays might be attributable, not to the European Communities, but to the applicant. Other delays might be attributable to the European Communities, but they might be justifiable. In the case of applications which were submitted under Directive 90/220 – and the application concerning the Transgenic potato is one of these – it must also be remembered that in accordance with Article 35 of Directive 2001/18, applications submitted under Directive 90/220, but not approved by October 2002 became subject to Directive 2002/18 and had to be re-assessed by the lead CA. As a necessary consequence, applications which had progressed to an advanced stage in the approval process under Directive 90/220 and then were resubmitted to the lead CA under Directive 2001/18 were pending for long periods of time. Yet despite the fact that Article 35 of Directive 2001/18 resulted in certain approval procedures – including that concerning the Transgenic potato – being delayed, the United States did not question the provisions of Article 35. In these circumstances, it would be incongruous not to take account of the fact that some of the total time taken to assess a relevant application was a direct consequence of the operation of Article 35.

7.1930 Moreover, even if the United States were correct in asserting that before there was an EC moratorium, approval procedures used to be completed in less than three years, it must be remembered that the European Communities assesses applications on a case-by-case basis. Thus, the fact that the approval procedure concerning the Transgenic potato was not completed in less than

three years in our view does not demonstrate that it was not justifiable for the European Communities to take more time to process the application concerning the Transgenic potato.[1458]

7.1931 The United States further argues that in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, the fact that the application in question had been pending for more than seven years demonstrates the existence of undue delay. We recall in this respect our finding that the record supports the conclusion that the European Communities applied a *de facto* moratorium on approvals as of June 1999. At that time, the application concerning the Transgenic potato had already been pending for more than two years and ten months. Thus, some of the total time taken cannot be explained by the moratorium. Moreover, the mere fact that a general moratorium was in effect does not necessarily imply that a particular application was affected by it. The United States itself has repeatedly stated that "the moratorium was a decision by the EC not to move products to a *final* decision in the approval process" and that "certain progress in the process, short of a final decision, is not the least bit inconsistent with a moratorium on final approvals".[1459] Therefore, by itself, the fact that a moratorium on approvals was in effect between June 1999 and August 2003 is not sufficient to demonstrate that the period of time during which the application concerning the Transgenic potato was pending as of August 2003 reflects a failure on the part of the lead CA to complete the relevant approval procedure without undue delay.

7.1932 Accordingly, the Panel is unable to accept the United States' assertion that the total period of time during which the application concerning the Transgenic potato had been pending as of August 2003 demonstrates that the time taken was unjustifiably long.

Conclusion

7.1933 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that it has not been established that the time taken by the Commission to prepare and forward a draft measure to the Regulatory Committee once the SCP had issued its opinion – no draft measure was forwarded between late July 2002 and October 2002 – was unjustifiably long, or that the total amount of time taken by the European Communities up to August 2003 was unjustifiably long. Based on these findings, the Panel is unable to accept the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning the Transgenic potato for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning the Transgenic potato, the United States has failed to establish that the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

[1458] It is worth recalling, more generally, that the approval procedures which were completed before there was a moratorium on approvals were not affected by the special circumstance that Directive 90/220 was repealed in 2002.

[1459] *See, e.g.*, US second written submission, para. 51 (emphasis in original).

(viii) Liberator oilseed rape (EC-68)

7.1934 One Complaining Party, the United States, claims that the completion of the approval procedure concerning Liberator oilseed rape has been unduly delayed.

7.1935 The **United States** argues that after Liberator oilseed rape received a favourable opinion from the SCP the Commission failed to submit a draft measure to the Regulatory Committee. The United States notes that this resulted in a two-year delay, since no action was taken on the application until November 2002 when the applicant was requested to provide an update in light of the entry into force of Directive 2001/18. The United States submits that there is no indication of any problem with the application during the two-year gap, nor of any additional information needed for final approval. According to the United States, the two-year delay was therefore undue.

7.1936 The United States submits, in addition, that the application concerning Liberator oilseed rape is one of nine applications identified by the United States which were stalled at the Commission level at the time Directive 90/220 expired and which, as of the date of establishment of the Panel, have been pending for an average of six and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning Liberator oilseed rape is undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.1937 The **European Communities** argues that the SCP opinion on Liberator oilseed rape recommended "an agreed code of practice for field management of the particular modified crop involving the active participation of the applicant to promote best practice by farmers".[1460] The European Communities submits that contrary to what it had done in the parallel dossier on Falcon oilseed rape, the applicant did not present any proposal for a code of practice following the opinion of the SCP and that it did not manifest itself with the lead CA at all until the lead CA in November 2002 sent the applicant a letter reminding it of the need to up-date the application by January 2003. The European Communities submits that it cannot be held responsible for delays that are caused by the lack of diligence or the failings of an applicant.

7.1938 The **Panel** begins its analysis by addressing the delay allegedly caused by the Commission.

Failure by the Commission to submit a draft measure to the Regulatory Committee

7.1939 The Panel recalls that the SCP issued a favourable opinion on 30 November 2000. Following the issuance of the SCP opinion, the Commission did not submit a draft measure to the Regulatory Committee until Directive 90/220 was repealed in October 2002. After the repeal of Directive 90/220, on 5 November 2002, the lead CA contacted the applicant to remind it of the need to update the application so that it could be further considered under Directive 2001/18. The United States argues that the Commission should have submitted a draft measure to the Regulatory Committee before October 2002.

7.1940 The preparation by the Commission of a draft measure and its submission to the Regulatory Committee is not a process which inherently takes more than twenty-two months. In other approval procedures, the Commission was able to prepare and submit draft measures to the Regulatory Committee within a matter of a few months. For example, in the procedure concerning Bt-531 cotton,

[1460] Exhibit EC-68/At. 88.

the Commission prepared a draft measure and launched a vote in the Regulatory Committee in less than three months.[1461] Likewise, in the procedure concerning NK603 maize, the Regulatory Committee voted on the application less than three months after EFSA issued its opinion.[1462] It may be inferred from these examples that the Commission could in principle have submitted a draft measure to the Regulatory Committee well before October 2002.

7.1941 The fact that the Commission could in principle have submitted a draft measure to the Regulatory Committee before October 2002 does not necessarily mean that the Commission could have done so in the specific circumstances of this case. The European Communities essentially asserts that its failure to do so is justified in view of the applicant's failure to present a code of practice for the field management of Liberator oilseed rape once the SCP had issued its opinion. However, in its earlier analysis of the approval procedure in question, the Panel found that it was not persuaded that the applicant was supposed to present a proposal for a code of practice, nor that the Commission failed to submit a draft measure to the Regulatory Committee because it was waiting for the applicant to propose a code of practice. The Panel further found that, in any event, the Commission in this case did not launch inter-service consultations on a draft measure to be submitted to the Regulatory Committee, and that the fact that the applicant did not present a proposal was not an obstacle to the Commission launching such consultations.[1463] Accordingly, the Panel is unable to agree with the European Communities that the applicant's failure to present a code of practice justified the Commission's failure to forward a draft measure to the Regulatory Committee before October 2002.

7.1942 Separately, it should be noted that the SCP opinion in this procedure dates from November 2000. Directive 90/220 was not repealed until almost two years later. There was thus enough time for the Commission to launch and complete inter-service consultations on a draft measure to be submitted to the Regulatory Committee and for the Commission to adopt its draft measure in the event of a favourable vote in the Regulatory Committee. In the Panel's assessment, the Commission's inaction cannot, therefore, be excused on the grounds that the approval procedure concerning Liberator oilseed rape could not be completed while Directive 90/220 was still in force.

7.1943 In its earlier findings on the application concerning Liberator oilseed rape, the Panel noted that the Commission could have considered that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority and that the Commission would then have to complete the procedure by adopting its draft measure. In the Panel's view, even in this scenario, there was enough time for the Commission to complete the procedure in question while Directive 90/220 was still in force. But even if it the Commission considered it doubtful that there would be enough time in view of anticipated member State opposition, the Panel does not consider that this would have justified the Commission's failure to forward a draft measure to the Regulatory Committee. The Commission would have anticipated a "blocking minority" on the basis of the June 1999 declaration by the Group of Five countries. As pointed out above, there is no indication that the June 1999 declaration was intended to legally bind the Governments of the Group of Five countries *vis-à-vis* other member States or the Commission. In other words, the Group of Five countries retained the freedom under EC law to vote in favour of applications in the Regulatory Committee and Council. In the light of this, we think the Commission could not have legitimately invoked the June 1999 declaration as a justification for not submitting a draft measure to the Regulatory Committee prior to October 2002.

[1461] Exhibit EC-65/Ats. 48 and 51.
[1462] Exhibit EC-76/Ats. 70 and 72.
[1463] *See supra*, para. 7.687.

7.1944 Based on the above considerations, the Panel is of the view that, in the specific circumstances of this procedure, the time actually taken by the Commission to prepare and forward a draft measure to the Regulatory Committee – no draft measure was forwarded between late November 2000 and October 2002 – was unjustifiably long.

7.1945 In addition, we recall that the United States claims that the approval procedure concerning Liberator oilseed rape was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to submit a draft measure to the Regulatory Committee following the issuance of the SCP's opinion is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Commission's inaction was a consequence of the general moratorium on approvals.

7.1946 In view of our conclusion with regard to the Commission's failure to submit a draft measure to the Regulatory Committee, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.1947 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to prepare and forward a draft measure to the Regulatory Committee once the SCP had issued its opinion – no draft measure was forwarded between late November 2000 and October 2002 – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's inaction was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning Liberator oilseed rape for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning Liberator oilseed rape, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ix) Bt-11 maize (EC-69)

7.1948 One Complaining Party, the United States, claims that the completion of the approval procedure concerning Bt-11 maize (EC-69) has been unduly delayed.

7.1949 The **United States** argues that after the application concerning Bt-11 maize (EC-69) received a favourable opinion from the SCP in November 2000, the Commission failed to submit a draft measure to the Regulatory Committee. The United States notes that, under the EC approval system, the next step after the SCP favourable opinion should have been to submit the application for approval by the Regulatory Committee. According to the United States, however, there was no action on the application for two years after the SCP opinion and instead the next entry in the chronology provided by the European Communities is an "evaluation of updates by the lead CA" in October 2002, which is

unexplained and unsupported by any exhibit or attachment. According to the United States, the lengthy delay after the SCP opinion was issued provides compelling evidence of the existence of a general moratorium.

7.1950 The United States submits, in addition, that the application concerning Bt-11 maize (EC-69) maize is one of nine applications identified by the United States which were stalled at the Commission level at the time Directive 90/220 expired and which, as of the date of establishment of the Panel, have been pending for an average of six and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning Bt-11 maize (EC-69) is undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.1951 The **European Communities** argues that, after the SCP opinion, further discussions were held between the lead CA, the applicant and the Commission, and they went on until well into 2002. The European Communities notes in this respect that the SCP recommended a monitoring plan, and that the issue of the monitoring plan remained unsettled. The European Communities further points out that in May 2002 the applicant submitted additional information, including supplementary sequence information on the molecular characterization of the Bt-11 line, taking into account the provisions of the new Directive, *inter alia* on monitoring, traceability and labelling.

7.1952 The **United States** responds that the monitoring plan referred to in the SCP opinion is an "Insect Resistance Management" (IRM) plan, and that the SCP never recommended any changes to the applicant's proposed IRM plan. The United States also notes that the only other mention of monitoring was with respect to changes in field populations of non-target insects, but that the SCP did not request a monitoring plan on non-target insects, or note any deficiency in the application. Moreover, the United States argues that nothing in the record indicates that EC regulators ever approached the applicant either to identify a problem or to request additions to the application.

7.1953 The **Panel** begins its analysis by addressing the delay allegedly caused by the Commission.

Failure by the Commission to submit a draft measure to the Regulatory Committee

7.1954 The Panel recalls that in the approval procedure concerning Bt-11 maize (EC-69), the SCP issued a favourable opinion on 30 November 2000. Following the issuance of the SCP opinion, the Commission did not submit a draft measure to the Regulatory Committee. In October 2002, Directive 90/220 was repealed. The United States argues that the Commission should have submitted a draft measure to the Regulatory Committee before October 2002.

7.1955 The preparation by the Commission of a draft measure and its submission to the Regulatory Committee is not a process which inherently takes more than twenty-two months. In other approval procedures, the Commission was able to prepare and submit draft measures to the Regulatory Committee within a matter of a few months. For example, in the procedure concerning Bt-531 cotton, the Commission prepared a draft measure and launched a vote in the Regulatory Committee in less than three months.[1464] Likewise, in the procedure concerning NK603 maize, the Regulatory Committee voted on the application less than three months after EFSA issued its opinion.[1465] It may

[1464] Exhibit EC-65/Ats. 48 and 51.
[1465] Exhibits EC-76/At. 70-72.

be inferred from these examples that the Commission could in principle have submitted a draft measure to the Regulatory Committee well before October 2002.

7.1956 The fact that the Commission could in principle have submitted a draft measure to the Regulatory Committee before October 2002 does not necessarily mean that the Commission could have done so in the specific circumstances of this case. The Panel understands the European Communities to assert that the Commission did not send a draft measure to the Regulatory Committee because, after the SCP opinion, the lead CA, the applicant and the Commission continued discussions on a monitoring plan well into 2002. The Panel also understands the European Communities to assert that the applicant submitted additional information in May 2002, just before the new Directive entered into force.

7.1957 Regarding the monitoring plan, we stated in earlier findings on this approval procedure that we are not persuaded by the European Communities' assertion that the Commission did not submit a draft measure to the Regulatory Committee because the SCP recommended a monitoring plan and the issue remained unsettled. We further found that, in any event, the Commission in this case did not launch inter-service consultations on a draft measure to be submitted to the Regulatory Committee, and that the fact that the SCP stated that monitoring should be carried out was not an obstacle to the Commission launching inter-service consultations on a draft measure. Accordingly, we are unable to agree with the European Communities that the fact that the SCP recommended a monitoring plan justified the Commission's failure to forward a draft measure to the Regulatory Committee before October 2002.

7.1958 Regarding the additional information submitted by the applicant in May 2002, we have already observed earlier that this information was apparently voluntarily submitted with a view to updating the application in anticipation of the entry into force of the new requirements contained in Directive 2001/18. There is no evidence that this additional information was submitted at the request of the Commission or the lead CA. In other words, there is no reason to believe that the Commission was waiting for this information. In our view, therefore, the May 2002 information does not justify the Commission's failure to submit a draft measure to the Regulatory Committee between November 2000 and May 2002.

7.1959 Separately, it should be noted that the SCP opinion in this procedure dates from November 2000. Directive 90/220 was not repealed until almost two years later. In our assessment, there was thus enough time for the Commission to launch and complete inter-service consultations on a draft measure to be submitted to the Regulatory Committee and for the Commission to adopt its draft measure in the event of a favourable vote in the Regulatory Committee.[1466] In our assessment, the Commission's inaction cannot, therefore, be excused on the grounds that the approval procedure concerning Bt-11 maize (EC-69) could not be completed while Directive 90/220 was still in force.

7.1960 In our earlier findings on the application concerning Bt-11 maize (EC-69), we noted that the Commission could have considered that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority and that the Commission would then have to complete the procedure by adopting its draft measure. In our view, even in this scenario, there was enough time for the Commission to complete the procedure in question while Directive 90/220 was still in force. But even if it the Commission considered it doubtful that there would be enough time in view of

[1466] We note, by way of example, that in the procedure concerning NK603 maize, the Regulatory Committee voted on the application less than three months after the SCP issued its opinion. Exhibit EC-76/At. 72.

anticipated member State opposition, the Panel does not consider that this would have justified the Commission's failure to forward a draft measure to the Regulatory Committee. On the other hand, the Commission could have anticipated a "blocking minority" on the basis of the June 1999 declaration by the Group of Five countries. Yet, as pointed out above, there is no indication that the June 1999 declaration was intended to bind the Governments of the Group of Five countries *vis-à-vis* other member States or the Commission. In other words, the Group of Five countries retained the freedom under EC law to vote in favour of applications in the Regulatory Committee and Council. In the light of this, we think the Commission could not have invoked the June 1999 declaration as a justification for not submitting a draft measure to the Regulatory Committee prior to October 2002.

7.1961 Based on the above considerations, the Panel is of the view that, in the specific circumstances of this procedure, the time actually taken by the Commission to prepare and forward a draft measure to the Regulatory Committee – no draft measure was forwarded between late November 2000 and October 2002 – was unjustifiably long.

7.1962 In addition, we recall that the United States claims that the approval procedure concerning Bt-11 maize (EC-69) was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to submit a draft measure to the Regulatory Committee following the issuance of the SCP's opinion is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Commission's inaction was a consequence of the general moratorium on approvals.

7.1963 In view of our conclusion with regard to the Commission's failure to submit a draft measure to the Regulatory Committee, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.1964 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to prepare and forward a draft measure to the Regulatory Committee once the SCP had issued its opinion – no draft measure was forwarded between late November 2000 and October 2002 – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's inaction was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning Bt-11 maize (EC-69) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning Bt-11 maize (EC-69), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(x) RR oilseed rape (EC-70)

7.1965 Two Complaining Parties, the United States and Canada, claim that the completion of the approval procedure concerning RR oilseed rape (EC-70) has been unduly delayed.

7.1966 The **United States** argues that this application was delayed at the member State level for more than four years. The United States submits that although the applicant in this procedure provided answers to all of the questions raised by the lead CA, the lead CA failed to approve the product under Directive 90/220. More specifically, the United States argues that the total time taken at the member State level for the initial review was 54 months (7 July 1998 to 22 January 2003), of which 12 months were taken by the applicant to respond to questions. The United States asserts that an additional 10 months of the total time taken were spent resolving confidentiality issues in relation to detection methods. Thus, according to the United States, the lead CA in this procedure took 32 months for its review instead of the 90 days referred to in Article 12 of Directive 90/220. The United States considers this delay in completing the approval procedure concerning RR oilseed rape (EC-70) to be undue.

7.1967 The United States notes, in addition, that Denmark, Italy, Belgium, Austria, France and Germany all objected to the lead CA's favourable initial assessment on the grounds that new EC rules concerning the traceability and labelling of biotech products needed to be in place before they could support the approval of any application. The United States submits that this shows an unwillingness to acknowledge the strength of the scientific conclusions reached by the lead CA and opposition to approval regardless of the merits of the application in question. The United States notes, in addition, that Austria and Denmark also objected because in their view issues concerning liability and coexistence remained to be resolved. The United States submits that a desire for rules addressing these issues cannot justify delay. Otherwise, a Member could always say it would like a better regulatory regime in aspects unrelated to the environment, human or animal health and delay approvals indefinitely, rendering the "no undue delay" discipline meaningless.

7.1968 The United States also points out that the application concerning RR oilseed rape (EC-70) is one of nine applications identified by the United States which have been pending at the member State level for an average of three years and ten months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning RR oilseed rape (EC-70) is undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.1969 **Canada** notes that in February 2000, the Dutch State Institute for Quality Control of Agricultural Products (RIKILT-DLO), which is responsible for providing scientific opinions relating to feed safety, issued a favourable assessment of RR oilseed rape (EC-70). On 10 January 2001, the Dutch Committee on Genetic Modification (COGEM), which is responsible for providing scientific advice relating to human health and the environment, concluded its assessment with a favourable conclusion. In January 2003, the Netherlands CA published a favourable overall assessment report. Canada submits that the two-year delay by the Netherlands CA in completing its overall assessment report and forwarding it to the Commission is unjustified and excessive.

7.1970 Canada also argues that the total time taken by the Netherlands to review this file was 54 months (7 July 1998 to 22 January 2003). Out of these 54 months, the applicant took a total of 12 months to respond to questions. Another 10 months were used for discussions of the confidentiality status of certain information submitted by the applicant beyond the legal requirements of the approval

legislation then in force. Canada submits that even if the latter period of time were not taken into account in this calculation, the remaining 32 months are in stark contrast to the 90 days foreseen in Directive 90/220 for this procedural step. In Canada's view, it is reasonable to infer from this that in the light of the moratorium, the Dutch authorities were taking a decidedly go-slow approach.

7.1971 Regarding the delay caused by the issue of confidentiality, Canada notes that Annex C(1)(d) of the *SPS Agreement* states that WTO Members shall ensure "the confidentiality of information about imported products arising from or supplied in connection with control, inspection and approval is respected […] in such a manner that legitimate commercial interests are protected". Under Article 25 of Directive 2001/18, an applicant is entitled to request that commercially sensitive information be protected, which the applicant in this case did in March 2001. Canada is therefore of the view that delays arising from an applicant seeking to ensure the fulfilment of obligations, both under the *SPS Agreement* and domestic law, relating to the protection of legitimate commercial interests should not be attributed to the applicant.

7.1972 In addition to the foregoing, Canada submits that the failure by the European Communities to approve this product under Directive 2001/18 compounds the already unjustified and excessive delay. Canada submits that repeated, unjustified "road-blocks" that have been imposed by member States resulting in excessive delays – unjustified objections to the lead CA's favourable initial assessment in March 2003, the failure of the Regulatory Committee to obtain a qualified majority at its meeting of 16 June 2004 – demonstrate that the European Communities has violated its obligations under Annex C(1) of the *SPS Agreement*.

7.1973 Regarding member State objections, Canada notes that Denmark, Italy, France, Austria and Belgium raised objections, not on the basis of safety concerns, but on the grounds that approval of the application in question should be suspended pending the adoption of new EC legislation on traceability and labelling. Canada further contends that Denmark (in relation to transport of RR oilseed rape (EC-70)) and Italy (in relation to herbicide use) raised objections outside the scope of the assessment foreseen by Directive 2001/18. Finally, Canada argues that objections were raised which were irrelevant in the light of the scope of the requested approval (*i.e.* for import and processing). Denmark requested that a monitoring plan should include observations on dispersal and gene transfer to oilseed rape and wild relatives.[1467] Likewise, Italy, the United Kingdom, Spain and Austria objected on the basis that a post-market monitoring plan needed to be proposed to assess seed spillage. Canada submits that the European Communities' scientific committee has confirmed repeatedly, and in particular for oilseed rape, that the mere fact of potential dispersal of seeds and gene transfer among domesticated or wild relatives is not *per se* negative for human health or the environment. Moreover, Canada points out that the scope of the approval was for import only, as opposed to planting – a fact that does not normally attract attention to seed spillage, because the imported grain is processed at the port of entry where spillage is controlled in compliance with statutory standards and to avoid economic loss.

7.1974 Canada also argues that the total time for member State review of the lead CA's initial assessment was eight months (22 January 2003 to 6 October 2003) instead of 105 days, the time-period envisaged in Article 15 of Directive 2001/18.

7.1975 Regarding the failure of the Regulatory Committee to obtain a qualified majority at its meeting of 16 June 2004, Canada notes that prior to the vote, EFSA rendered a favourable opinion and that in rendering its favourable opinion, EFSA considered all of the member States' objections in relation to safety issues. Canada considers, therefore, that whatever the rationalization for member

[1467] Exhibit EC-70/At. 26.

States to vote against or abstain from voting, such rationalizations were not justified by science-based health or safety considerations. In Canada's view, it follows that the failure of the Regulatory Committee to approve the application forced additional unwarranted delays.

7.1976 Finally, Canada contends that the length of time it has taken, so far, for this application to move through the approval system – seven years – is, by any reasonable standard, "undue" and therefore a violation of Annex C(1)(a), keeping in mind that it still has not been approved. However, the amount of time this application has languished in the approval procedure is not the sole reason for Canada's claim that the delay has been undue. First and foremost, the European Communities has had in place, since October 1998, an unjustified moratorium on approvals. Furthermore, the refusal to approve the application concerning RR oilseed rape (EC-70) is not based on a risk assessment, despite numerous favourable risk assessments conducted by the European Communities' own scientific committees.

7.1977 The **European Communities** argues that in this procedure there was a continuous exchange of correspondence between the lead CA and the applicant until December 2002, when the applicant updated its application in accordance with the requirements of Directive 2001/18. According to the European Communities, this period of time was entirely dedicated to resolving scientific and technical issues, such as molecular characterisation and feed safety. The lead CA requested additional information on molecular characterization and on certain feed safety aspects, and exchanges regarding these issues continued until the year 2000. After the adoption of Directive 2001/18 in March 2001, the lead CA asked the applicant to provide information on a detection method as required under the new legislation. The applicant requested confidentiality status for the information to be provided. The lead CA initially did not accept the reasons provided for requesting that status and several letters were exchanged on the issue. The lead CA also requested reference material which again triggered a debate on confidentiality. The European Communities notes that these issues were only settled in the autumn of 2002. By that time, Directive 2001/18 had entered into force and the lead CA and applicant worked on up-dating the application according to Directive 2001/18. As regards the issue of confidentiality, the European Communities submits that it was at the request of the applicant that the discussion on these issues was undertaken and that the European Communities cannot be responsible for any slippage in the timetable resulting from a request made by an applicant.

7.1978 The European Communities further points out that once the applicant had provided an update, the application moved immediately to the Community level. A few member States requested additional information and six member States raised objections. The objections related to issues of molecular characterisation (insufficient data), feeding studies, the monitoring plan, allergenicity, detection/identification methods as well as traceability and labelling. Meetings were held with the applicant to settle these issues and the applicant provided additional information. The European Communities contends that the objections raised by member States were based on legitimate and scientifically sound concerns, or regulatory requirements outside the scope of this dispute (traceability and labelling).

7.1979 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.1980 We note that in the approval procedure concerning RR oilseed rape (EC-70), the applicant submitted an application to the lead CA (the Netherlands) on 7 July 1998. When Directive 90/220 was repealed on 17 October 2002, the lead CA had not yet forwarded the dossier to the Commission. The dossier was forwarded to the Commission with a favourable assessment report on 16 January 2003, after the applicant had provided an updated application in accordance with Directive 2001/18.

7.1981 The United States and Canada assert that the lead CA took too long to complete its assessment. They note that the lead CA took much more time for its own assessment of the application than the 90 days envisaged in Article 12(2) of Directive 90/220.[1468] We consider that this is correct.[1469] However, whether or not the lead CA complied with the 90-day deadline stipulated in Directive 90/220 in our view is not dispositive, *per se*, of whether the European Communities met its WTO obligation to complete its approval procedures without undue delay. Indeed, legislation of different WTO Members may stipulate deadlines for this type of assessment which are more or less strict. Nevertheless, we consider that the deadline set forth in Directive 90/220 provides a useful indicator to guide the Panel's analysis. The 90-day deadline is binding and applies to all relevant applications submitted under Directive 90/220. It may therefore be assumed that the EC legislator set this binding deadline in such a way as to make it possible for the CAs of all member States to assess even complex applications within the prescribed deadline.[1470]

7.1982 In the present case, however, the European Communities contends that all of the time taken by the lead CA until December 2002, when the applicant complemented its application in accordance with the requirements of Directive 2001/18, was necessary to resolve scientific and technical issues.[1471] Since we do not view the fact that the 90-day deadline was exceeded as dispositive, *per se*, we go on to examine whether the lead CA was justified in forwarding an assessment report to the Commission only in mid-January 2003.

7.1983 In its earlier findings on the approval procedure concerning RR oilseed rape (EC-70), the Panel noted its understanding that when evaluating applications for placing on the market, the Netherlands CA notably took into consideration the advice from the COGEM and the opinion of the RIKILT-DLO. In the approval procedure in question, the RIKILT-DLO submitted its favourable opinion in February 2000[1472], and the lead CA advised the applicant in March 2000 in an e-mail that no further technical information for the risk assessment needed to be supplied.[1473] The COGEM did not provide its favourable advice until 10 January 2001.[1474]

7.1984 Regarding the advice from the COGEM, it should be recalled that the COGEM met in September 1998 to discuss the application in question. This led to a request for additional information on molecular characterization, which was transmitted to the applicant also in September 1998.[1475] The applicant provided the requested information in December 1998.[1476] Yet the COGEM did not meet again to discuss the application and the additional information for another two years. The relevant meeting took place in December 2000, a month before the COGEM provided its final

[1468] We recall that the 90 days envisaged in Directive 90/220 do not include any periods of time during which the lead CA is awaiting further information which it requested from the applicant.

[1469] For instance, as is clear from Exhibit EC-70, the lead CA was assessing the application between 13 August 1998 and 25 September 1999; between 2 April 1999 and 17 August 1999; and between 18 November 1999 and 21 January 2000 when the RIKILT-DLO appears to have requested additional information (Exhibit EC-70/At. 17). These periods of time, which are but examples, already add up to more than seven months.

[1470] Our remarks concerning the 90-day deadline set out in Article 12(2) of Directive 90/220 are also applicable, *mutatis mutandis*, to the corresponding 90-day deadline set out in Article 14(2) of Directive 2001/18.

[1471] EC second written submission, para. 199.

[1472] Exhibit EC-70/At. 66, Summary of the evaluation carried out by the Netherlands Competent Authority (GT73), p. 5; *see also* Exhibit CDA-57.

[1473] Exhibit EC-70/At. 18; Exhibit CDA-132.

[1474] Exhibit EC-70/At. 66, Summary of the evaluation carried out by the Netherlands Competent Authority (GT73), p. 5; *see also* Exhibit CDA-57.

[1475] Exhibit EC-70/At. 7.

[1476] Exhibit EC-70/Ats. 9 and 10.

advice.[1477] The record does not support the inference that the COGEM provided its advice only in January 2001 because it needed to resolve scientific or technical issues. Nor is there any indication in the record that the COGEM had other reasons for delaying the provision of its advice. There is therefore no apparent reason why the COGEM could not have provided its advice before or by the time the lead CA informed the applicant by e-mail that no further technical information needed to be submitted, *i.e.*, before or by March 2000.

7.1985 In the light of the foregoing, the Panel considers that at the latest in March 2000 the lead CA could have had all the elements to complete its assessment report. The European Communities notes that the applicant submitted additional information in April and May 2000. It is correct that in the aforementioned e-mail of March 2000 from the lead CA to the applicant, the lead CA also noted that the legal name and registration of the applicant would need to be confirmed, and that the original application would need to be modified to take into account the additional information submitted in the course of the assessment process.[1478] In April 2000, the applicant confirmed its legal name and registration.[1479] And in mid-May 2000, the applicant sent a draft document to the lead CA to indicate how it intended to modify the original application and to ask for comments and suggestions.[1480] The lead CA replied that it would communicate its "findings" as soon as possible, probably within less than a fortnight.[1481] This estimate demonstrates that the document submitted in mid-May 2000 did not call for a lengthy analysis by the lead CA. Moreover, the Panel does not consider that the March 2000 e-mail from the lead CA constitutes a formal request for information which triggered a clock-stop.[1482]

7.1986 If, as the Panel believes, the lead CA could have obtained all necessary elements at least by March 2000, it may reasonably be assumed that the lead CA could have completed its assessment report at the latest 90 days later, *i.e.*, around the end of June 2000. It should be recalled that Article 12(2) of Directive 90/220 requires that "at the latest 90 days after receipt" of an application, the lead CA must, in the case of a favourable assessment, forward the application to the Commission with a favourable opinion. The Panel has already observed in respect of the corresponding 90-day deadline stipulated in Directive 2001/18 that that deadline provides a useful indicator for determining how much time might be needed to complete an member State level assessment. Assuming that 90 days would have been sufficient seems all the more reasonable as by March 2000 the lead CA had already assessed the application for more than the 90 days envisaged in Article 12(2) of Directive 90/220.[1483]

7.1987 Based on the foregoing considerations, the Panel considers that the lead CA could have forwarded its assessment report to the Commission well before the end of 2000 and thus much before

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[1477] Exhibit EC-70/At. 17, p. 2 (in Dutch), Letter of 10 January 2001 by the COGEM to the Netherlands CA, p. 2. *See also* Exhibit EC-70/At. 66, Summary of the evaluation carried out by the Netherlands Competent Authority (GT73), p. 5.

[1478] Exhibit EC-70/At. 18.

[1479] Exhibit EC-70/At. 19. In addition, the applicant sent some information which the European Communities acknowledges had already been transmitted to the lead CA. EC reply to Panel question No. 152.

[1480] Exhibit EC-70/At. 21. The Panel fails to see a basis for the European Communities' contention that the relevant draft document was "a new element in the authorization process because it change[d] the terms of the application". Nor does the Panel think that Exhibit EC-70/At. 23 supports the conclusion that the lead CA was still "analys[ing] the update" in November 2000. EC reply to Panel question No. 152.

[1481] Exhibit EC-70/At. 22.

[1482] Indeed, the chronology provided to the Panel by the European Communities does not describe the communication as such, which is in contrast to other entries in the chronology. Exhibit EC-70/At. 18.

[1483] As noted previously and by way of example, the lead CA was assessing the application between 13 August 1998 and 25 September 1999 as well as between 2 April 1999 and 17 August 1999. These periods of time add up to more than 90 days. Exhibit EC-70.

mid-January 2003. This means that, contrary to the European Communities' contention, not all of the time taken by the lead CA up to December 2002 was necessary to resolve scientific and technical issues. Moreover, the lead CA's failure to complete and forward an assessment report before the end of 2000 could not, in the Panel's view, be excused on the basis that there was insufficient time to complete the approval procedure concerning RR oilseed rape (EC-70) while Directive 90/220 was still in force. Directive 90/220 was not repealed until October 2002. There was thus enough time for the other member States to review the lead CA's assessment report within 60 days following the circulation of the assessment report and, in the absence of objections, for the lead CA to give its consent to the placing on the market of RR oilseed rape (EC-70).[1484]

7.1988 In its earlier findings, the Panel also stated that even assuming that the COGEM could not have provided its advice before January 2001, the Netherlands could still have completed and forwarded its assessment report sooner than it did. Specifically, the Panel noted that when the COGEM provided its advice in January 2001, the lead CA did not complete its assessment report but on 12 March 2001 – the date of adoption of Directive 2001/18 – requested a detection method based on the provisions of Directive 2001/18, even though that Directive did not enter into force until October 2002. The applicant provided a detection method four days later.[1485] However, the applicant requested confidential treatment of the detection method. This resulted in an eight-month exchange with the applicant. As we noted earlier, during that exchange, the lead CA caused delays by not requesting clarification promptly. Our examination focuses on the delays caused by the lead CA during the course of the exchange over confidentiality issues.

7.1989 We begin our examination by recalling relevant facts. In May 2001, the lead CA asked the applicant to reconsider its request for confidential treatment of the detection method it had submitted, or else to provide further substantiation. The lead CA also stated that in the absence of further substantiation by June 2001, it would take a decision with respect to the request.[1486] In September 2001, after providing further clarification at the request of the lead CA and "in order to keep the approval process moving forward", the applicant agreed to disclose the protocol for the detection of RR oilseed rape (EC-70). But the applicant requested that the primer sequences in the protocol remain confidential until the first patent application was published.[1487] In response, the lead CA again sought further substantiation. After receiving additional substantiation, the lead CA in January 2002 granted the request that the primer sequences should be treated as confidential.

7.1990 It is clear from these facts that there was a disagreement between the lead CA and the applicant regarding whether certain information was by nature confidential. Article 19 of

[1484] In its earlier findings on the application concerning RR oilseed rape (EC-70), the Panel noted that the Netherlands could have considered that for as long as Directive 90/220 was still in force, there was no realistic prospect that the Group of Five countries and the Commission would allow the final approval of the application in question. However, the Panel does not consider that this would have justified the Netherlands' failure to forward an assessment report to the Commission. The Netherlands might have anticipated opposition from the Group of Five countries on the basis of their June 1999 declaration. As pointed out above, notwithstanding this declaration, the Group of Five countries retained the freedom under EC law to approve applications. The same is true for the Commission, which had not issued a declaration comparable to that of the Group of Five countries.

[1485] As Directive 2001/18 was not yet in force on the date of the lead CA's request, the applicant was arguably not obliged, as a matter of EC law, to comply with it. In our view, there can be no doubt in view of the wording of the lead CA's request for a detection method that the applicant was aware that the basis for the request was legislation not yet in force. But there is no indication in the record that the applicant contested the propriety of the request.

[1486] Exhibit EC-70/At. 26.

[1487] Exhibit EC-70/At. 30.

Directive 90/220 provides that in such cases it is for the lead CA to decide, after consultation with the applicant, whether the information should be treated as confidential.[1488] It appears to the Panel that the lead CA was following this procedure. However, it took a long time – eight months – to resolve the issue of the confidentiality status of the relevant information. While the applicant took a total of three and a half months to reply to the several requests for further substantiation, in June 2001 the lead CA waited for more than a month after receiving further substantiation before it followed up with a request for yet more substantiation.[1489] A similar situation arose in September 2001 when the lead CA waited for more than two months before following up with another request.[1490] The substantiation provided by the applicant in June and September 2001 was neither very extensive nor particularly complex.[1491] Moreover, in June and September 2001, there was no apparent reason for the lead CA to consider that there was insufficient time to approve the application before Directive 90/220 was repealed in October 2002. The Panel therefore does not see any justification for the lead CA's failure to follow up more promptly. In the Panel's view, the lead CA's delayed action in response to the June and September submissions of the applicant demonstrates that, contrary to the European Communities' contention, not all of the time taken by the lead CA up to December 2002 was necessary to resolve scientific and technical issues.

7.1991 Based on the above considerations, the Panel concludes that the time taken by the lead CA for its assessment of the application concerning RR oilseed rape (EC-70) – notably the time spent waiting for COGEM to provide its advice, and the time taken to follow up on substantiation provided by the applicant for its request for confidential treatment of certain information – was unjustifiably long.

7.1992 In relation to DS291, we recall that the United States claims that the approval procedure concerning RR oilseed rape (EC-70) was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the time taken by the Netherlands to complete its assessment is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Netherlands' conduct was a consequence of the general moratorium on approvals.

7.1993 In view of our conclusion with regard to the time taken by the Netherlands for its assessment, we do not go on to examine other arguments put forward by the United States and Canada in support of their claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusions

7.1994 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning RR oilseed rape (EC-70) was unjustifiably long, and that it can reasonably be inferred from surrounding

[1488] Canada refers to the analogous provisions of Article 25 of Directive 2001/18. However, these provisions were not applicable at the time.

[1489] Exhibit EC-70/At. 28.

[1490] Exhibit EC-70/At. 33.

[1491] The June letter from the applicant is two pages long, that of September is only one page long.

circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning RR oilseed rape (EC-70) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning RR oilseed rape (EC-70), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ii) DS292 (Canada)

With reference to DS292, the Panel recalls its finding that the time taken by the lead CA for its assessment of the application concerning RR oilseed rape (EC-70) was unjustifiably long. Based on this finding, the Panel accepts Canada's contention that the European Communities failed to "consider or approve, without undue delay", the application concerning RR oilseed rape (EC-70), and that it consequently did not complete the relevant approval procedure without "undue delay". Accordingly, the Panel concludes that in respect of the approval procedure concerning RR oilseed rape (EC-70), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(xi) LL soybeans (EC-71)

7.1995 Two Complaining Parties, the United States and Argentina, claim that the completion of the approval procedure concerning LL soybeans (EC-71) has been unduly delayed.

7.1996 The **United States** submits that although the applicant in this procedure provided answers to all of the questions raised by the lead CA, the lead CA failed to approve the product under Directive 90/220.

7.1997 The United States also points out that the application concerning LL soybeans (EC-71) is one of nine applications identified by the United States which have been pending at the member State level for an average of three years and ten months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning LL soybeans (EC-71) is excessive and unjustified and, hence, undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.1998 **Argentina** claims that the application was delayed at the member State level for 68 months without a final decision on its approval. Argentina asserts that the European Communities neither processed the application nor conducted the required risk assessment. Argentina argues that there is no scientific justification for the delay, as the "initial reports" were not prepared.

7.1999 The **European Communities** provides three explanations for the delay at the member State level: (1) requests by the lead CA for further information during the period from September 1998 to 2001; (2) procedural problems arising from the fact that the applicant submitted an application for the same product in Portugal; and (3) delays caused by the applicant's lack of response to requests for additional information on 25 February 2003.

7.2000 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.2001 We note that in the approval procedure concerning LL soybeans (EC-71), the applicant submitted an application to the lead CA (Belgium) on 28 September 1998. In September 1999, the applicant submitted an application for this same product to Portugal. When Directive 90/220 was repealed on 17 October 2002, the lead CA had not yet forwarded the dossier to the Commission. The applicant updated the application on 15 January 2003. Also in January 2003, the applicant withdrew the parallel application to Portugal.

7.2002 We recall that in relation to Belgium's assessment of LL soybeans (EC-71) three separate time periods can be usefully distinguished: (1) the time period between the submission of the application to the Belgian CA and the concurrent submission in Portugal; (2) the time period between the submission of the concurrent application in Portugal and the repeal of Directive 90/220; and (3) the time period between the submission of the application under Directive 2001/18 and the applicant's withdrawal of the application.

7.2003 The Panel begins its analysis with the alleged delay at member State level during the period before the parallel application was submitted to Portugal. We recall that in a letter dated 31 March 1999, the Belgian Biosafety Council stated that it was "of the opinion that the file [concerning the application submitted under Directive 90/220] in its present form (with addition of molecular data and after minor corrections) can be passed on to the European Commission with a positive opinion".[1492] Based on the March 1999 advice by the Biosafety Council the Belgian CA on 28 May 1999 asked for more information, including information on molecular characterization, nutritional analysis (concerning the approval procedure for LL soybeans (EC-93)) and herbicide aspects.[1493] The applicant did not respond to the May 1999 request until July 2001.

7.2004 The European Communities provides no justification for the time taken by the lead CA to forward the request for additional information from the Belgian Biosafety Council. While the lead CA as the responsible agency could review the request in order to determine whether it was appropriate to transmit it to the applicant, we are not convinced, in the absence of any justification offered by the European Communities, that two months were needed to review this straightforward request for additional information. Indeed, at an earlier stage in the approval procedure, the lead CA forwarded a similar request from the Biosafety Council within a matter of several days.[1494] We therefore consider that the lead CA could and should have acted more promptly than it did when the Biosafety Council suggested a request for additional information in March 1999.

7.2005 As noted, the applicant did not respond to the lead CA's May 1999 additional request for information until July 2001, *i.e.*, more than two years later. Meanwhile, however, the applicant had submitted an application to Portugal. The time during which a parallel application was maintained concurrently in Portugal contributed to the delayed progress of the application in Belgium. We note in this regard that in a communication to Belgium dated 1 December 2000, the applicant explicitly indicated its intention of maintaining dual applications.[1495] In this letter the applicant also stated it would take all necessary measures to ensure that only one application would circulate at the Community level. On 5 December 2000, the Biosafety Advisory Council of the Belgian CA

[1492] Exhibit EC-71/At. 16.
[1493] Exhibit EC-71/Ats. 17 and 22.
[1494] Exhibit EC-71/Ats. 4 and 5.
[1495] Exhibit EC-71/At. 23.

confirmed the continuation of the evaluation process in Belgium and requested that the applicant forward the questions posed by the Portuguese CA in the approval procedure concerning LL soybeans (EC-81) in order to complete the application dossier in Belgium.[1496] On 5 September 2001, ten months after confirming the continuation of the evaluation process in Belgium, the Belgian CA indicated to the applicant that further evaluation of the application would be suspended until the applicant specified a single country to handle the application.[1497] The applicant responded on 8 October 2001 by asserting the maintenance of double concurrent applications.[1498] No further exchanges appear to have occurred between the applicant and the lead CA until January 2003, when the applicant updated the application submitted to Belgium under Directive 2001/18. While there is no evidence on the record to confirm this, it appears that in view of the applicant's response the lead CA did not further assess the application concerning LL soybeans (EC-71) between October 2001 and January 2003. Thus, the consideration of the application appears to have been suspended as from September 2001 as a result of the applicant's refusal to discontinue one of the two applications submitted under Directive 90/220.

7.2006 We note that the applicant was of the view that Directive 90/220 did not prevent it from filing identical applications to different lead CAs. It nevertheless acknowledged that this approach could give rise to procedural problems, and it therefore indicated that it would withdraw one of the two applications as soon as one of the applications was ready for transmission to the Commission. The Belgian CA appears to have considered that the approach followed by the applicant was either not permitted by Directive 90/220 or otherwise inappropriate.

7.2007 The United States and Argentina did not submit arguments or evidence which would indicate that Belgium's position rested on an incorrect interpretation of Directive 90/220. While Directive 90/220 does not explicitly require that applications be maintained with a single competent authority, it also does not explicitly state that applications may be maintained with more than one competent authority. We note that the issue of parallel applications arose also in the approval procedure concerning Bt-11 maize (EC-80). In that procedure, the lead CA in Spain did not appear to consider this a problem.[1499] On the other hand, it should also be noted that the applicant in the procedure concerning LL soybeans (EC-71) apparently did not contest Belgium's refusal to continue to consider its application.

7.2008 From the information before us, it is not apparent that Belgium's position on this issue, which appears to have led it to suspend consideration of the application concerning LL soybeans (EC-71) under Directive 90/220, was a mere pretext for delaying the consideration of the application. Indeed, Belgium indicated to the applicant that it would continue considering the relevant application if the applicant decided to discontinue the application submitted to Portugal. Furthermore, in applying the provisions of Annex C(1)(a), first clause, we think we must be mindful of Members' limited resources and the consequent need to avoid unnecessary duplication and administrative inefficiencies. Thus, a delay in the consideration of an application which was caused by a Member's refusal to conduct concurrent approval procedures in respect of an identical application does not appear to us to be unjustifiable *per se*. Taking account of these elements, we are not convinced that in the specific circumstances of this case, Belgium's refusal to continue its assessment of the application concerning LL soybeans (EC-71) while the applicant maintained its concurrent application to Portugal resulted in a loss of time which was unjustifiable.

[1496] Exhibit EC-71/At. 24.
[1497] Exhibit EC-71/At. 28.
[1498] Exhibit EC-71/At. 29.
[1499] Exhibit EC-80/At. 12.

7.2009 Regarding the consideration of this application under Directive 2001/18, we note that after the applicant updated its application under Directive 2001/18 (15 January 2003) and withdrew its application in Portugal (27 January 2003), the Belgian CA acknowledged receipt of the updated application and requested further information regarding molecular characterization, detection methods and reference materials. The applicant provided preliminary informal answers regarding information for labelling requirements and detection methods in March 2003. There is no record of further exchanges between the applicant and the lead CA until the applicant withdrew the application in July 2004.

7.2010 The European Communities claims that the delay which occurred after the applicant had provided preliminary informal answers was attributable to the applicant. The record shows that the applicant provided a partial response to the lead CA's request for additional information and indicated that further information would be forthcoming regarding reference samples of genomic DNA for this product. Given the applicant's stated intention of submitting further information to address questions from the lead CA and the lack of arguments addressing this issue from the United States and Argentina, it is reasonable to believe that the lead CA was waiting for the submission of further information. Accordingly, we have no reason to disagree with the European Communities' contention that the delay in question was attributable to the applicant rather than the lead CA.

7.2011 Based on the above considerations, the Panel concludes that the time taken by the lead CA for its assessment of the application concerning LL soybeans (EC-71) – specifically the time taken by the lead CA to forward the request for additional information suggested by the Biosafety Council in March 1999 – was unjustifiably long.

7.2012 In relation to DS291, we recall that the United States claims that the approval procedure concerning LL soybeans (EC-71) was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier finding that the record supports the conclusion that the European Communities applied a *de facto* moratorium on approvals as of June 1999. Our finding that the time taken by Belgium for its assessment of the application concerning LL soybeans (EC-71) was unjustifiably long is based on the view that the lead CA could and should have transmitted its May 1999 request for additional information earlier than it did. Thus, our finding above relates to a time period which pre-dates June 1999. In the light of this, we do not consider that we can infer that Belgium's conduct in March, April and May 1999 was a consequence of the general moratorium on approvals which we found was in effect between June 1999 and August 2003.

7.2013 In view of our conclusion above, in relation to DS291 we need to go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Total amount of time taken since submission of application

7.2014 The United States also puts forward the argument that the total amount of time during which the application concerning LL soybeans (EC-71) was pending is excessive and unjustified. The application concerning LL soybeans (EC-71) was first submitted for approval under Directive 90/220 in September 1998. This means that as of August 2003, the approval procedure had been pending for four years and eleven months.

7.2015 The Panel agrees with the United States that, in absolute terms, this is a long period of time for the assessment by the lead CA. However, as we have explained earlier, the mere identification of

the total amount of time during which an application has been pending does not demonstrate, in and of itself, that the time taken was unjustifiably long.

7.2016 Moreover, even if the United States were correct in asserting that before there was an EC moratorium, approval procedures used to be completed in less than three years, it must be remembered that the European Communities assesses applications on a case-by-case basis. Thus, the fact that the approval procedure concerning LL soybeans (EC-71) was not completed in less than three years in our view does not demonstrate that it was not justifiable for the European Communities to take more time to process the application concerning LL soybeans (EC-71).[1500]

7.2017 The United States further argues that in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, the fact that the application in question lingered at the member State level for almost five years demonstrates the existence of undue delay. We recall in this respect our finding that the record supports the conclusion that the European Communities applied a *de facto* moratorium on approvals as of June 1999. At that time, the application concerning LL soybeans (EC-71) had already been pending for almost nine months. Thus, some of the total time taken cannot be explained by the moratorium. Moreover, the mere fact that a general moratorium was in effect does not necessarily imply that each particular application was affected by it at all stages of the procedure. The United States itself has repeatedly stated that "the moratorium was a decision by the EC not to move products to a *final* decision in the approval process" and that "certain progress in the process, short of a final decision, is not the least bit inconsistent with a moratorium on final approvals".[1501] Therefore, by itself, the fact that a moratorium on approvals was in effect between June 1999 and August 2003 is not sufficient to demonstrate that the period of time during which the application concerning LL soybeans (EC-71) was pending as of August 2003 reflects a failure on the part of the lead CA to complete the relevant approval procedure without undue delay.

7.2018 Accordingly, the Panel is unable to accept the United States' assertion that the total period of time during which the application concerning LL soybeans (EC-71) had been pending as of August 2003 demonstrates that the time taken was unjustifiably long.

Conclusions

7.2019 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that it has not been established that the time taken by the lead CA for its assessment of the application concerning LL soybeans (EC-71) was unjustifiably long, or that the total period of time during which the application concerning LL soybeans (EC-71) had been pending as of August 2003 demonstrates that the time taken by the European Communities was unjustifiably long. Based on these findings, the Panel is unable to accept the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning LL soybeans (EC-71) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval

[1500] It is worth recalling, more generally, that the approval procedures which were completed before there was a moratorium on approvals were not affected by the special circumstance that Directive 90/220 was repealed in 2002.

[1501] *See, e.g.*, US second written submission, para. 51 (emphasis in original).

procedure concerning LL soybeans (EC-71), the United States has failed to establish that the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, the Panel recalls its finding that the time taken by the lead CA for its assessment of the application concerning LL soybeans (EC-71) was unjustifiably long. In the light of this finding, the Panel concludes that the European Communities failed to complete the approval procedure concerning LL soybeans (EC-71) without "undue delay", thus breaching its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement.*

(xii) LL oilseed rape (EC-72)

7.2020 One Complaining Party, the United States, claims that the completion of the approval procedure concerning LL oilseed rape has been unduly delayed.

7.2021 The **United States** argues that the total time taken at the member State level for the initial review of this application was over four years, as this product still had not been forwarded to the Commission at the time of establishment of the Panel. The United States contrasts this with the 90 days referred to in Directives 90/220 and 2001/18. Although the United States initially indicated that the applicant had provided answers to all of the questions from the lead CA, in response to a question from the Panel the United States recognized that the applicant failed to provide some of the data requested.[1502] Nonetheless, the United States contends that the delays by the lead CA in completing the approval procedure concerning LL oilseed rape are undue.

7.2022 The United States also points out that the application concerning LL oilseed rape is one of nine applications identified by the United States which have been pending at the member State level for an average of three years and ten months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning LL oilseed rape is excessive and unjustified and, hence, undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2023 The **European Communities** argues that the time taken by the lead CA was necessary in order to ensure a valid safety assessment. Following receipt of the application, the lead CA requested further information from the applicant. The lead CA also requested a preliminary review by its scientific committee, the Advisory Committee on Releases to the Environment (hereafter "ACRE"). The ACRE found that the dossier contained inconsistent data on molecular characterization and was presented in a manner which made assessment difficult. In December 1999, the lead CA requested the applicant to provide a substantial revision and clarification.

7.2024 According to the European Communities, the applicant did not get back to the lead CA on this dossier for almost two years. In January 2003, the applicant provided some up-dated documents in accordance with Directive 2001/18, but the European Communities argues that the full dossier was not submitted. During the first half of 2003, there were various exchanges between the lead CA and the applicant, and the applicant provided additional updates and information. Following a request in

[1502] US answer to Panel question No. 168.

June 2003 for the re-submission of a complete dossier, in March 2004 the applicant withdrew the pending notification and submitted a new notification. The European Communities maintains that it cannot be responsible for delays arising at the instigation of the applicant.

7.2025 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.2026 We note that in the approval procedure concerning LL oilseed rape the applicant submitted an application to the lead CA (the United Kingdom) on 28 January 1999. When Directive 90/220 was repealed on 17 October 2002, the lead CA had not yet forwarded the dossier to the Commission. An updated application was submitted following the entry into force of Directive 2001/18, although the record is not clear as to when a complete dossier was actually submitted. At the time of establishment of the Panel, this application was still under consideration by the lead CA.

7.2027 The United States contends that the lead CA took too long to complete its assessment. It is correct that the lead CA took much more time for its assessment of the application than the 90 days envisaged in Directives 90/220 and 2001/18. However, we have observed that that deadline was not dispositive, *per se*, of whether the European Communities met its WTO obligation to complete its approval procedures without undue delay. Moreover, the European Communities contends that much of the time taken by the lead CA until August 2003 is attributable to failures by the applicant promptly to provide requested information. The European Communities submits that without this information, it was not possible for the lead CA to complete its assessment and submit a report to the Commission. We therefore need to examine whether the lead CA was justified in not completing its assessment by August 2003.

7.2028 As we noted in our previous consideration of this application, the record before us is not complete. Following receipt of the application, the lead CA promptly requested additional information from the applicant in February and March 1999. This information was provided in June 1999, and the lead CA acknowledged on 30 June 1999 that the clock had been "restarted". One month later, the lead CA requested further information, but this information was not provided by the applicant before the date of repeal of Directive 90/220. The letter from the lead CA dated 20 July 1999 requests that the applicant provide further information and clarification on points raised in an annex to the letter, but the annex was not provided to us.[1503]

7.2029 In November 1999, the lead CA apparently requested the ACRE to provide guidance to the lead CA as to where the application needed improvement and noted that the ACRE would be asked for formal advice only at a later stage. The preliminary advice by ACRE was that there were a number of inconsistencies in the molecular data provided, some deficiencies in the molecular studies and too much important material was in annexes rather than being in the core dossier. It was noted that the appropriate experimental data may have been supplied somewhere in the application dossier but it was not immediately obvious where it might be.[1504] As advised by ACRE, the lead CA in December 1999 requested that the applicant undertake substantial revision and clarification of the dossier. The lead CA suggested a meeting with the applicant later in the same month to provide the applicant with some guidance. There is no evidence in the information before the Panel that such a meeting took place, and that the applicant provided what was requested in December 1999. Indeed, the record shows no further communication from the applicant until January 2003, when the applicant updated its application under Directive 2001/18.

[1503] Exhibit EC-72/At. 11.
[1504] Exhibit EC-72/At. 12.

7.2030 On 16 January 2003, the applicant submitted an updated application under Directive 2001/18 to the lead CA.[1505] In acknowledging receipt of the updated application, the lead CA indicated, on 27 January 2003, that the dossier was still incomplete and information requested in July and December 1999 was still missing.[1506] Further requests for clarifications or modification of the application were made by the lead CA in the first half of 2003, with responses apparently provided by the applicant in May 2003.[1507] On 13 June 2003, the lead CA requested further clarifications and suggested that a complete version of the application be re-submitted.[1508] On 26 March 2004, the applicant withdrew the application, saying that certain elements of that application were incomplete or out-of-date, and submitted a new one (C/GB/04/M5/4).[1509]

7.2031 In reviewing the lead CA's conduct in this approval procedure, we note that the exchanges between the lead CA and the applicant generally took place in a timely fashion, with the lead CA reacting promptly to information provided by the applicant. It is clear from the foregoing, however, that the consideration of the application concerning LL oilseed rape was delayed for almost two years between 2 December 1999 and the repeal of Directive 90/220 in October 2002, following a letter from the lead CA advising the applicant that the dossier required substantial revision and clarification. Based on the information submitted to us, we understand that this gap was caused by the failure of the applicant to provide the additional information and clarification requested by the lead CA in July and December 1999. However, the precise reasons for the failure of the applicant to respond to the information solicited by the lead CA in July and December 1999 are unclear.

7.2032 We note that the United States has not specifically challenged the justifiability of any of the requests for additional data or clarifications made by the lead CA. We nonetheless asked the experts advising us whether the information requested by the lead CA up to and in December 1999 was necessary to ensure that conclusions of the safety assessment were valid.[1510] Dr. Nutti, the only expert who responded to this question, concurred that the deficiencies in the application as identified by the ACRE were such that the requested information was necessary for the safety assessment.[1511] Taking account of these elements, we have no grounds for considering that the lead CA's requests of July and December 1999 which led to the gap between December 1999 and January 2003 were not justified.

7.2033 Regarding the assessment of the application concerning LL oilseed rape under Directive 2001/18, we note that the United States has offered no specific arguments relating to the consideration of this application under Directive 2001/18. At any rate, the facts as summarized by us above do not suggest that the time taken by the lead CA up to August 2003 for assessing the application under Directive 2001/18 was unjustifiably long. We note in particular the repeated requests by the lead CA for completion of the updated application, and the fact that the applicant itself withdrew the application in March 2004 saying that certain elements of its application were incomplete.

7.2034 Based on the above considerations, the Panel is not persuaded that the time taken by the lead CA for its assessment of the application concerning LL oilseed rape was unjustifiably long.

[1505] Exhibit EC-72/At. 15.
[1506] Exhibit EC-72/At. 16.
[1507] Exhibit EC-72/Ats. 18 and 19.
[1508] Exhibit EC-72/At. 28.
[1509] Exhibit EC-72/At. 29.
[1510] Annex H, Panel Question 29.
[1511] Annex H, para. 600.

Total amount of time taken since submission of application

7.2035 The United States also puts forward the argument that the total amount of time during which the application concerning LL oilseed rape was pending is excessive and unjustified. The application concerning LL oilseed rape was first submitted for approval under Directive 90/220 in January 1999. This means that as of August 2003, the approval procedure had been pending for four years and seven months.

7.2036 The Panel agrees with the United States that, in absolute terms, this is a long period of time for the assessment by the lead CA. However, as we have explained earlier, the mere identification of the total amount of time during which an application has been pending does not demonstrate, in and of itself, that the time taken was unjustifiably long.

7.2037 Moreover, even if the United States were correct in asserting that before there was an EC moratorium, approval procedures used to be completed in less than three years, it must be remembered that the European Communities assesses applications on a case-by-case basis. Thus, the fact that the approval procedure concerning LL oilseed rape was not completed in less than three years in our view does not demonstrate that it was not justifiable for the European Communities to take more time to process the application concerning LL oilseed rape.[1512]

7.2038 The United States further argues that in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, the fact that the application in question lingered at the member State level for over four and a half years demonstrates the existence of undue delay. We recall in this respect our finding that the record supports the conclusion that the European Communities applied a *de facto* moratorium on approvals as of June 1999. At that time, the application concerning LL oilseed rape had already been pending for almost six months. Thus, some of the total time taken cannot be explained by the moratorium. Moreover, the mere fact that a general moratorium was in effect does not necessarily imply that a particular application was affected by it. The United States itself has repeatedly stated that "the moratorium was a decision by the EC not to move products to a *final* decision in the approval process" and that "certain progress in the process, short of a final decision, is not the least bit inconsistent with a moratorium on final approvals".[1513] Therefore, by itself, the fact that a moratorium on approvals was in effect between June 1999 and August 2003 is not sufficient to demonstrate that the period of time during which the application concerning LL oilseed rape was pending as of August 2003 reflects a failure on the part of the lead CA to complete the relevant approval procedure without undue delay.

7.2039 Accordingly, the Panel is unable to accept the United States' assertion that the total period of time during which the application concerning LL oilseed rape had been pending as of August 2003 demonstrates that the time taken was unjustifiably long.

[1512] It is worth recalling, more generally, that the approval procedures which were completed before there was a *de facto* moratorium on approvals were not affected by the special circumstance that Directive 90/220 was repealed in 2002.

[1513] *See, e.g.*, US second written submission, para. 51 (emphasis in original).

Conclusions

7.2040 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that it has not been established that the time taken by the lead CA for its assessment of the application concerning LL oilseed rape was unjustifiably long, or that the total period of time during which the application concerning LL oilseed rape had been pending as of August 2003 demonstrates that the time taken by the European Communities was unjustifiably long. Based on these findings, the Panel is unable to accept the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning LL oilseed rape for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning LL oilseed rape, the United States has failed to establish that the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(xiii) BXN cotton (EC-73)

7.2041 One Complaining Party, the United States, claims that the completion of the approval procedure concerning BXN cotton has been unduly delayed.

7.2042 The **United States** argues that the total time taken at the member State level for the initial review of this application was over four years, as this product still had not been forwarded to the Commission at the time of establishment of the Panel. The United States contrasts this with the 90 days referred to in Directives 90/220 and 2001/18. The United States contends that although the applicant had provided answers to all of the questions from the lead CA, the lead CA still failed to complete its assessment. The United States contends that the delays by the lead CA in completing the approval procedure concerning BXN cotton are undue.

7.2043 The United States also points out that the application concerning BXN cotton is one of nine applications identified by the United States which have been pending at the member State level for an average of three years and ten months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning BXN cotton is undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2044 The **European Communities** argues that the time taken by the lead CA was necessary in order to ensure a valid safety assessment. Following receipt of the application, the lead CA requested further information from the applicant to address deficiencies in the application. Spain's scientific committee, the National Biosafety Committee, found that a considerable amount of information was missing on issues such as compositional analysis, environmental impact, toxicity and nutritional analysis. In addition, a number of points required clarification, such as the scope of the application and the labelling proposal. The lead CA requested this information from the applicant in July 1999.

7.2045 The European Communities contends that the applicant did not respond to the lead CA's request for three years, until January 2003. At that time, the lead CA was informed of a change in the company submitting the application, and the new applicant company submitted an up-dated notification in accordance with Directive 2001/18. However, according to the European Communities, the new dossier was also incomplete with regard to the molecular characterization of the product. The European Communities points out that further information was requested of the applicant in October 2003.

7.2046 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.2047 We note that in the approval procedure concerning BXN cotton, the applicant submitted an application to the lead CA (Spain) on 3 May 1999. When Directive 90/220 was repealed on 17 October 2002, the lead CA had not yet forwarded the dossier to the Commission. On 16 January 2003, an updated application was submitted following the entry into force of Directive 2001/18. At the time of establishment of the Panel, this application was still under consideration by the lead CA.

7.2048 The United States contends that the lead CA took too long to complete its assessment. It is correct that the lead CA took much more time for its assessment of the application than the 90 days envisaged in Directives 90/220 and 2001/18. However, we have observed that that deadline was not dispositive, *per se*, of whether the European Communities met its WTO obligation to complete its approval procedures without undue delay. Moreover, the European Communities contends that much of the time taken by the lead CA until August 2003 is attributable to failures by the applicant to promptly provide requested information. The European Communities submits that without this information, it was not possible for the lead CA to complete its assessment and submit a report to the Commission. We therefore need to examine whether the lead CA was justified in not completing its assessment by August 2003.

7.2049 As we noted in our previous consideration of this application, the record before us is very incomplete. This said, it is clear that within two months of receipt of the application, the Spanish National Biosecurity Committee identified a number of concerns with the application, and these were communicated to the applicant in July 1999. Two months later, the applicant provided the information requested. The applicant clarified, *inter alia*, that the application was both for the import and processing of seeds of BXN cotton as well as for the cultivation of BXN cotton. Following the further examination of the application in January 2000 by the Spanish National Biosafety Committee, the lead CA requested further clarifications on some of the same issues in a communication dated 2 February 2000.[1514] The applicant did not respond to this request before an updated application was submitted in January 2003 under Directive 2001/18.[1515]

7.2050 On 15 January 2003, the lead CA was informed of a change in the company pursuing the application, and on 16 January 2003 an updated application was submitted under Directive 2001/18 and completed in March 2003. It appears that the updated application concerns only the importation of seed for processing, but not for cultivation. In August 2003, when this Panel was established, the application appears to have been under review by the National Biosafety Committee.[1516]

[1514] Exhibit EC-73/At. 6.
[1515] This is confirmed by Exhibit EC-73/At. 12.
[1516] There is no information about when the application was submitted to the National Biosafety Committee.

7.2051 It is clear from the foregoing that in this procedure a delay of more than two and a half years occurred between February 2000, when the lead CA requested clarifications, and October 2002, when Directive 90/220 was repealed. Based on the information submitted to us, we understand that this gap was caused by the failure of the applicant to provide the requested clarifications. However, the precise reasons for the failure of the applicant to respond to the lead CA's February 2000 request are unclear.

7.2052 The United States has not specifically challenged the justifiability of any of the requests for additional data or clarifications made by the lead CA. In the light of the three-year delay in response from the applicant following the request in February 2000 for additional information, we asked the experts advising us whether the information requested by the lead CA up to and in February 2000 was necessary to ensure that conclusions of the safety assessment were valid.[1517] The experts noted that only the table of contents of the actual submission by the applicant had been provided, and the response from the applicant. On the basis of this limited information, Dr. Nutti was of the view that the responses provided by the applicant in September 1999 appeared to be satisfactory as far as food safety was concerned. These responses provided clarification or explanations of information that presumably was contained in the original application.[1518] Dr. Andow noted that the information previously requested by the lead CA was normally necessary to assess environmental risks, particularly those related to the cultivation of the plant. However, without the application itself, he could not determine to what extent relevant information may have already been provided by the applicant, or how much additional information might be necessary. Dr. Andow further observed that, according to the table of contents, only two pages of the text of the application were devoted to issues relating to environmental impact studies, herbicide or residue toxicity or ecotoxicity tests or proposals to manage, monitor and handle the crop to reduce the risk of herbicide resistance in weeds.[1519]

7.2053 Like the experts advising us, we consider that the incomplete information before us does not permit us to form a definitive view on whether the clarifications requested by the lead CA in February 2000 were justified to ensure that conclusions of the safety assessment were valid and hence on whether the resulting three-year delay in the consideration of the application was justified by the need to check and ensure that relevant requirements of Directive 90/220 were fulfilled.

7.2054 Turning to Spain's assessment of the application concerning BXN cotton under Directive 2001/18, we note that the updated notification was submitted to Spain on 16 January 2003. It was not until 14 February 2003, *i.e.*, almost one month later, that the lead CA requested the applicant to submit a summary of the application as required by Directive 2001/18. The applicant provided such a summary on 19 March 2003, and thus the updated application appears to have been complete as of that date. The application was apparently forwarded to the National Biosafety Committee for an assessment, but as of August 2003 that assessment had not yet been completed. The record shows that the assessment was completed in September 2003.[1520]

7.2055 The European Communities offers no justification for the time taken by the lead CA to follow up with the applicant to request a summary of the application. We are not persuaded that almost a full month was required to determine the completeness of the updated application and forward an appropriate request to the applicant.

[1517] Annex H, Panel Questions 30 and 31.
[1518] Annex H, para. 601.
[1519] Annex H, paras. 604-612.
[1520] Exhibit EC-73/At. 12.

7.2056 Furthermore, with regard to the time taken by the lead CA to assess the application once it had been completed by the applicant in March 2003, we recall that in accordance with Article 14(2) of Directive 2001/18, the lead CA should have prepared an assessment report within 90 days. The 90 days do not include any periods of time during which the lead CA is awaiting further information which it requested from the applicant. In the present case, the record shows that the lead CA requested additional information only in October 2003.[1521] Thus, the lead CA should have completed its assessment at the latest 90 days after 19 March 2003, which is the date on which the applicant completed its updated application. However, as of August 2003, the lead CA had still not completed its assessment. Thus, as of 29 August 2003, the lead CA had already taken more than five months to assess the application, and first request for additional information was forwarded more than a month later.

7.2057 As we have said, the question of whether or not the lead CA complied with the 90-day deadline stipulated in Directive 2001/18 is not dispositive, *per se*, of whether the European Communities met its WTO obligation to complete its approval procedures without undue delay. However, as we have also noted earlier, the deadline set forth in Directive 2001/18 nonetheless provides a useful indicator to guide the Panel's analysis. The 90-day deadline is binding and applies to all relevant applications submitted under that Directive. It may therefore be assumed that the EC legislator set this binding deadline in such a way as to make it possible for the CAs of all member States to assess even complex applications within the prescribed deadline.

7.2058 The European Communities provides no justification for the time taken by the lead CA in excess of the 90-day period, other than the assertion that the updated application was incomplete with regard to the molecular characterization of the product. It is correct that the lead CA in October 2003 requested additional information, including on molecular characterization of the product. However, we are not convinced that more than five months were needed to identify this and other substantive shortcomings in the updated application.

7.2059 From the record of the consideration of this application by the National Biosafety Committee, it is clear that the Committee had also been reviewing the applications concerning Bt-531 cotton and RR-1445 cotton, for which Spain was also the lead CA. However, we recall that pursuant to Directive 2001/18, the lead CA was to prepare an assessment report within 90 days after receipt of an application. It should also be noted in this connection that the National Biosafety Committee's assessment concerning BXN cotton is quite short, *i.e.*, there is no indication that the preparation of the Committee's assessment required much time. Additionally, we note that the lead CA in this case was not examining the application concerning BXN cotton for the first time. While it is true that the lead CA in 2003 had to undertake an assessment in accordance with the partly new requirements of Directive 2001/18, it seems equally clear that the prior assessments rendered the lead CA's task less complex than it would have been if the lead CA had had to undertake an assessment of the application for the first time.

7.2060 Taking account of the foregoing elements, we consider that the lead CA could and should have acted more promptly than it did when it received an updated, but incomplete, application in January 2003 and subsequently, when the applicant submitted the missing summary in March 2003. Accordingly, we conclude that the time taken by the lead CA up to August 2003 for its assessment of the application concerning BXN cotton under Directive 2001/18 was unjustifiably long.

7.2061 In addition, we recall that the United States claims that the approval procedure concerning BXN cotton was unduly delayed because, due to the moratorium, the European Communities failed to

[1521] Exhibit EC-73/At. 13.

consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the time taken by Spain to assess the application concerning BXN cotton under Directive 90/220 and subsequently under Directive 2001/18 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that Spain's conduct after the entry into force of Directive 2001/18 was a consequence of the general moratorium on approvals.

7.2062 In view of our conclusion with regard to the time taken by Spain for its assessment, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusions

7.2063 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning BXN cotton under Directive 2001/18 was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning BXN cotton for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning BXN cotton, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(xiv) Bt-1507 maize (EC-74)

7.2064 One Complaining Party, the United States, claims that the completion of the approval procedure concerning Bt-1507 maize (EC-74) has been unduly delayed.

7.2065 The **United States** argues that the application concerning Bt-1507 maize (EC-74) was delayed at the member State level. The United States submits that although the applicant provided answers to all of the questions, the lead CA nonetheless delayed its consideration of the product. The United States explicitly contests the justifiability of one of the information requests by the lead CA, as well as of a number of the objections raised by other member States following the circulation of the application by the Commission.

7.2066 The United States also points out that the application concerning Bt-1507 maize (EC-74) is one of nine applications identified by the United States which have been pending at the member State level for an average of three years and ten months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning Bt-1507 maize (EC-74) is undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2067 The **European Communities** argues that the time taken by the lead CA was necessary in order to ensure a valid safety assessment. Exchanges between the lead CA and the applicant regarding data relating to molecular characterization, allergenicity, toxicity of CRY1F and labelling went on until late 2002. In two instances, the applicant requested an extension of the time granted by the lead CA to submit further data or information. The applicant updated the notification just after the entry into force of Directive 2001/18. After a further exchange on compositional data, a monitoring plan, and confidentiality of the detection method, the lead CA submitted the full application and its assessment report to the Commission in August 2003. The European Communities observes that once the application reached the Community level, a considerable number of objections were raised by member States, including on environmental effects, the monitoring plan, molecular characterisation, sampling and detection methods, allergenicity and toxicity.

7.2068 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.2069 We recall that in the approval procedure concerning Bt-1507 maize (EC-74), the applicant submitted an application to the lead CA (the Netherlands) on 23 November 2000. When Directive 90/220 was repealed on 17 October 2002, the lead CA had not yet forwarded the dossier to the Commission. The dossier was forwarded to the Commission with a favourable assessment report on 15 August 2003, after the applicant had provided an updated application in accordance with Directive 2001/18.

7.2070 The United States contends that the lead CA took too long to complete its assessment. On the other hand, the European Communities contends that all of the time taken by the lead CA until August 2003 when the lead CA forwarded its assessment report to the Commission was necessary to resolve scientific and technical issues. It therefore needs to be examined whether the lead CA was justified in forwarding an assessment report to the Commission only in August 2003.

7.2071 As we noted previously, there was frequent communication between the lead CA and the applicant on this product from the initial application on 23 November 2000 until the lead CA sent its assessment report to the Commission on 15 August 2003. The United States explicitly challenges the justifiability of only one of the requests for additional data made by the lead CA, namely, the lead CA's follow-up request of 13 December 2001. We recall that in response to a March 2001 request from the lead CA the applicant on 16 October 2001 provided field trials from Chile, France and Italy, which it considered representative for the cultivation areas exporting maize to the European Communities.[1522] Yet on 13 December 2001 the lead CA indicated that it was not convinced by the response and maintained its request. Specifically, the lead CA indicated that it was not convinced that these locations would be representative of locations exporting maize to the European Communities. It therefore requested that the applicant conduct additional field trials and provide compositional data for two consecutive growing seasons.[1523]

7.2072 The applicant addressed this further request for additional field trials in its responses of 21 November 2002. It provided arguments as to why the results of the field trials for 1998/1999 from Chile, France and Italy should be considered to be sufficient, and also submitted the results of field trials for 1999/2000 from Bulgaria, France and Italy.[1524] On 10 February 2003, the lead CA indicated that it accepted this response, but requested that the data provided from the field trials in Chile be

[1522] Exhibit EC-74/At. 33.
[1523] Exhibit EC-74/At. 52.
[1524] Exhibit EC-74/At. 65, response to Panel Question 3.

presented in the same detail and manner as for France and Italy, and suggested a format.[1525] This was apparently done by the applicant on 24 March 2003.[1526]

7.2073 The United States argues that when the lead CA on 13 December 2001 rejected the applicant's compositional data from field trials that had been conducted in France, Italy and Chile, on the grounds that these locations were insufficiently representative of locations exporting maize to the European Communities, the lead CA provided no explanation for its conclusion that the locations were "insufficiently representative." The United States argues that the data provided by the applicant in October 2001 would generally be considered "representative" and relevant for evaluating maize that might be imported into the European Communities. The United States maintains that, in the absence of some further explanation, such as an anomaly in the submitted data, the only explanation for the lead CA's request for additional field trials of 13 December 2001 appeared to be the resulting two-year delay caused by the time it would take for the applicant to generate the data.

7.2074 Even assuming that the additional field trials were not necessary, we note that the applicant's response of 21 November 2002 was provided together with responses to a request of March 2002 for other additional information which has not been questioned by the United States. It is therefore not clear that the delay in the consideration of the application until 21 November 2002 is attributable to the request for additional field trials.

7.2075 At any rate, we note that on 21 November 2002 the applicant also updated its application in the light of the new requirements of Directive 2001/18. This resulted in the lead CA requesting further information from the applicant on 10 February 2003 with respect to a surveillance plan and the confidentiality of the proposed detection method. Furthermore, as noted, in February 2003 the lead CA dropped its request for the additional field trials, but requested that the data be presented in a uniform manner. The responses to these requests were provided by the applicant on 24 March 2003, and on 28 May 2003 the applicant withdrew the request for confidentiality with respect to the detection method.

7.2076 In the light of the foregoing, we consider that by the end of March 2003 the lead CA had all the elements to complete its safety assessment. The outstanding clarification of the confidentiality issue should not have delayed the completion of the safety assessment itself. In any event, as we have noted, the confidentiality issue was resolved in May 2003. Notwithstanding this, the lead CA did not send its completed assessment report to the Commission until 15 August 2003.

7.2077 We recall that in accordance with the requirements of Directive 2001/18 the lead CA was to have transmitted its completed assessment report at the latest 90 days after receipt of the updated application. As we have already pointed out, following the receipt of the application in November 2002, the lead CA reviewed the application for more than two and a half months before forwarding its request for additional information. After receiving the applicant's response in March 2003, the lead CA took an additional period of time of more than four and a half months to complete its assessment report and transmit it to the Commission. Thus, by the time the lead CA sent its assessment report to the Commission it had taken more than seven months to evaluate the updated application instead of the 90 days envisaged in Directive 2001/18.

7.2078 We have observed earlier in respect of the 90-day deadline stipulated in Directive 2001/18 that that deadline provides a useful indicator for determining how much time might be needed to complete an assessment. As we have said, in the case of the application concerning Bt-1507 maize

[1525] Exhibit EC-74/At. 84.
[1526] Exhibit EC-74/Ats. 87-88.

(EC-74), by the end of March 2003 the lead CA had all the elements to complete its safety assessment. If the lead CA at that point in time had taken a full 90-day period to complete its assessment, it would have completed its assessment before the end of June 2003.

7.2079 The European Communities has offered no justification for the time taken by the lead CA between March and August 2003. It is pertinent to note in this respect that the lead CA in 2003 was not examining the application concerning Bt-1507 maize (EC-74) for the first time. While it is true that the lead CA in 2003 had to undertake an assessment in accordance with the partly new requirements of Directive 2001/18, the lead CA had already spent two and a half months assessing the application in question. Moreover, it seems clear that the lead CA's prior assessment of the same application under Directive 90/220 rendered the lead CA's task considerably less complex than it would have been if the lead CA had had to undertake an assessment for the first time. Yet notwithstanding this, even when the lead CA had all the necessary information, it failed to complete and transmit its assessment report within 90 days.

7.2080 Thus, even if we were to accept that it was legitimate for the lead CA to insist on the confidentiality issue being resolved before it transmitted its assessment report to the Commission, in the light of the generally applicable 90-day period stipulated in Directive 2001/18, and in the absence of any justification offered by the European Communities, we are not convinced that the lead CA could not have completed and transmitted its assessment report considerably earlier than mid-August 2003. Hence, taking account of the aforementioned elements, we consider that the lead CA should have transmitted its assessment report to the Commission more promptly than it did.

7.2081 Based on the above considerations, the Panel concludes that the time taken by the lead CA for its assessment of the application concerning Bt-1507 maize (EC-74) – notably the time taken by the lead CA after May 2003, when the applicant withdrew the request for confidentiality with respect to the detection method – was unjustifiably long.

7.2082 In relation to DS291, we recall that the United States claims that the approval procedure concerning Bt-1507 maize (EC-74) was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the failure of the Netherlands to complete its assessment of the application concerning Bt-1507 maize (EC-74) earlier than in August 2003 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Netherlands' conduct was a consequence of the general moratorium on approvals.

7.2083 In view of our conclusion with regard to the time taken by the Netherlands for its assessment, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.2084 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning Bt-1507 maize (EC-74) was

> unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning Bt-1507 maize (EC-74) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning Bt-1507 maize (EC-74), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(xv) Bt-1507 maize (EC-75)

7.2085 One Complaining Party, the United States, claims that the completion of the approval procedure concerning Bt-1507 maize (EC-75) has been unduly delayed. To recall, this application concerns the same product as above, however it was submitted to Spain and concerns the cultivation of the product. The previous application was for processing, food and feed use, but not for cultivation.

7.2086 The **United States** argues that the application concerning Bt-1507 maize (EC-75) was delayed at the member State level.. The United States submits that although the applicant provided answers to all of the questions, the lead CA nonetheless delayed consideration of the product. The United States also contests the justifiability of some of the information requested by the lead CA, and particularly of a number of the objections raised by other member States following its circulation by the Commission.

7.2087 The United States also points out that the application concerning Bt-1507 maize (EC-75) is one of nine applications identified by the United States which have been pending at the member State level for an average of three years and ten months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning Bt-1507 maize (EC-75) is undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2088 The **European Communities** argues that the time taken by the lead CA was necessary in order to ensure a valid safety assessment. The European Communities argues that following a preliminary assessment of this application by the Spanish National Biosafety Committee, the lead CA requested further data relating to molecular characterization, allergenicity and toxicity of CRY1F, environmental impact and a monitoring plan. These requests were dealt with by the applicant during the following 12 months, until 17 July 2002.[1527] After the entry into force of Directive 2001/18, the applicant updated the application in line with the requirements of the new legislation. Exchanges between the applicant and the lead CA continued until the 28 May 2003. The lead CA submitted the full application and its assessment report to the Commission on 5 August 2003.

7.2089 The European Communities further observes that once the application reached the Community level, a considerable number of objections were raised by member States, including on the monitoring plan, molecular characterization, effects on non-target organisms, toxicity, allergenicity, and detection methods.

[1527] Exhibit EC-75/Ats. 1-3.

7.2090 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.2091 We recall that following the receipt of the application concerning Bt-1507 maize (EC-75), the lead CA (Spain) consulted with its National Biosafety Committee, which took more than two and a half months to review the application. The lead CA then waited over a month, until 30 October 2001, before requesting additional information from the applicant based on the advice received from the Committee. This request was apparently repeated in a communication of 28 November 2001. A response was provided by the applicant on 14 February 2002. Once again, the lead CA consulted with the National Biosafety Committee. The Committee took three months to review the additional information submitted in February 2002. As it had done previously, the lead CA waited over a month, until 17 June 2002, before submitting another request for additional information to the applicant. The applicant responded to these requests on 17 December 2002. This was after the date of repeal of Directive 90/220.

7.2092 Even assuming that the October/November 2001 and June 2002 requests were necessary to ensure that the conclusions of the safety assessment were valid, we recall that in accordance with the requirements of Directive 90/220 the lead CA was to have completed its assessment at the latest 90 days after receipt of the application concerning Bt-1507 maize (EC-75). As we have already pointed out, following the receipt of the application in July 2001, the lead CA exceeded the 90-day period even before it submitted its initial request for additional information to the applicant. Of particular concern in this connection is the circumstance that the lead CA waited for more than one month before forwarding the questions suggested by the National Biosafety Committee in September 2001.

7.2093 The European Communities has offered no justification for the time taken by the lead CA to transmit the October/November 2001 request for additional information. We note that the time taken by the lead CA in this instance contrasts with other approval procedures where Spain was also the lead CA and where the Spanish CA forwarded requests for information from the National Biosafety Committee more promptly.[1528] Furthermore, we note that the lead CA did not modify the questions suggested by the National Biosafety Committee, but simply forwarded them.

7.2094 We recognize that the application in this case was submitted and acknowledged just fifteen months before the date of repeal of Directive 90/220. However, we do not consider that in September 2001, when the lead CA received the suggested questions from the National Biosafety Committee, the lead CA could have legitimately concluded that it was impossible to complete the required steps and have the application approved or rejected while Directive 90/220 was still in force.

7.2095 Taking account of the aforementioned elements, we consider that the lead CA could, and should, have forwarded the questions suggested by the National Biosafety Committee in September 2001 more promptly than it did.

7.2096 We recall that in May 2002 the lead CA received a further suggested request for additional information from the National Biosafety Committee. The lead CA again waited for over a month before forwarding the request in June 2002, even though it did not modify the Committee's request.

7.2097 We recognize that May 2002 was relatively close to the date of repeal of Directive 90/220. However, even if we were to accept, *arguendo*, that the application could not go through the required steps before the repeal of Directive 90/220, in our view, this would not have justified the lead CA in

[1528] *See, e.g.*, the approval procedure concerning BXN cotton. Exhibit EC-73/Ats. 2-3 and 5 and 6.

delaying the transmission of the new request for information. We note in this regard that Directive 2001/18 entered into force in October 2002. If the application submitted under Directive 90/220 remained incomplete or required further clarification, knowledge of this would have assisted the applicant in correcting any deficiencies and submitting an updated, more complete application soon after the entry into force of Directive 2001/18.[1529]

7.2098 Therefore, as with the previously discussed delayed transmission of a request for additional information, we consider that the lead CA could, and should, have forwarded the Committee's request more promptly than it did.

7.2099 Based on the above considerations, the Panel concludes that the time taken by the lead CA for its assessment of the application concerning Bt-1507 maize (EC-75) – notably the time taken by the lead CA to forward questions from the National Biosafety Committee – was unjustifiably long.

7.2100 In relation to DS291, we recall that the United States claims that the approval procedure concerning Bt-1507 maize (EC-75) was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the failure of Spain to complete its assessment of the application concerning Bt-1507 maize (EC-75) earlier than in August 2003 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that Spain's conduct was a consequence of the general moratorium on approvals.

7.2101 In view of our conclusion with regard to the time taken by Spain for its assessment, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.2102 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning Bt-1507 maize (EC-75) was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning Bt-1507 maize (EC-75) for final approval, and that this resulted in "undue delay" in the completion of the

[1529] We note that Spain could have considered that for as long as Directive 90/220 was still in force, there was no realistic prospect that the Group of Five countries and the Commission would allow the final approval of the application in question. However, the Panel does not consider that this would have justified the time taken by Spain to forward the questions suggested by the National Biosafety Committee. Spain might have anticipated opposition from the Group of Five countries on the basis of their June 1999 declaration. As pointed out above, notwithstanding this declaration, the Group of Five countries retained the freedom under EC law to approve applications. The same is true for the Commission, which had not issued a declaration comparable to that of the Group of Five countries.

relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning Bt-1507 maize (EC-75), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(xvi) NK603 maize (EC-76)

7.2103 Two Complaining Parties, the United States and Argentina, claim that the completion of the approval procedure concerning NK603 maize has been unduly delayed.

7.2104 The **United States** argues that the application was delayed at the first stage of the approval process under 90/220 because the lead CA declined to forward the application to the Commission. Although the applicant provided answers to all of the questions raised by the lead CA, the lead CA nonetheless delayed this product under Directive 90/220. The application remained at member State level for a period of 25 months. This product was resubmitted under Directive 2001/18, and received favourable initial assessments from the Spanish CA.

7.2105 The United States also points out that the application concerning NK603 maize is one of nine applications identified by the United States which have been pending at the member State level for an average of three years and ten months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning NK603 maize is undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2106 **Argentina** notes that a risk assessment of NK603 maize was initiated under Directive 90/220 and re-initiated under Directive 2001/18. This was concluded with a favourable opinion from the scientific panel. Argentina notes that, as of April 2004, the approval procedure concerning NK603 maize, which was initiated on 4 August 2000, had lasted 3 years and 8 months and no final decision had been reached on the application for approval.

7.2107 The **European Communities** claims that the only delays in the application for NK603 maize arose due to questions on additional information; otherwise the application process has proceeded smoothly. In addition, the European Communities asserts that the application submitted in August 2000 was incomplete and therefore not considered as received until January 2001. The European Communities further claims that 44 days after the application was submitted, the clock was stopped because the scientific committee of the lead CA requested additional information on issues such as molecular characterization, nutritional composition, and environmental impact.[1530]

7.2108 The **United States** notes that using the January 2001 date of receipt suggested by the European Communities, and taking account of the "clock stop" when requested information was awaited from the applicant, out of the total 25 months for which the application was at the CA level, the European Communities had delayed action on the application for NK603 maize under Directive 90/220 for 12 months.

7.2109 The **European Communities** responds that, given that the applicant had taken 13 months to gather additional information, it was not unreasonable that the lead CA required 12 months to digest and process that information.

[1530] Exhibit EC-76/At. 1.

7.2110 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at the member State level

7.2111 We recall that the applicant sent the first application to the Spanish CA on 4 August 2000. Four months later, on 20 December 2000, the applicant resubmitted the application in Spanish and apparently with additional studies added to the application.[1531] We note that there is no record of these additional studies. The Spanish CA acknowledged receipt of the information in a letter of 2 January 2001.

7.2112 The record shows that the lead CA requested additional information in February 2001, October 2001 and May 2002.[1532] The progress of the application was adversely affected notably by the February and October 2001 requests, in that the applicant took more than six months to respond to the February 2001 request and more than five months to respond to the October 2001 request.

7.2113 We recall that we asked the experts advising us whether the information requested by the lead CA in February 2001 was necessary to ensure that conclusions of the product's safety assessment were valid. Dr. Nutti concluded that the further studies requested were not necessary for the assessment of the safety of NK603 as a food. Furthermore, given that the application was for import and use in the European Communities and not for cultivation, Dr. Andow concluded that requests for additional detailed environmental studies were not justified, although some information relating to potential adverse effects of spillage could be considered reasonable. The European Communities submits that the expert replies with respect to the food safety studies were based on the mistaken premise that certain studies had already been provided, which the European Communities argues was not the case. We note that on the basis of the information provided to us, we cannot determine whether or not such information had been previously provided.

7.2114 Turning to the October 2001 request for additional information, we note that this request concerned additional information which the Spanish CA emphasized was "essential for product traceability". Further details were also requested on the potential environmental impact of accidental dissemination or germination. When the applicant provided the additional information requested more than five months later, in March 2002, the applicant stressed that the conclusion provided in relation to safety was not altered by the new studies that had been requested. In response to a question from the Panel regarding this second request for information, Dr. Andow noted that information on the potential environmental impact of accidental release could be useful to the lead CA, but also observed that the lead CA could have been more specific regarding its particular concerns.[1533]

7.2115 Even if we were to accept that all of the information requested by the lead CA in February and October 2001 and in May 2002 was necessary to ensure the validity of the safety assessment, it is apparent from the record that the lead CA in this approval procedure exceeded the maximum period of 90 days envisaged in Directive 90/220 for a lead CA assessment. Between January 2001 and August 2002, when the applicant of its own motion updated its application in accordance with the requirements of Directive 2001/18[1534], the lead CA spent six and a half months evaluating the application without finishing its assessment report. This is more than twice the length of time established in Directive 90/220.

[1531] Exhibit EC-76/At. 3.
[1532] Exhibit EC-76/Ats. 6, 10 and 14, respectively.
[1533] Annex H, Dr. Andow's response to Panel Question 38.
[1534] Exhibit EC-76/Ats. 15 and 18.

7.2116 Specifically, the lead CA initially took one and a half months to assess the application before it forwarded the February 2001 request for additional information.[1535] Subsequently, the lead CA reviewed the application for over one month before it transmitted its October 2001 request for additional information.[1536] Then, the lead CA spent just under two months prior to sending its last request for additional information in May 2002.[1537] The applicant responded to this last request in June 2002. However, the lead CA did not complete its assessment in the following two months, *i.e.*, prior to the end of August of 2002, when the applicant updated its application based on the new requirements of Directive 2001/18. This is despite the fact that at its meeting of 11 July 2002, the Spanish scientific body assessing the application, the National Biosafety Committee, recommended for adoption a favourable report on the application.[1538]

7.2117 As we have said before, we recognize that the question of whether or not the lead CA complied with the 90-day deadline stipulated in Directive 90/220 is not dispositive, *per se*, of whether the European Communities met its WTO obligation to complete its approval procedures without undue delay. However, we have also said that the deadline set forth in Directive 90/220 provides a useful indicator to guide the Panel's analysis. The 90-day deadline is binding and applies to all relevant applications submitted under that Directive. It may therefore be assumed that the EC legislator set this binding deadline in such a way as to make it possible for the CAs of all member States to assess even complex applications within the prescribed deadline.

7.2118 The European Communities provides no justification for the time taken by the lead CA in excess of the 90-day period, other than the assertion that the time taken by the lead CA was not unreasonable in view of the need to digest and process the information provided by the applicant. While we agree that the lead CA needs to be able to "digest and process" information provided at its request, it is clear from Directive 90/220 that the EC legislator considered that 90 days was a reasonable period of time within which to do so. Also, the European Communities does not argue that in the case at hand the replies and documents provided by the applicant at the lead CA's request were particularly voluminous or complex, such that more than double the amount of time was required than the maximum amount of time Directive 90/220 allows lead CAs for the assessment of applications. From a review of the relevant documents, it is not apparent to us that they are any more voluminous or complex than others on the record which concern different applications.

7.2119 We have previously pointed out that Spain was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, in this instance, we are not convinced that the Spanish CA's conduct reflects a precautionary approach. Notably, we are not convinced that the Spanish CA could not have identified its needs for additional information and forwarded appropriate requests for information to the applicant sooner than it did, even while following a precautionary approach.

7.2120 Moreover, we do not think that there was insufficient time to complete the approval procedure while Directive 90/220 was still in force. We note that as of July 2002, the lead CA had all necessary information, including positive scientific advice from the National Biosafety Committee, to complete its assessment. We recognize that as of July 2002 there was not much time left to complete the approval procedure under Directive 90/220. However, if Spain had proceeded more rapidly at earlier stages in the procedure, there would certainly have been enough time for the other member States to

[1535] Exhibit EC-76/Ats. 4 and 5.
[1536] Exhibit EC-76/Ats. 7 and 10.
[1537] Exhibit EC-76/Ats. 11 and 14.
[1538] Exhibit EC-76/At. 17.

review the lead CA's assessment report within 60 days following the circulation of the assessment report and, in the absence of objections, for the lead CA to give its consent to the placing on the market of NK603 maize.[1539] As indicated above, we consider that Spain could have identified its needs for additional information and forwarded appropriate requests for information sooner than it did, particularly prior to forwarding its request for information of May 2002.

7.2121 Based on the above considerations, the Panel concludes that the time taken by the lead CA for its assessment of the application concerning NK603 maize – notably the time taken by the lead CA up to August 2002, when the applicant updated its application in accordance with the requirements of Directive 2001/18 – was unjustifiably long.

7.2122 In relation to DS291, we recall that the United States claims that the approval procedure concerning NK603 maize was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the failure of Spain to complete its assessment of NK603 maize earlier than in January 2003 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that Spain's conduct was a consequence of the general moratorium on approvals.

7.2123 In view of our conclusion with regard to the time taken by Spain for its assessment, we do not go on to examine other arguments put forward by the United States and Argentina in support of their claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusions

7.2124 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning NK603 maize was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning NK603 maize for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning NK603 maize, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

[1539] We note that Spain could have considered that for as long as Directive 90/220 was still in force, there was no realistic prospect that the Group of Five countries and the Commission would allow the final approval of the application in question. However, the Panel does not consider that this would have justified Spain's failure to forward an assessment report to the Commission prior to the date of repeal of Directive 90/220. Spain might have anticipated opposition from the Group of Five countries on the basis of their June 1999 declaration. As pointed out above, notwithstanding this declaration, the Group of Five countries retained the freedom under EC law to approve applications. The same is true for the Commission, which had not issued a declaration comparable to that of the Group of Five countries.

(ii) DS293 (Argentina)

With reference to DS293, the Panel recalls its finding that the time taken by the lead CA for its assessment of the application concerning NK603 maize was unjustifiably long. In the light of this finding, the Panel concludes that the European Communities failed to complete the approval procedure concerning NK603 maize without "undue delay", thus breaching its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(xvii) GA21 maize (EC-78)

7.2125 Two Complaining Parties, the United States and Argentina, claim that the completion of the approval procedure concerning GA 21 maize (EC-78) has been unduly delayed.

7.2126 The **United States** argues that even though GA21 maize (EC-78) was forwarded by the lead CA to the Commission with a favourable opinion, received a positive opinion from the SCP in September 2000, the consultations with relevant member States were completed, and the scope of the application was reduced to exclude cultivation, the Commission failed to submit a draft measure to the Regulatory Committee. The United States argues that there was no action or communication by the Commission on this application. The United States adds that the only activity that occurred after the SCP's positive opinion was efforts by the applicant to re-start the process, including the applicant's voluntary offer in September 2001 to update the application (in the form of undertakings) to the requirements of the impending Directive 2001/18. Furthermore, the United States argues that although the applicant submitted all necessary supplementary information according to Directive 2001/18 to the lead CA on 15 January 2003, no action was taken in the following eight months, either by the lead CA or the Commission, to move the product towards consideration by the Regulatory Committee.

7.2127 The United States submits, finally, that the application concerning GA21 maize (EC-78) is one of nine applications identified by the United States which were stalled at the Commission level at the time Directive 90/220 expired and which, as of the date of establishment of the Panel, have been pending for an average of six and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning GA21 maize (EC-78) is undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2128 **Argentina** argues that once the SCP issued its favourable opinion on 22 September 2000, the procedure on this application was suspended. Two years and two months had elapsed between the submission of the application and its suspension. Upon the replacement of Directive 90/220 by Directive 2001/18, the application had to be re-submitted. However, the approval process has not made any progress since that time. One year and eight months elapsed from the re-submission until September 2003, when the application was withdrawn. In total, counting the time that elapsed under Directives 90/220 and 2001/18, the procedure dragged on for 5 years and 2 months without a definitive response concerning approval.

7.2129 The **European Communities** argues that after assessment at both member State and Community level, the application was withdrawn by the applicant on 15 September 2003. The European Communities notes that the applicant, in its withdrawal letter, gave three reasons for the

withdrawal: *first*, the progress in the notification procedure of another Roundup Ready maize to a more advanced stage than the GA21 maize (EC-78) notification; *second*, the introduction of the new regulations concerning commercialisation of GM products in the European Communities; and *third*, the change of the company's commercial priorities.

7.2130 **Argentina** responds that although the applicant's letter of withdrawal does not have a specific reference to "undue delay", this does not imply that no "undue delay" occurred. Argentina considers that the silence of the applicants cannot be taken as evidence of satisfaction with the process, but rather that it was due to the applicant's concern with maintaining good relations with the approving authorities.

7.2131 The **Panel** begins its analysis by addressing the delay allegedly caused by the Commission.

Failure by the Commission to submit a draft measure to the Regulatory Committee

7.2132 We recall that the SCP issued a favourable opinion on 22 September 2000. Following the issuance of the SCP opinion, the Commission did not submit a draft measure to the Regulatory Committee until Directive 90/220 was repealed in October 2002. The United States and Argentina argue that the Commission should have submitted a draft measure to the Regulatory Committee before October 2002. The European Communities argues that the application was being assessed according to the procedures.

7.2133 We recall that according to the procedures set out in Directive 90/220, after the issuance of the SCP opinion, it was for the Commission to submit a draft measure to the Regulatory Committee for a vote. The Commission did not do so, however. Indeed, it seems that unlike in other procedures[1540], the Commission in this procedure never launched inter-service consultations on a draft measure. We are therefore not persuaded by the European Communities' assertion that the application concerning GA21 maize (EC-78) was being assessed according to the procedures.

7.2134 At any rate, we observe that the preparation by the Commission of a draft measure and its submission to the Regulatory Committee is not a process which inherently takes more than two years. In other approval procedures, the Commission was able to prepare and submit draft measures to the Regulatory Committee within a matter of a few months. For example, in the procedure concerning Bt-531 cotton, the Commission prepared a draft measure and launched a vote in the Regulatory Committee in less than three months.[1541] It may be inferred from this that the Commission could in principle have submitted a draft measure to the Regulatory Committee well before October 2002.

7.2135 The fact that the Commission could in principle have submitted a draft measure to the Regulatory Committee before October 2002 does not necessarily mean that the Commission could have done so in the specific circumstances of this case. We note in this respect that the SCP's favourable opinion stated that "[t]he applicant should however establish a monitoring plan to identify unexpected and unusual events and analyse grower experiences, in order to develop and implement any necessary changes in crop management practices in response to the results of monitoring."[1542] However, as with the approval procedures we have considered earlier, there is no evidence that the Commission or the lead CA ever requested the applicant to propose a monitoring plan in accordance with the SCP's opinion. In January 2003, the applicant submitted an updated application, including a monitoring plan. But this information was submitted at the applicant's initiative, in anticipation of the

[1540] *See, e.g.*, Exhibits EC-62/At. 76; EC-65/At. 48.
[1541] Exhibit EC-65/Ats. 48 and 51.
[1542] Exhibit EC-78+85/At. 90.

entry into force of the new requirements contained in Directive 2001/18, and not because the applicant was requested to address the SCP opinion.[1543] Therefore, there is no reason to believe that the Commission was waiting for the applicant to put forward a monitoring plan, or, indeed, to provide any of the other additional information submitted by the applicant in January 2003. Consequently, we do not consider that the SCP's recommendation justified the Commission's failure to forward a draft measure to the Regulatory Committee before October 2002

7.2136 We further note that four months after the SCP issued its opinion, in January 2001, the applicant sent a letter to the lead CA requesting that the scope of its application be limited to import only and no longer include cultivation.[1544] In March 2001, the lead CA informed the Commission that it had no objection to the applicant's request.[1545] There is no indication that the Commission opposed the applicant's request. While the scope of the application was relevant to the draft measure to be submitted by the Commission to the Regulatory Committee, the requested change of scope did not, in our view, present an obstacle to the Commission launching, or continuing, inter-service consultations on a draft measure.

7.2137 Nor do we see a possible obstacle in the fact that Directive 90/220 was repealed in October 2002. Indeed, the SCP opinion in this procedure dates from September 2000. In our assessment, there was thus enough time for the Commission to launch and complete inter-service consultations on a draft measure to be submitted to the Regulatory Committee and for the Commission to adopt its draft measure in the event of a favourable vote in the Regulatory Committee.[1546] In our assessment, the Commission's inaction cannot, therefore, be excused on the grounds that the approval procedure concerning GA21 maize could not be completed while Directive 90/220 was still in force.

7.2138 In its earlier findings on the application concerning GA21 maize, the Panel noted that the Commission could have considered that due to the "blocking minority" of the Group of Five countries in the Regulatory Committee and the Council, a favourable draft measure would not achieve the required qualified majority and that the Commission would then have to complete the procedure by adopting its draft measure. In the Panel's view, even in this scenario, there was enough time for the Commission to complete the procedure in question while Directive 90/220 was still in force. But even if it was doubtful that there would be enough time in view of anticipated member State opposition, the Panel does not consider that this would have justified the Commission's failure to forward a draft measure to the Regulatory Committee. The Commission would have anticipated a "blocking minority" on the basis of the June 1999 declaration by the Group of Five countries. As pointed out above, there is no indication that the June 1999 declaration was intended to bind the Governments of the Group of Five countries *vis-à-vis* other member States or the Commission. In other words, the Group of Five countries retained the freedom under EC law to vote in favour of applications in the Regulatory Committee and Council. In the light of this, we think the Commission could not have legitimately invoked the June 1999 declaration as a justification for not submitting a draft measure to the Regulatory Committee prior to October 2002.

7.2139 Based on the above considerations, the Panel is of the view that, in the specific circumstances of this procedure, the time actually taken by the Commission to prepare and forward a draft measure

[1543] Exhibit EC-78+85/At. 94.
[1544] Exhibit EC-78+85/At. 91.
[1545] Exhibit EC-78+85/At. 92.
[1546] We note, by way of example, that in the procedure concerning NK603 maize, the Regulatory Committee voted on the application less than three months after the SCP issued its opinion. Exhibit EC-76/At. 72.

to the Regulatory Committee – no draft measure was forwarded between September 2000 and October 2002 – was unjustifiably long.

7.2140 Regarding DS291, we recall that the United States claims that the approval procedure concerning GA21 maize (EC-78) was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to submit a draft measure to the Regulatory Committee following the issuance of the SCP's opinion is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Commission's inaction was a consequence of the general moratorium on approvals.

7.2141 In view of our conclusion with regard to the Commission's failure to submit a draft measure to the Regulatory Committee, we do not go on to examine other arguments put forward by the United States and Argentina in support of their claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusions

7.2142 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to prepare and forward a draft measure to the Regulatory Committee once the SCP had issued its opinion – no draft measure was forwarded between September 2000 and October 2002 – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's inaction was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning GA21 maize (EC-78) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning GA21 maize (EC-78), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, the Panel recalls its finding that the time taken by the Commission to prepare and forward a draft measure to the Regulatory Committee – no draft measure was forwarded between September 2000 and October 2002 – was unjustifiably long. In the light of this finding, the Panel concludes that the European Communities failed to complete the approval procedure concerning GA21 maize (EC-78) without "undue delay", thus breaching its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(xviii) MON810 x GA21 maize (EC-82)

7.2143 One Complaining Party, the United States, claims that the completion of the approval procedure concerning MON810 x GA21 maize has been unduly delayed.

7.2144 The **United States** argues that this application never reached the Community level stage of review due to the moratorium. On 30 November 1999, the lead CA requested that the applicant provide several additional studies to support the application for this product.[1547] The applicant responded in August 2001 to all requests, except for a scientifically unjustified study on the nutritional composition of milk from dairy cows fed this product.[1548] Given the demonstrated safety of maize in feed generally, as well as the substantial data submitted to support the feed safety of both transgenic parents, there is no scientific basis to suggest a concern. One of the parental lines (MON810 maize) was approved by the European Communities several years prior to this application, and the feed safety was established as part of that process.[1549] In addition, as part of its original submission, the applicant had relied on substantial compositional analyses of the other parent (GA21 maize), as well as feeding studies.[1550] None of these studies identified anything that would provide any basis for the concern raised by the member State.

7.2145 The United States notes that the lead CA also requested additional studies of the hybrid in order to verify the stability of both events jointly. In the view of the United States, there was no logical basis for this request, which implies some interaction between the MON810 and GA21 events. The United States submits that the applicant had already shown the stability of these transformation events in each parental line. The insertions, having been shown to be stable in the parental lines, would be no more likely to be affected by crossing than any other gene already present in either parent.

7.2146 The United States notes that the applicant provided translations in January 2002 of various studies it had previously submitted. Following that, the only activity by the lead CA was a meeting held in April 2002.[1551] No further action was taken on this application for over 18 months, until the applicant volunteered to update the application under Directive 2001/18 on 16 January 2003.[1552] The applicant, however, subsequently withdrew the application on 15 September 2003, at the same time it withdrew the application for GA21 maize (EC-78), as the delays caused by the moratorium had rendered the applications for GA21 maize (EC-78) and MON810 x GA21 maize commercially obsolescent.[1553]

7.2147 The United States also points out that the application concerning MON810 x GA21 maize is one of nine applications identified by the United States which have been pending at the member State

[1547] Exhibit EC-82/At. 8.

[1548] Exhibit EC-82/ Ats. 9, 10 and 11. According to the United States, conducting the dairy cattle feeding study would have involved considerable cost and delay to the applicant. Such a test would require the applicant to obtain approval for further experimental plantings to generate sufficient maize for the feeding study; employ external consultants to undertake the required study; grow maize for the feeding study in the 2000 season; harvest, transport and ensile the maize under rigorous experimental conditions; undertake the cow-feeding phase; analyse the milk samples; and produce all reports to the Standards of Good Laboratory Practice.

[1549] Commission Decision concerning the placing on the market of genetically modified maize (zea mays L. line MON810) pursuant to Council Directive 90/220/EEC, (98/294/EC), April 22, 1998, Official Journal of the European Communities, L 131/32, May 5, 1998 (Exhibit US-131).

[1550] Exhibit EC-82/Ats. 2 and 5.

[1551] Exhibit EC-82/At. 18.

[1552] Exhibit EC-82/At. 20.

[1553] Exhibit EC-82/At. 21.

level for an average of three years and ten months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning MON810 x GA21 maize is undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2148 The **European Communities** argues that the delays identified by the United States can be explained by the fact that the safety of one of the parental lines of this hybrid product, GA 21 maize, had not yet been assessed. The lead CA was awaiting that assessment. The European Communities maintains that it is obvious that the assessment of a hybrid cannot be concluded as long as the assessment of one of its parental lines is still open. Furthermore, according to the European Communities, the United States acknowledges that the delays were caused by the applicant when it stated in response to a question from the Panel that "the applicant was unable to devote resources to respond to the questions posed by the [lead CA] in a timely fashion".[1554]

7.2149 The European Communities further observes that after discussions between the lead CA and the applicant, the application was withdrawn with a letter of 15 September 2003. The applicant gave three reasons for the withdrawal: first, the progress in the procedure of NK603 maize to a more advanced stage than the GA21 maize (EC-78) application; second, the introduction of the new regulations concerning commercialisation of GM products in the European Communities; and third, the change of the company's commercial priorities.

7.2150 The **United States** denies acknowledging that the delays were caused by the applicant. The summary table of the US response to question 47 from the Panel was not intended to indicate that delay was the fault of the applicant. Rather, the applicant recognized that the application for MON810 x GA21 maize would not move forward as long as consideration of the application for the single trait parent GA21 maize (EC-78) remained suspended under the moratorium. The United States contends that it was pointless for the applicant to devote resources to pursue the application for MON810 x GA21 maize when the approval of GA21 maize (EC-78) had been stalled for years under the moratorium. Thus, the delay in the application for MON810 x GA21 maize was a direct consequence of the delay in the application for GA21 maize (EC-78) under the moratorium.

7.2151 The United States points out that because of the delay in the approval procedure concerning GA21 maize (EC-78), that product, as well as MON810 x GA21 maize, have been superseded by a second generation Roundup Ready maize product (NK603 maize and NK603 × MON810 maize, respectively). The United States maintains that the applicant may not have cited undue delays in its withdrawal letter because it had a strong incentive to maintain cordial relations with EC regulators and saw no advantage of complaining to EC regulators about the length of the delays.

7.2152 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.2153 We recall that the lead CA (Spain) in November 1999 requested additional information from the applicant. The applicant did not provide the information requested until August 2001. A translation into Spanish of the documents submitted in the August 2001 response was provided to the Spanish CA in January 2002. The United States has pointed out that the applicant did not comply

[1554] The European Communities refers to the United States' response to question 47 of the Panel, table in Annex I.

with the Spanish CA's request that it provide a study on the nutritional composition of milk from dairy cows which had been fed the product in question.

7.2154 It was only in April 2002 that the Spanish National Biosafety Committee completed its review of the January 2002 Spanish translation of the applicant's documents. The National Biosafety Commission concluded that it still needed the results of feeding studies on cows, and other information.[1555] However, there is no indication in the record that a further request for information was ever sent to the applicant prior to the repeal of Directive 90/220 in October 2002.

7.2155 According to the European Communities, the failure of the lead CA to forward the application concerning MON810 x GA21 maize to the Commission prior to the date of repeal of Directive 90/220 is justified by the fact that the lead CA was waiting for the result of the Community level assessment of one of the parental lines of this hybrid product, GA21 maize (EC-78). The European Communities maintains that it is obvious that the assessment of a hybrid cannot be concluded as long as the assessment of one of its parental lines is still open.

7.2156 We recall that the Spanish CA in May 1999 had given a favourable assessment to the application concerning GA21 maize (EC-78) and forwarded that application to the Commission. When the application concerning MON810 x GA21 maize was submitted, the application concerning GA21 maize (EC-78) was under assessment at Community level. Furthermore, in September 2000 the SCP also issued a favourable opinion on the application concerning GA21 maize (EC-78).[1556] It is therefore not clear to us why the Spanish CA would not be in a position to reach a conclusion also with regard to the application concerning the hybrid product, *i.e.*, MON810 x GA21 maize. Indeed, the record does not indicate that the Spanish CA ever indicated to the applicant that it was unable to proceed due to the failure of the European Communities to approve the GA21 maize (EC-78) parent.

7.2157 As a general matter, it may be correct to say, as the European Communities does, that "the assessment of a hybrid cannot be concluded as long as the assessment of one of its parental lines is still open". However, it would seem that the assessment of the parental lines could also be made in the context of the assessment of the hybrid. At any rate, the Spanish CA could not "conclude" the assessment of the application concerning MON810 x GA21 maize completely on its own. If other member States had concerns with Spain's assessment of GA21 maize (EC-78), even though that assessment appears to have been confirmed by the SCP, they could have raised an objection on that basis to Spain's assessment of MON810 x GA21 maize and the assessment of that application would then also have been "concluded" at Community level.

7.2158 For these reasons, it is not apparent to us that the Spanish CA needed to keep the application at the member State level in order to avoid the possibility of conflicting assessments of GA21 maize, and we therefore do not consider that the fact that one of the parental lines was still pending justified Spain in not completing its assessment of the application concerning MON810 x GA21 maize.

7.2159 We note that after receiving a translation of the additional information requested from the applicant, it was incumbent on the Spanish CA either to seek further clarifications or to complete its assessment within the 90-day period provided for in Directive 90/220. As indicated, the National Biosafety Commission did not complete its review of the information until two and a half months later. Moreover, there is no evidence that the Spanish CA requested additional or missing information once the National Biosafety Commission had completed its review of the applicant's documents. Nor

[1555] Exhibit EC-82/At. 18.
[1556] Exhibit EC-78+85/At. 90.

did the Spanish CA complete its assessment after receiving further advice from the National Biosafety Commission in April 2002.

7.2160 We recognize that, by April 2002, the date of repeal of Directive 90/220 was approaching. However, we note that in another approval procedure, the Spanish CA forwarded questions from the National Biosafety Commission as late as mid-June 2002.[1557] Moreover, even if the lead CA had taken another two or three months to complete its assessment[1558], we think that there was still enough time for the other member States to review the lead CA's assessment report within 60 days following the circulation of the assessment report and, in the absence of objections, for the lead CA to give its consent to the placing on the market of MON810 x GA21 maize.[1559]

7.2161 Taking account of the aforementioned elements, we see no justification for the lead CA's failure, after receiving further advice from the National Biosafety Commission in April 2002, to follow up with the applicant to seek more information or additional clarifications, or for the lead CA's failure to complete its assessment in April 2002 or soon thereafter. We therefore are not convinced that the lead CA could not have proceeded more promptly than it did.

7.2162 Based on the above considerations, the Panel concludes that the time taken by the lead CA for its assessment of the application concerning MON810 x GA21 maize – notably the time taken by the lead CA between January and October 2002 – was unjustifiably long.

7.2163 In addition, we recall that the United States claims that the approval procedure concerning MON810 x GA21 maize was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the failure of Spain to complete its assessment of the application concerning MON810 x GA21 maize prior to the repeal of Directive 90/220 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that Spain's conduct was a consequence of the general moratorium on approvals.

7.2164 In view of our conclusion with regard to the time taken by Spain for its assessment, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

[1557] Exhibit EC-75/At. 13.

[1558] We note, however, that by April 2002 the 90-day period envisaged in Directive 90/220 for a lead CA assessment had already been exceeded.

[1559] We note that Spain could have considered that for as long as Directive 90/220 was still in force, there was no realistic prospect that the Group of Five countries and the Commission would allow the final approval of the application in question. However, the Panel does not consider that this would have justified Spain's failure to complete its assessment prior to the date of repeal of Directive 90/220. Spain might have anticipated opposition from the Group of Five countries on the basis of their June 1999 declaration. As pointed out above, notwithstanding this declaration, the Group of Five countries retained the freedom under EC law to approve applications. The same is true for the Commission, which had not issued a declaration comparable to that of the Group of Five countries.

Conclusion

7.2165 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning MON810 x GA21 maize was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning MON810 x GA21 maize for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning MON810 x GA21 maize, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(xix) RR sugar beet (EC-88)

7.2166 One Complaining Party, the United States, claims that the completion of the approval procedure concerning RR sugar beet has been unduly delayed.

7.2167 The **United States** claims that the application for RR sugar beet was delayed at the first stage of the approval process under 90/220 because the lead CA (Belgium) declined to forward the application to the Commission. The United States argues that although the applicant provided answers to all of the questions raised by the lead CA, the lead CA failed to complete its review.

7.2168 The United States also points out that the application concerning RR sugar beet is one of nine applications identified by the United States which have been pending at the member State level for an average of three years and ten months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning RR sugar beet is undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2169 The **European Communities** notes that after discussions between the lead CA and the applicant, the application was withdrawn by the companies producing the product on 16 April 2004. As the reason for the withdrawal, the applicant pointed to a decision to stop any further development of the RR sugar beet derived from event T9100152.

7.2170 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.2171 We recall that the application was considered at a meeting of the Belgian Biosafety Advisory Council held on 26 April 1999. The questions which were generated by this meeting were transmitted to the applicant in June 1999 and included questions on agricultural practices, molecular

characterization, toxicology, allergenicity, and food/feed equivalence.[1560] The applicant provided responses to some of these questions in July 1999.[1561] Other questions were answered in December 1999.[1562]

7.2172 In October 1999 the lead CA requested additional information on gene transfer in digestive tracts.[1563] The applicant provided such information in January 2000.[1564] We asked the experts advising us whether the information regarding allergenicity, molecular characterization and gene transfer in digestive tracts requested by the lead CA was necessary to ensure that conclusions of the safety assessment were valid. Dr. Nutti stated that the information provided by the applicant prior to October 1999 on these three topics was adequate to ensure that the conclusions of the assessment were valid.[1565]

7.2173 In February 2000, the lead CA requested missing bibliographical references. The applicant provided the relevant references in February and March 2000.[1566] According to the chronology provided to us, in April 2000 the applicant met with the CA to discuss issues relating to identity preservation, Good Agricultural Practices, post-market monitoring, traceability, public information, line-specific detection methods and primers. The record of this meeting was not provided to us, however. In July 2000, the applicant at its own initiative provided additional information on the characterization of a protein and detection protocols. The applicant noted that this data did not change the conclusions of the safety assessment.[1567]

7.2174 In November 2000, the lead CA requested further clarifications regarding molecular characterization and allergenicity of "event '77'".[1568] We asked the experts if the information regarding molecular characterization and allergenicity of "event '77'" requested by the lead CA was necessary to ensure that conclusions of the safety assessment were valid. Dr. Nutti emphasized that the information "for allergenicity was not necessary to ensure that the conclusions of the safety assessment were valid", as the initial application had satisfactorily established the safety of this product in this respect.[1569] The applicant apparently did not provide the requested information.

7.2175 In January 2001 the lead CA "invited" the applicant to provide a proposal for labelling and traceability as well as a proposal for a monitoring plan and Good Agricultural Practices in accordance with the principles of the Common Position of the Council on the amendment of Directive 90/220. The lead CA indicated that in the absence of voluntary compliance with these principles, it seemed that the Commission and the other member States would oppose the approval of the application even if the lead CA forwarded it with a positive assessment.[1570] The applicant apparently did not reply to the lead CA's invitation. In June 2001, the lead CA sent the applicant some comments on its application, asking the applicant to make corresponding corrections.[1571] After the June 2001 communication from the lead CA there appear to have been no further exchanges between the lead CA and the applicant until the repeal of Directive 90/220 in October 2002.

[1560] Exhibit EC-88/Ats. 8 and 9.
[1561] Exhibit EC-88/At. 10.
[1562] Exhibit EC-88/At. 13.
[1563] Exhibit EC-88/At. 12.
[1564] Exhibit EC-88/At. 15.
[1565] Annex H, Dr. Nutti's response to Panel Question 42.
[1566] Exhibit EC-88/Ats. 17-21.
[1567] Exhibit EC-88/At. 22.
[1568] Exhibit EC-88/At. 27.
[1569] Annex H, Dr. Nutti's response to Panel Question 43.
[1570] Exhibit EC-88/At. 29.
[1571] Exhibit EC-88/At. 30.

7.2176 We begin our examination of the lead CA's assessment of the application under Directive 90/220 by recalling that the applicant did not respond to the lead CA's November 2000 request for additional information.[1572] It would therefore appear that after November 2000 the lack of progress of the application under Directive 90/220 is attributable to the applicant. The focus of our examination is therefore on the lead CA's conduct prior to the November 2000 request.

7.2177 We note in this respect that by the end of March 2000 the applicant had provided all additional information requested by the lead CA. Moreover, there is no indication that the Biosafety Advisory Council had been asked for further scientific input either before or after March 2000. Notwithstanding this, the lead CA did not complete its assessment in the next several weeks. Instead, more than seven months later, in November 2000, the lead CA requested further clarification on molecular characterization and allergenicity issues previously addressed by the applicant. As indicated previously, notably in the case of the clarifications sought concerning allergenicity, Dr. Nutti questioned the need for the information that was requested. Even ignoring this, we note that the European Communities did not provide an explanation for why the Belgian CA could not have sought these clarifications much earlier, given that the applicant had provided additional information on these issues before the end of 1999.

7.2178 Furthermore, even assuming *arguendo* that the lead CA could not have finished its assessment between March 2000, when the applicant provided all additional information requested by the lead CA, and the end of July 2000, when the applicant voluntarily submitted additional information, and accepting, again *arguendo*, that the lead CA required some time to review the July 2000 information, we recall that the November 2000 request came more than seven months after the applicant had provided all information requested by the lead CA. We are not persuaded that the completion of the review of the March and July 2000 information required more than twice the maximum 90-day period envisaged in Directive 90/220 for the entire assessment by a lead CA. We note in this connection that by November 2000, Belgium had already far exceeded the 90-day period provided for in Directive 90/220.

7.2179 Moreover, the seven-month delay after March 2000 could not, in our view, be excused on the basis that there was insufficient time to complete the approval procedure concerning RR sugar beet while Directive 90/220 was still in force. Directive 90/220 was not repealed until October 2002. There was thus enough time for the other member States to review the lead CA's assessment report within 60 days following the circulation of the assessment report and, in the absence of objections, for the lead CA to give its consent to the placing on the market of RR sugar beet.[1573]

7.2180 Taking account of the aforementioned elements, we consider that, even assuming that the lead CA's November 2000 request for additional information was justified, the lead CA could have sought that information earlier than it did. We also consider that the lead CA should have done so, as we think that by November 2000 the lead CA should have been able to resolve all other outstanding scientific or technical issues.

[1572] The lead CA in January 2001 reminded the applicant of its November 2000 request for information. Exhibit EC-88/At. 29.

[1573] We note that Belgium could have considered that for as long as Directive 90/220 was still in force, there was no realistic prospect that the Group of Five countries and the Commission would allow the final approval of the application in question. However, the Panel does not consider that this would have justified the seven-month delay after March 2000. Belgium might have anticipated opposition from the Group of Five countries on the basis of their June 1999 declaration. However, as pointed out above, notwithstanding this declaration, the Group of Five countries retained the freedom under EC law to approve applications. The same is true for the Commission, which had not issued a declaration comparable to that of the Group of Five countries.

7.2181 Based on the above considerations, the Panel concludes that the time taken by the lead CA for its assessment of the application concerning RR sugar beet – notably the time taken by the lead CA between March and November 2000 – was unjustifiably long.

7.2182 In addition, we recall that the United States claims that the approval procedure concerning RR sugar beet was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the time taken by Belgium to complete its assessment is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that Belgium's conduct was a consequence of the general moratorium on approvals.

7.2183 In view of our conclusion with regard to the time taken by Belgium for its assessment, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.2184 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning RR sugar beet was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning RR sugar beet for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning RR sugar beet, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the SPS Agreement.

(xx) MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape (EC-90)

7.2185 One Complaining Party, Canada, claims that the completion of the separate approval procedures for MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape have been unduly delayed. While we are mindful of the fact that Canada is making separate product-specific claims in respect of the two approval procedures concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape, in view of the very similar facts of these procedures, we examine the two claims together.

7.2186 **Canada** argues that the delays in completing the approval procedures for MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape are both excessive and unjustified, and hence undue. The EC decisions authorizing the placing on the market of MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape in July 1997 stated that "consent shall be given by the competent authority of France to

the placing on the market" of the products in question[1574], yet in 2003, when the Panel was established, the lead CA had still failed to give its consent for either product.

7.2187 Canada notes that although the Commission took the procedural step of sending a "reasoned opinion" to France in relation to the withholding of consent for these products on 7 July 1999, the Commission has not pursued legal proceedings against France for infringement of European law before the European Court of Justice.[1575] No explanation has been provided by France for its refusal to comply with the Commission decisions and Directive 90/220, nor by the Commission for not pursuing legal action against France. This is despite the November 2000 judgment of the French Conseil d'Etat that, without new information concerning the risks associated with MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape, the French Ministry could not call into question the decision taken by the Commission.[1576]

7.2188 Canada contends that the length of time it has taken, so far, for these applications to move through the approval system – more than eight years – is, by any reasonable standard, "undue" and therefore a violation of Annex C(1)(a), keeping in mind that the final approval for these products still has not been given. However, the amount of time these applications have languished in the approval procedure is not the sole reason for Canada's claim that the delays have been undue. First and foremost, the European Communities has had in place, since October 1998, an unjustified moratorium on approvals. Furthermore, the refusal to approve the applications concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape are not based on risk assessments, particularly since both products were formally approved by the Commission in 1997.

7.2189 The **European Communities** argues that these products obtained a market authorization by virtue of Commission decisions of 6 June 1997. The European Communities submits that from the point of view of EC law, the absence of the final consent does not mean that the applicant is not entitled to place MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape on the market. The doctrine of "direct effect" in Community law means that the applicant could assert the rights granted them through the provisions of EC law.[1577]

7.2190 The European Communities confirms that the Commission initiated infringement proceedings against France in 1998, however it decided not to take the case to the Court. This was because the very legislation on the basis of which the approval had been granted had been identified to be insufficient and was being revised. Furthermore, France had raised the same environmental risk concerns regarding these two products as it had for the products for which it subsequently adopted safeguard measures (*i.e.* the identical product MS1/RF1 oilseed rape which had been approved for breeding activities in 1996).

7.2191 The approvals of MS1/RF1 and MS1/RF2 oilseed rape for import, processing and cultivation in 1996 and 1997 did not provide for any reporting or monitoring of marketing in the European

[1574] Article 1(1) of each Decision respectively. Exhibits CDA-48 and -49.

[1575] European Commission, GMOs: Commission moves against Luxembourg and France, Commission Press Release, IP/99/438, Brussels, 7 July 1999 (Exhibit CDA-52). *See also* European, Commission, Seventeenth Annual Report on Monitoring the Application of Community Law (1999), COM (2000) 92 final, Brussels, 23 June 2000 (Sector on Chemicals and Biotechnology), p. 80 (Exhibit CDA-53)

[1576] European Commission, Eighteenth Annual Report on Monitoring the Application of Community Law (2000), COM (2001) 309 final, Brussels, 16 July 2001 (Sector on Chemicals and Biotechnology), p. 67 (Exhibit CDA-50); *see also*, European Court of Justice, *Association Greenpeace France v. Ministère de l'Agriculture et de la Pêche*, C-6/99 [2000] ECR I-01651 (Exhibit CDA-51).

[1577] The European Communities refers to European Court of Justice, *Leberpfennig*, Case 9/70 [1970] ECR 825.

Communities. Accordingly, the European Communities claims it is unable to say whether these products have been sold in the European Communities. According to the European Communities, no oilseed rape varieties derived from MS1/RF1 or MS1/RF2 oilseed rape have been registered in member States' national catalogues or in the Common Catalogue of varieties of agricultural plant species – which is a prerequisite for allowing their commercial cultivation – because there has been no application from companies to do so.

7.2192 **Canada** rejects the EC argument that the absence of the final consent does not mean that the applicant is not entitled to place MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape on the market. Canada submits that this would require the applicant to pursue legal proceedings within the European Communities in order to bring to an end the approval procedures. According to Canada, under these circumstances it is obvious that the European Communities has failed to complete the relevant approval procedures under Directive 90/220. The applicant has been unable to market its products in the European Communities as a result of the failure of France to issue the letters of consent and the consequent uncertainty regarding the legal status of the products. Therefore, the European Communities has failed to "complete" the relevant approval procedures without "undue delay" in patent violation of Annex C(1)(a) of the *SPS Agreement*. Moreover, Canada argues that by failing to complete the approval procedures, the European Communities has instituted and maintained effective product-specific marketing bans for MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape.

7.2193 The **Panel** begins its analysis by addressing the delay allegedly caused by France as the lead CA.

Member State failure to give consent to placing on the market

7.2194 The Panel notes that although the two applications concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape were formally approved by the Commission for placing on the market in June 1997, the lead CA subsequently failed to take the final step of the approval procedure provided for in Article 13(4) of Directive 90/220, which is to grant written consent to the placing on the market of a product. The relevant Commission decisions, which are addressed to the member States, also provide in their Article 1(1) that "consent shall be given by the competent authority of France to the placing on the market" of the oilseed rape products in question.[1578]

7.2195 Neither Article 13(4) of Directive 90/220 nor the relevant Commission decisions lay down specific time periods within which the lead CA had to give consent. However, it is clear to us that this does not mean that the lead CA could take any amount of time to complete the step required of it. If it were otherwise, the deadlines stipulated in Directive 90/220 for the completion of other steps of the approval procedure, such as the 90-day member State assessment period set out in Article 12, the 60-day objection period set out in Article 13 and the three-month action period set out in Article 21, could easily be nullified and rendered meaningless. We recall that in the case of the two applications at issue, the approval for both applications was given by the Commission on 6 June 1997. As of October 2002, when Directive 90/220 was repealed, France had not granted its consent to the placing on the market of the products at issue. Thus, under Directive 90/220, France did not grant its consent for more than five years.[1579]

[1578] Exhibits CDA-48 and -49.

[1579] We note, by way of example, that in the approval procedure concerning the Red-hearted chicory, which was also conducted under Directive 90/220, the lead CA gave its written consent two-and-a-half months after the Commission approved the application for breeding activities. Exhibit EC-77/At. 42.

7.2196 There is some uncertainty as to the status of the applications concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape after the repeal of Directive 90/220. Article 35 of Directive 2001/18 provides that applications submitted under Directive 90/220 in respect of which the approval procedures under Directive 90/220 have not been completed by 17 October 2002 are subject to Directive 2001/18. It further provides that by 17 January 2003 applicants had to complement their applications in accordance with Directive 2001/18. There is no indication that the applications concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape were complemented in accordance with Directive 2001/18.

7.2197 The European Communities appears to argue, however, that the approval procedures concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape were completed under Directive 90/220. The European Communities contends that in accordance with the jurisprudence of the European Court of Justice the absence of the final consent from the lead CA does not mean that the applicant is not legally entitled to place MS1/RF1 oilseed rape (EC-89) and/or MS1/RF2 oilseed rape on the market. According to the European Communities, the applicant could invoke before French courts the obligation imposed by the above-noted Commission decisions on France to give its consent to the placing on the market of the products in question. Canada did not contest that the applicant would have this right under EC law. In these circumstances, and in the absence of evidence to the contrary, we see no grounds for rejecting the European Communities' contention regarding the position under its own law.

7.2198 Accepting the European Communities' contention means that as of the date of establishment of this Panel, the above-noted Commission decisions were still legally binding, and that as of that date the applicant could still invoke the above-noted Commission decisions against France, since France had not given its written consent by then. This does not mean, however, that either before or after the repeal of Directive 90/220 France itself was no longer required to comply with the Commission decisions and was not obliged to grant its written consent.

7.2199 We must not, and hence do not, express a view on whether the approval procedures conducted under Directive 90/220 concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape were "completed" as a matter of EC law.[1580] However, we may express a view on whether these approval procedures were "completed" within the meaning of Annex C(1)(a), first clause. We have observed earlier that the verb "complete" as it appears in Annex C(1)(a), first clause, indicates that approval procedures are not only to be undertaken, but are also to be finished, or concluded, and that the phrase "undertake and complete", which also appears in Annex C(1)(a), first clause, covers all stages of approval procedures and should be taken as meaning that approval procedures are to be started and carried out from beginning to end.[1581]

7.2200 We do not consider that the European Communities finished, or concluded, the approval procedures concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape, or that the European Communities carried out these procedures from beginning to end. Indeed, Directive 90/220 provides for the granting of the lead CA's written consent to the placing on the market as an integral and last step of the approval procedure.[1582] In our view, the fact that the applicant could invoke before French courts the obligation imposed by the above-noted Commission decisions on France to give its consent to the placing on the market of the products in question does not demonstrate that the relevant approval procedures have already been "completed" within the meaning of Annex C(1)(a), first

[1580] We note that Article 35 of Directive 2001/18 uses the phrase "not [...] completed" in connection with procedures commenced under Directive 90/220.

[1581] *See supra*, para. 7.1494.

[1582] Article 13(4) of Directive 90/220.

clause. Rather, it indicates that, notwithstanding France's failure to finish the procedures, the Commission decisions may be enforceable *vis-à-vis* France.

7.2201 Having determined that the approval procedures concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape have not been completed, we now turn to address whether the time taken by France to grant its written consent is unjustifiably long. The European Communities asserts in this respect that France's inaction after June 1997 was due to concerns about environmental risks, and that these same risks led France in November 1998 to adopt a safeguard measure on MS1/RF1 oilseed rape (EC-161).[1583] In considering the EC assertion, we note that we have been provided very little information on the approval procedures concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape. In particular, we have seen no evidence which points to the alleged environmental concerns by France. To the contrary, the Commission decisions approving the applications concerning MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape make clear that France forwarded the application to the Commission with a favourable opinion.

7.2202 Furthermore, there is no indication that France after June 1997 sought additional information from the applicant, or proposed to the applicant voluntarily to accept stricter conditions to meet France's alleged environmental concerns. Moreover, the Commission decisions approving the two products specify that Directive 90/220 provides for additional safeguards if new information on risks of the products in question became available. In the light of this, even if France considered that by June 1997 there were justifiable reasons for it to consider that the products in question constituted a risk to the environment, it could have taken a safeguard measure, as it did for MS1/RF1 oilseed rape (EC-161), *after* giving its written consent to the placing on the market of the two products in question.[1584] The concerns underlying France's safeguard measure would then have been examined by the SCP, and a decision on the validity of France's concerns would then have had to be taken at Community level.

7.2203 For these reasons, we are not persuaded that there were outstanding environmental issues which were specific to the products in question, and which France was trying to have the applicant address prior to giving its written consent to the placing on the market of these products.

7.2204 The European Communities offered no other explanation for France's prolonged inaction. We recall in this regard that in June 1999 France was one of the Group of Five countries which declared that they would take steps to suspend further approvals under Directive 90/220 pending the adoption of new EC rules on labelling and traceability. We found earlier that at least as from June 1999 France's conduct is consistent with the June 1999 declaration by the Group of Five countries. Indeed, despite a clear legal obligation to give written consent to the placing on the market of MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape, France withheld its consent and thus prevented these products from being approved. As we have explained earlier[1585], however, we consider that the perceived need for new EC rules on labelling and traceability does not provide a sufficient justification for not completing the approval procedures for the products in question and for preventing their final approval.

[1583] The application concerning MS1/RF1 oilseed rape (EC-161) had been submitted to the United Kingdom and was approved for breeding activities in 1996.

[1584] There is nothing in Directive 90/220 which says that a lead CA forwarding an application with a positive opinion and giving written consent to the placing on the market of a product may not subsequently take a safeguard measure in respect of that product.

[1585] *See supra*, paras. 7.1511-7.1518.

7.2205 Based on the above considerations, the Panel concludes that the time taken by France up to August 2003, including the time taken after June 1999, for the purpose of giving its written consent to the placing on the market of MS1/RF1 oilseed rape (EC-89) and MS1/RF2 oilseed rape following the approval of both applications by the Commission in June 1997 is unjustifiably long.

7.2206 In view of this conclusion, we do not go on to examine other arguments put forward by Canada in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusions

7.2207 In the light of the above, the Panel reaches the following conclusions:

(i) DS292 (Canada) – MS1/RF1 oilseed rape (EC-89)

With reference to DS292, the Panel recalls its findings that the time taken by France to give its written consent for the placing on the market of MS1/RF1 oilseed rape (EC-89) following its approval by the Commission in June 1997 – no consent was given between June 1997 and August 2003 – was unjustifiably long. Based on these findings, the Panel accepts Canada's contention that the European Communities failed to "consider or approve, without undue delay" the application concerning MS1/RF1 oilseed rape (EC-89), and that it consequently did not complete the relevant approval procedure without "undue delay". Accordingly, the Panel concludes that in respect of the approval procedure concerning MS1/RF1 oilseed rape (EC-89), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ii) DS292 (Canada) – MS1/RF2 oilseed rape (EC-90)

With reference to DS292, the Panel recalls its findings that the time taken by France to give final consent for the placing on the market of MS1/RF2 oilseed rape following its approval by the Commission in June 1997 – no consent was given between June 1997 and August 2003 – was unjustifiably long. Based on these findings, the Panel accepts Canada's contention that the European Communities failed to "consider or approve, without undue delay" the application concerning MS1/RF2 oilseed rape, and that it consequently did not complete the relevant approval procedure without "undue delay". Accordingly, the Panel concludes that in respect of the approval procedure concerning MS1/RF2 oilseed rape, the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(c) Novel Foods – Applications submitted under Regulation 258/97

7.2208 We now turn to examine the approval procedures which were conducted under Regulation 258/97 for the applications identified by the Complaining Parties. Before embarking on an examination of individual approval procedures, however, we should briefly address certain issues presented by the application of Annex C(1)(a), first clause, to approval procedures conducted under Regulation 258/97.

(i) Application of Annex C(1)(a), first clause, to approval procedures conducted under Regulation 258/97

7.2209 We have found earlier that the approval procedure set out in Regulation 258/97, to the extent it is applied to check and ensure the fulfilment of the requirement that novel foods not present a danger for the consumer, constitutes an "approval procedure" within the meaning of Annex A(1) of the *SPS Agreement*. On the other hand, we found that to the extent the same approval procedure is applied to check and ensure the fulfilment of the requirements that novel foods not mislead the consumer and that they not be nutritionally disadvantageous for the consumer, that procedure is not an "approval procedure" within the meaning of Annex A(1) of the *SPS Agreement*.

7.2210 Under Regulation 258/97, once an application for the approval of a novel food product is submitted, the fulfilment of the aforementioned three requirements is to be checked through one single approval procedure. Regulation 258/97 also envisages that if an application does not meet one of three requirements, the relevant food product may not be placed on the market. We recall that the Complaining Parties did not challenge Regulation 258/97 as such, and thus did not question the European Communities' decision to conduct one single approval procedure to check all three requirements and to grant approvals only in cases where applications comply with all three requirements.

7.2211 It follows from the design of Regulation 258/97 that in the event there is a delay in the processing of an application due to the need to check the fulfilment of the requirement that novel foods not mislead the consumer, or that they not be nutritionally disadvantageous for the consumer, that delay would also affect the SPS approval procedure conducted for the same application, *i.e.*, the procedure applied to check and ensure the fulfilment of the requirement that novel foods not present a danger for the consumer. In other words, the SPS approval procedure would be delayed if, and to the extent that, there was a delay in the non-SPS approval procedure.

7.2212 We have previously stated that, in our view, Annex C(1)(a), first clause, requires that SPS approval procedures be undertaken and completed with no unjustifiable loss of time. In the context of Regulation 258/97, the issue thus arises whether a delay caused by the need to check the fulfilment of, *e.g.*, the non-SPS requirement that novel foods not be nutritionally disadvantageous for the consumer should be considered to constitute, *ipso facto*, unjustifiable loss of time.

7.2213 In addressing this issue, we recall that the Complaining Parties did not challenge or question the fact that Regulation 258/97 provides that for each application a single procedure is to be conducted, leading to a single approval. We consider that, in these circumstances, a delay in the SPS approval procedure should not be viewed as "undue" merely because it arose from the need to check the fulfilment of one of the two non-SPS requirements contained in Regulation 258/97, *e.g.*, the requirement that novel foods not be nutritionally disadvantageous for the consumer. Indeed, if it were otherwise, a situation might arise where the European Communities would have to complete the procedure with a substantive decision on the application concerned even if it had not yet been able adequately to determine whether the application meets the requirement that the novel food product not be nutritionally disadvantageous for the consumer. The European Communities might thus have to approve a novel food product the consumption of which is nutritionally disadvantageous for the consumer, and this even though the Complaining Parties never questioned the fact that in accordance with Regulation 258/97 the requirement that a product not be nutritionally disadvantageous must be fulfilled before a product is approved.

7.2214 While we thus do not consider that, in the specific circumstances of this case, a delay in the SPS approval procedure should be treated as "undue" merely because it arose from the need to check

the fulfilment of one of the two non-SPS requirements contained in Regulation 258/97, it is our view that for instance if the time taken to check the fulfilment of one of those non-SPS requirements exceeded the time that is required to do so, the resulting delay in the SPS approval procedure would be at least partly "undue".

7.2215 In view of the above considerations, we think that for the purposes of our examination of the relevant approval procedures in the light of Annex C(1)(a), first clause, we need not, and hence do not, make specific findings on whether any delays in a relevant approval procedure arose from the need to check the fulfilment of the SPS requirement that novel foods not present a danger for the consumer or whether they arose from the need to check the fulfilment of the non-SPS requirements that novel foods not mislead the consumer and that they not be nutritionally disadvantageous for the consumer. In the circumstances of this case, either type of delays would be relevant to an inquiry under Annex C(1)(a), first clause.

7.2216 As an additional, but separate, matter, we should recall that the Regulation 258/97 applications covering foods or food ingredients which contain or consist of GMOs are subject to Article 9 of Regulation 258/97 which provides that the Commission decision approving the placing on the market under Regulation 258/97 must "respect the environmental safety requirements laid down by [Directive 90/220] to ensure that all appropriate measures are taken to prevent the adverse effects on human health and the environment which might arise from the deliberate release of [GMOs]". As we have said earlier, it would seem to follow from Article 9 that if the applicant did not submit an environmental risk assessment, a Regulation 258/97 application could not be approved by the Commission unless a Directive 90/220 application concerning the same biotech product had previously been approved. We observe in this context that it would in our view be contrary to the requirements of Annex C(1)(a), first clause, for the European Communities to proceed with a Regulation 258/97 procedure at a delayed pace merely because of delays which have occurred, or are anticipated to occur, in a parallel Directive 90/220 (or Directive 2001/18) procedure concerning the same biotech product, provided that further progress in the Regulation 258/97 procedure is still possible. In other words, we consider that the European Communities must proceed as far as possible with a Regulation 258/97 procedure as promptly as possible, unless the applicant requests that the Regulation 258/97 procedure proceed more slowly, or that it not proceed faster or further, than a parallel Directive 90/220 (or Directive 2001/18) procedure. In the case of the Regulation 258/97 applications at issue in this dispute, we are not aware of the existence of such a request by an applicant or of a situation where no further progress in the relevant Regulation 258/97 procedure was possible.

7.2217 Finally, we recall that in Section VII.D we have addressed whether the reason for the general EC moratorium on final approvals could have provided a justification for delays which might have occurred as a result of that moratorium. These earlier observations are relevant and applicable also to our examination of the Regulation 258/97 approval procedures identified by the Complaining Parties.

7.2218 With these general observations in mind, we now proceed with the examination of the individual product-specific measures complained against.

(ii) GA21 maize (food) (EC-91)

7.2219 Two Complaining Parties, the United States and Argentina, claim that the completion of the approval procedure concerning GA21 maize (food) has been unduly delayed.

7.2220 The **United States** argues that the application concerning GA21 maize (food) under Regulation 257/98 was delayed first at the member State level in that the lead CA (the Netherlands)

took at least 10 months more than required to complete its initial assessment. Subsequently, the SCF failed to consider the application for 11 months, and later delayed issuing its assessment for 11 months without explanation. Finally, following the positive assessment of the SCF, the Commission failed to submit a draft decision to the Regulatory Committee for approval of this product prior to the establishment of the Panel. The United States considers these delays to be unwarranted and thus undue.

7.2221 The United States observes that this product was under consideration by the lead CA between the submission of the application in July 1998 and the lead CA's opinion in January 2000. In February 1999, the lead CA requested the applicant to perform a further study on compositional analysis, and the applicant provided its response in October 1999. Therefore, of the total 18 months during which this product was considered at the member State level, only 8 were used by the applicant to answer questions.

7.2222 The United States points out that the application was forwarded to the Commission on 21 January 2000. The official member State consultation period was over by April 2000. The United States notes that the Commission asked the SCF for an opinion on 18 May 2000. However, it was eleven months later that the SCF contacted the applicant for the first time, asking for additional information.[1586] Within less than one month, the applicant provided answers to all questions.[1587] It took a further 11 months for the SCF to issue an opinion on 27 February 2002.[1588] Hence the application was delayed for 17 months at the Community level before the SCF rendered its positive opinion on 27 February 2002. In its opinion, the SCF concluded that the data submitted, including the two whole food studies, were "sufficient for evaluation"[1589] and cited these studies in support of its ultimate conclusion that "from the point of view of consumer health, maize grain from maize line GA21 and derived products […] are as safe as grain and derived products from conventional maize lines."[1590]

7.2223 According to the United States, almost two months passed after the positive SCF opinion with no activity on this application. On 23 April 2002, the applicant offered to reduce the scope of the application to include only processed grain and derived ingredients, but not unprocessed grains, in order to enable the authorization procedure under Regulation 258/97 to proceed immediately.[1591] The applicant explained that the reason for this proposal was because the food use of unprocessed grains is also subject to Directive 90/220 and that "progress under this Directive has been suspended for some time, with the result that GA21 maize grain has not yet been considered for consent."[1592]

7.2224 The United States argues that despite the efforts of the applicant to remove any possible impediments, the Commission still failed to forward the application to the Regulatory Committee after the positive SCF opinion. Instead, as reflected in the minutes of a meeting on 5 June 2002 between the Commission and the applicant, the Commission noted that although the next step was to take a Community Decision, "[i]t is desirable that such a Decision would take into account in an appropriate manner the legislative developments with respect to the authorization of GM food and

[1586] Exhibit EC-91/At. 39.
[1587] Exhibit EC-91/At. 40.
[1588] The current revised regulatory framework recognizes that a period of six months is an achievable timeframe for the EC's Scientific Authority (EFSA GMO Panel) to come to an opinion. Regulation (EC) No. 1829/2003, Article 6.1.
[1589] Exhibit EC-91/At. 43, pp. 11-12.
[1590] Exhibit EC-91/At. 43.
[1591] Exhibit EC-91/At. 44.
[1592] Exhibit EC-91/At. 44.

feed as well as the labelling of GM products".[1593] The United States maintains that the European Communities simply halted the processing of this application in anticipation of possible upcoming changes to its regulations, an action entirely consistent with the moratorium which the European Communities and member State officials had announced. Although both the new food and feed and traceability and labelling legislations would not enter into force until 2004, and although the applicant stated its preference to apply the labelling requirements currently in effect under Regulation 258/97, the Commission noted that "it is clear that it would be more difficult to obtain a favourable opinion by a majority of Member States in the Comitology procedure" if the applicant were not required to anticipate the new labelling requirements before the new legislation was adopted.[1594] In other words, the applicant was required to wait until the requirements for labelling under pending legislation were finalized. Thus the Commission failed to forward a draft measure to the Regulatory Committee as is required to complete the approval process, resulting in further delay that lasted until the new Food and Feed regulation was passed in September 2003.

7.2225 The United States submits, in addition, that the application concerning GA21 maize (food) is one of five applications identified by the United States which are pending at Commission level and which, as of the date of establishment of the Panel, have been pending for an average of four years and six months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning GA21 maize (food) is undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2226 **Argentina** argues that consideration of the application for GA-21 maize (food) under Regulation 258/97 dragged on for a total of 5 years and 2 months without a definitive response. Argentina further contends that the chronologies provided by the European Communities verify the numerous opportunities in which information additional to what is necessary for appropriate control, inspection and approval procedures was required from the applicant. Argentina contends that since 27 February 2002, the date on which the SCF expressed its favourable opinion, there has been no further progress in the approval process. Argentina indicates that the application was withdrawn in September 2003 because no progress had been made since 27 February 2002.

7.2227 The **European Communities** argues that the 18 months spent at member State level were due to the incompleteness of the dossier initially submitted and to the need for additional scientific data.[1595] The dossier was circulated at the Community level in January 2000, as required by the regulation. Many member States requested additional information and raised questions, several raised objections mainly on grounds of insufficient data on molecular characterisation and on compositional analysis (substantial equivalence). In May 2000, the Commission requested the opinion of the SCF. The SCF found that the dossier did not contain sufficient information concerning substantial equivalence and toxicity testing, and had to request the relevant information from the applicant.[1596] The SCF finally issued its opinion February 2002.

7.2228 The European Communities notes the difference between risk assessment and risk management and argues that the former is the task of the scientific committees, while the latter is the function of the Regulatory Committee. Since the Regulatory Committee fulfils risk management functions, it has to take into account all relevant factors, including risk assessment *stricto sensu*. The

[1593] Exhibit EC-91/At. 45, p. 1.
[1594] Exhibit EC-91/At. 45**,** p. 2.
[1595] Exhibit EC-91/At. 1-6.
[1596] *See* Request of 24 April 2001 (Exhibit EC-91/At. 17).

European Communities argues that the draft measures forwarded by the Commission to the Regulatory Committee are therefore supported by scientific assessments, but also address other legitimate issues, including risk management issues, which are not addressed by a scientific committee.

7.2229 In relation to Regulation 258/97, the European Communities contends that in terms of risk management it became clear in 1999 that there would have to be new legislation addressing issues such as labelling and traceability, and also the development and validation of detection methods. In relation to the application concerning GA21 maize (food), the European Communities submits that the SCF's opinion did not address sufficiently all relevant elements. The elements which determined the insufficiency of the SCF's opinion related to the issues of validation of detection methods, which were requirements to be included in the new legislation on "Food and Feed" and on whose importance the applicant agreed. More particularly, the European Communities notes that in view of the pending legislative proposal for "Food and Feed", in June 2002 the applicant committed on a voluntary basis to providing detection and validation methods for its product in collaboration with the Joint Research Centre of the Commission (hereafter the "JRC").

7.2230 The European Communities notes that agreement on the amount of data and material and the circumstances of their submission to the JRC took a considerable amount of time. All the necessary data were received in proper condition in mid-September 2003. The pre-validation study was initiated in October and was concluded after the applicant delivered the full data set at the end of November 2003. Some additional testing on the method and materials was carried out in early 2004. The collaborative study of method validation was launched in April 2004 and was expected to be finished by the end of June 2004.

7.2231 The **Panel** begins its analysis by addressing the Commission's failure up to August 2003 to submit a draft measure to the Regulatory Committee.

Failure by the Commission to submit a draft measure to the Regulatory Committee

7.2232 We recall that the SCF issued a positive evaluation of this application in February 2002. Following the issuance of the SCF opinion, the Commission did not submit a draft measure to the Regulatory Committee at any point up to August 2003. The United States and Argentina argue that the Commission should have prepared and submitted a draft measure to the Regulatory Committee shortly after the issuance of the SCF opinion.

7.2233 The record shows that some two months after the issuance in February 2002 of the favourable opinion by the SCF Instead, on 23 April 2002, the applicant informed the Commission that it was no longer seeking to obtain approval to place on the market unprocessed GA21 maize grain for food use. The applicant explained that this food use would be subject to Directive 90/220[1597], and noted that the progress of the application concerning GA21 maize (EC-78) under Directive 90/220 had been suspended for some time. The applicant was hoping that this move would enable the application under Regulation 258/97 to proceed immediately.[1598]

[1597] Pursuant to Article 9 of Regulation 258/97, in the case of foods or food ingredients containing or consisting of GMOs, the approval decision to be taken must "respect the environmental safety requirements laid down by Directive 90/220 to ensure that all appropriate measures are taken to prevent the adverse effects on human health and the environment which might arise from the deliberate release of [GMOs]".

[1598] Exhibit EC-91/At. 44.

7.2234 The record further shows that more than a month later, on 5 June 2002, the Commission services met with the applicant. According to a Commission report about the meeting, the Commission indicated at the meeting that "it would be desirable that a [draft measure on the application] would take into account in an appropriate manner the legislative developments with respect to the authorization of GM food and feed as well as the labelling of GM products".[1599] Specifically, the Commission sought voluntary commitments with regard to the labelling of foods and food ingredients derived from GA21 maize as well as with regard to detection methods and reference materials.

7.2235 At the June 2002 meeting, the applicant agreed to provide additional information and materials, including a detection method, so as to provide a basis for traceability, as envisaged in the new EC rules proposed by the Commission. The Commission's report of the meeting notes in this regard that the Commission might present a draft measure to the Regulatory Committee in November 2002, provided that a validated detection method was available by then. At the time of establishment of the Panel, the question of the validation of the detection method had not yet been resolved, and so by August 2003 no draft measure had been forwarded to the Regulatory Committee.

7.2236 The record of the approval procedure concerning GA21 maize (food) does not contain any evidence to show that the Commission in this procedure launched inter-service consultations on a draft measure after the issuance in February 2002 of the favourable opinion by the SCF. This contrasts with the record of other approval procedures which contains such evidence.[1600] Therefore, we cannot assume that inter-service consultations were launched on a draft measure on GA21 maize (food).

7.2237 Indeed, it appears that the Commission preferred first to explore whether the applicant would be willing to provide certain additional information, or to make certain additional commitments, on the basis of proposals for new EC legislation. While we accept that the applicant's response could have had an impact on the kind of draft measure on which the Commission would launch inter-service consultations, this circumstance would not explain why the Commission waited for more than three months after the issuance of the SCF opinion before approaching the applicant.

7.2238 Since the Commission was seeking voluntary commitments, it was possible that the applicant would reject the Commission's request in its entirety. Had the applicant done so, the Commission would have delayed the procedure by more than three months, as the Commission would have launched inter-service consultations only at that point.

7.2239 The record contains no information which suggests that June 2002 was the earliest date on which the Commission could have sought the relevant voluntary commitments. Indeed, the European Communities itself stated in relation to Regulation 258/97 that in terms of risk management it became clear in 1999 that there would have to be new legislation addressing issues such as labelling and traceability, and also the development and validation of detection methods. In the light of this, we fail to see why it would not have been possible for the Commission to explore the possibility of voluntary commitments with the applicant already in March 2002 rather than only in June 2002. Indeed, the Commission had circulated proposals for appropriate EC legislation as early as July 2001. Had the applicant said no to the Commission's request, this would have disposed of the issue.

7.2240 In fact, it is clear from the record that the applicant showed little interest in undertaking additional commitments with regard to labelling. However, the applicant did accept the

[1599] Exhibit EC-91/At. 45.
[1600] *See, e.g.*, Exhibits EC-62/At. 76; EC-65/At. 60.

Commission's request to provide reference material and a detection method which was to be validated by the Joint Research Centre of the Commission. It appears to us from the record that the applicant accepted this request on the basis of the Commission proposals for new legislation, since the European Parliament was apparently scheduled to debate the proposals only in July 2002. This supports our view that the Commission could have sought this particular commitment prior to June 2002.

7.2241 The Commission's report of the June 2002 meeting indicates that the Commission expected "no particular problem with respect to the validation. However, the availability of reference material has not been discussed."[1601] It is clear from this statement that the Commission was aware that relevant material might or might not have been available, and that it was therefore possible that the applicant would require time to put together relevant data and material. Moreover, as this approval procedure shows, a material transfer agreement needed to be reached before any materials would be transferred. Finally, the Commission in its report of the June 2002 meeting made clear that it would not forward a draft measure to the Regulatory Committee until a detection method had been validated. Therefore, had the applicant been made aware of the Commission's request earlier, the detection method could have been validated sooner, and a draft measure would also have been submitted to the Regulatory Committee sooner.

7.2242 Taking account of the foregoing elements, we consider that for the purposes of exploring the possibility of the applicant undertaking voluntary commitments, the Commission could, and should, have approached the applicant soon after the issuance of the SCF opinion (or before) rather than more than three months later.

7.2243 Based on the above considerations, the Panel is of the view that, in the specific circumstances of this procedure, the time taken by the Commission to prepare and forward a draft measure to the Regulatory Committee – and in particular the time taken by the Commission to explore the possibility of the applicant undertaking voluntary commitments – was unjustifiably long.

7.2244 Regarding DS291, we recall that the United States claims that the approval procedure concerning GA21 maize (food) was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to submit a draft measure to the Regulatory Committee meeting concerning GA21 maize (food) prior to August 2003 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Commission's conduct was a consequence of the general moratorium on approvals.

7.2245 In view of our conclusion with regard to the Commission's failure to submit a draft measure to the Regulatory Committee, we do not go on to examine other arguments put forward by the United States and Argentina in support of their claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

[1601] Exhibit EC-91/At. 45.

Conclusions

7.2246 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to prepare a draft measure to be submitted to the Regulatory Committee – and in particular the time taken to explore the possibility of the applicant undertaking voluntary commitments – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning GA21 maize (food) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning GA21 maize (food), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, the Panel recalls its finding that the time taken by the Commission to prepare a draft measure to be submitted to the Regulatory Committee – and in particular the time taken to explore the possibility of the applicant undertaking voluntary commitments – was unjustifiably long. In the light of this finding, the Panel concludes that the European Communities failed to complete the approval procedure concerning GA21 maize (food) without "undue delay", thus breaching its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(iii) Bt-11 sweet maize (food) (EC-92)

7.2247 One Complaining Party, the United States, claims that the completion of the approval procedure concerning the Bt-11 sweet maize (food) has been unduly delayed.

7.2248 The **United States** submits that the processing of this application had been delayed at the Commission stage of the process, as the Commission had refused to forward a draft measure to the Regulatory Committee as is required to complete the approval process, and the request remained blocked as of then.

7.2249 The United States also points out that the application concerning Bt-11 sweet maize (food) is one of five applications identified by the United States which are pending at Commission level and which, as of the date of establishment of the Panel, have been pending for an average of four years and six months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning Bt-11 sweet maize (food) is undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2250 The **European Communities** notes that, after the lead CA sent its initial assessment report to the Commission in May 2000, four member States raised objections and several more requested additional information, relating mainly to the antibiotic resistance marker used (PAT protein) and to the toxicity studies done in relation to this protein as well as to molecular characterization.

7.2251 The Commission requested the opinion of the SCF in December 2000. The SCF requested further data which the applicant only supplied in February 2002. The SCF issued its opinion in April 2002, stating that on the basis of the information supplied in the application and further material supplied by the applicant in response to queries raised by member States and in the light of the published literature, it was to be concluded that Bt-11 sweet maize (food) was as safe for human food use as its conventional counterparts.

7.2252 According to the European Communities, in view of the pending legislative proposal on "Food and Feed", the applicant, on a voluntary basis, agreed to provide detection and validation methods for its product in collaboration with the JRC. The amount of data and material and the circumstances of their submission to the JRC were agreed upon in a planning meeting in October 2002. The first set of material sent at the beginning of 2003 was inadequate in terms of necessary amounts and the method provided by the applicant performed very poorly in a pre-validation study. The applicant delivered a proper method and all the necessary materials only by July 2003. The JRC finalized the validation method in October 2003.

7.2253 In November 2003, the Commission submitted a draft measure to the Regulatory Committee. At member States' request, however, the Commission did not ask for a formal vote, given that several member States considered that the scientific questions they had formulated earlier on the basis of their conflicting national scientific evaluations were still open, and others were still awaiting further scientific risk assessments of their national scientific committees. Between October and early December 2003, three new risk assessments were issued by the member States, all of which conflicted with the SCF opinion.

7.2254 Finally, the Commission asked for the formal vote on its draft measure. However, the draft measure did not obtain a qualified majority in the Regulatory Committee, nor subsequently in the Council. The draft measure was adopted by the Commission on 19 May 2004.

7.2255 With regard to the period of time taken by the Commission before requesting the SCF for an opinion, the **United States** maintains that when the application was first evaluated at the Community level in 2000, member States objected on the basis not of scientific grounds, but the general moratorium. The United States cites, as an example, that Denmark's Agriculture and Fisheries Council recalled "[i]n August 2000, Denmark submitted an objection to the approval of Bt-11 maize in respect of the novel food regulation with reference to the declaration approved by Denmark, France, Italy, Greece and Luxembourg on the suspension of new GMO licenses (the moratorium declaration), which was made at the Council meeting (environment) on 24-25 June 1999. The objection included a reference to the fact that, pending the approval of a regulation that would guarantee the labelling and effective tracing of GMOs and products derived from them, the moratorium countries would block any new licenses for the cultivation and marketing of GMOs."[1602] Also in August 2000, France cited the yet to be implemented food and feed regulations as a reason for withholding support for Bt-11 sweet maize (food), choosing to disregard comprehensive scientific findings and instead continue the moratorium on biotech reviews.[1603]

[1602] Exhibit EC-92/At. 80.
[1603] Exhibit EC-92/At. 23, p.2.

7.2256 According to the United States, there is no scientific basis for the requests from Austria, France and Greece for additional long-term animal feeding studies given the results of the compositional analyses, and the fact that feeding studies conducted on Bt-11 field maize had been provided along with simulated digestibility studies, and acute toxicity tests.[1604] Greece had acknowledged that these latter studies "showed not a single adverse effect in the dosage tested."[1605] Furthermore, Greece did not identify, with any specificity, any deficiencies in the data provided, nor any reason to believe that these proteins would behave any differently than any other protein would spontaneously develop new or different toxic properties or would otherwise interact with other components of the food. Instead, Greece merely noted that "the *in vitro* methodology to study degradability of Btk and PAT proteins can be improved", but failed to specify how.

7.2257 The key difference between sweet and field maize being that sweet maize has a higher amount of natural sugars, the United States maintains that there is no reason to believe that this fact alone would render the results of the safety assessments conducted on the field maize inapplicable to this product. Nonetheless, Austria, Greece and the United Kingdom also argued that additional compositional and safety data were necessary to establish the equivalence between Bt-11 sweet maize (food) and Bt-11 field maize. Austria summarily rejected the applicant's reliance on the risk assessments conducted by the lead CA and the SCP on Bt-11 field maize, on the grounds that this evidence "cannot be considered adequate since sweet maize and field maize have different component spectrums."[1606] Greece required "analyses for all the parameters" (especially for amino acids, fatty acids, anti-nutrients and secondary plant substances) for both the Bt-11 sweet maize (food) and Bt-11 field maize, without identifying any unique property that would make the Bt-11 sweet maize (food) behave differently than all of the data indicated was likely.[1607] Even though the United Kingdom acknowledged that "it is accepted that the protein [in sweet maize] is the same as in the field maize", it nevertheless objected on the grounds that studies relating to the expression of the introduced genes in sweet maize were necessary.[1608] No further explanation was provided for rejecting the results of the safety data conducted on the parent field maize.

7.2258 The United States observes that these concerns were discounted by the SCF. Indeed, the SCF noted that "the distinction between the results for the sweet maize and field maize is not relevant to the assessment as long as the appropriate corresponding non-modified maize is used as control".[1609]

7.2259 With regard to the period after the positive assessment of the SCF in April 2002, the United States notes that the European Communities attempts to justify delays in the processing of the Bt-11 application by claiming that "[b]etween October and early December 2003 [after the SCF positive opinion], three new risks assessment were issued by the Member States, all of which conflicted with the SCF opinion".[1610] These risk assessments were supposedly provided by Austria, Belgium and France. The United States maintains that the EC contention is unsupported by the record. No risk assessments were submitted during that time period, according to the European Communities' own chronology. None of the documents submitted during that time period contain any purported risk assessments conducted by France, Austria, or Belgium. At the 10 November 2003 meeting of the

[1604] The applicant had referenced the whole food feeding studies it had performed on Bt-11 field maize in its submission of 28 November 1998. The European Communities did not provide the original submission of 6 April 1998 for processed products of sweet maize.

[1605] Exhibit EC-92/At. 28.

[1606] Exhibit EC-92/At. 25.

[1607] Exhibit EC-92/At. 28.

[1608] Exhibit EC-92/At. 22.

[1609] Exhibit EC-92/At. 53, section 3.10.

[1610] Responses by the European Communities to the questions posed by the Panel on 3 June 2004, Response to Question 1.

Regulatory Committee,[1611] only a comment was provided by France, not a risk assessment.[1612] At the Regulatory Committee meeting on 8 December 2003, Austria[1613], Belgium[1614] and France[1615] submitted written declarations to their votes. But none of these was a risk assessment. Rather, when the Regulatory Committee failed to obtain a qualified majority, it was because certain member States objected due to the proposed new traceability and labelling regulations (which did not become effective until April 2004).[1616]

7.2260 The **Panel** begins its analysis by addressing the Commission's failure up to August 2003 to submit a draft measure to the Regulatory Committee.

Failure by the Commission to submit a draft measure to the Regulatory Committee

7.2261 We recall that the SCF issued a positive evaluation of this application in April 2002. Following the issuance of the SCF opinion, the Commission did not submit a draft measure to the Regulatory Committee at any point up to August 2003, although subsequently it did submit a draft measure to the Regulatory Committee which was on the Committee's agenda in November 2003. The United States argues that the Commission should have prepared and submitted a draft measure to the Regulatory Committee shortly after the issuance of the SCF opinion in April 2002.

7.2262 More than a month and a half later, on 5 June 2002, the Commission services met with the applicant. The Commission in its report of the meeting states that "it would be desirable that a [draft measure on the application] would take into account in an appropriate manner the legislative developments with respect to the authorization of GM food and feed as well as the labelling of GM products".[1617]

7.2263 More specifically, the report of the meeting addresses the issue of "[d]etection methods, traceability, reference materials [and] identification". According to the report, the applicant "agree[d] to provide" the necessary information and materials to the JRC in a timely manner.[1618] There is nothing in the record which indicates that this "agreement" from the applicant was not voluntary. The report notes that a draft measure might be presented to the Regulatory Committee in November 2002, provided that a validated detection method was available by then. At the time of establishment of the

[1611] Exhibit EC-92/At. 67.

[1612] The French comment does not "evaluate the potential for adverse effects on human or animal health" posed by the sweet corn's different sugar metabolism from field corn. The comment is concerned with unintended effects, theoretical risks not identified by any of the existing protein toxicity or animal studies conducted. As the Commission stated in its Proposal for a Council Decision of 28 January 2004, "[t]he concerns raised in the opinion of the 'Agence française de sécurité sanitaire des aliments' (AFSSA) of 26 November 2003 do not bring any new scientific elements in addition to the initial assessment of sweet maize Bt-11 carried out by the competent authorities of the Netherlands". In fact, these concerns were also expressed in two AFSSA opinions of 21 July 2000 and 20 March 2001 and were duly considered by the SCF in its opinion of 17 April 2002, which confirmed the findings of the initial assessment that Bt-11 sweet maize is as safe for human food use as conventional maize. Exhibit EC-92/At. 77.

[1613] Exhibit EC-92/At. 71.

[1614] Exhibit EC-92/At. 73.

[1615] Exhibit EC-92/At. 72.

[1616] Exhibit EC-92/Ats. 67 ("Finally, several Member States questioned the opportunity to proceed with the authorization of this product in anticipation of the coming into application of Regulation (EC) 1829/2003 and 1830/2003."),71,74,75 and76.

[1617] Exhibit EC-92/At. 54.

[1618] *Ibid*.

Panel, the question of the validation of the detection method had not yet been resolved, and so by August 2003 no draft measure had been forwarded to the Regulatory Committee.

7.2264 The record of the approval procedure concerning Bt-11 sweet maize (food) does not contain any evidence to show that the Commission in this procedure launched inter-service consultations on a draft measure after the issuance in April 2002 of the favourable opinion by the SCF. This contrasts with the record of other approval procedures which contains such evidence.[1619] Therefore, we cannot assume that inter-service consultations were launched on a draft measure on Bt-11 sweet maize (food).

7.2265 Indeed, it appears that the Commission preferred first to explore whether the applicant would be willing to provide certain additional information, or to make certain additional commitments, on the basis of proposals for new EC legislation. While we accept that the applicant's response could have had an impact on the kind of draft measure on which the Commission would launch inter-service consultations, this circumstance would not explain why the Commission waited for more than a month and a half after the issuance of the SCF opinion before approaching the applicant.

7.2266 Since the Commission was seeking voluntary commitments, it was possible that the applicant would reject the Commission's request in its entirety. Had the applicant done so, the Commission would have delayed the procedure by more than a month and a half, as the Commission would have launched inter-service consultations only at that point.

7.2267 The record contains no information which suggests that June 2002 was the earliest date on which the Commission could have sought the relevant voluntary commitments. Indeed, the European Communities itself stated in relation to Regulation 258/97 that in terms of risk management it became clear in 1999 that there would have to be new legislation addressing issues such as labelling and traceability, and also the development and validation of detection methods. In the light of this, we fail to see why it would not have been possible for the Commission to explore the possibility of voluntary commitments with the applicant earlier than only in June 2002. Indeed, the Commission had circulated proposals for appropriate EC legislation as early as July 2001. Had the applicant said no to the Commission's request, this would have disposed of the issue.

7.2268 In fact, the applicant did accept the Commission's request to provide reference material and a detection method which was to be validated by the Joint Research Centre of the Commission. It appears to us from the record that the applicant accepted this request on the basis of the Commission proposals for new legislation, since the European Parliament was apparently scheduled to debate the proposals only in July 2002. This supports our view that the Commission could have sought this particular commitment prior to June 2002.

7.2269 As we have noted earlier in the context of the approval procedure concerning GA21 maize (food), we have reason to believe that in seeking the provision by the applicant of a detection method, the Commission was aware that relevant reference material might or might not have been available, and that it was therefore possible that the applicant would require time to put together relevant data and material. Moreover, as the European Communities itself points out, the amount of data and material and the circumstances of their submission to the JRC needed to be agreed upon. Finally, the Commission in its report of the June 2002 meeting made clear that it would not forward a draft measure to the Regulatory Committee until a detection method had been validated. Therefore, had the applicant been made aware of the Commission's request earlier, the detection method could have been

[1619] *See, e.g.*, Exhibits EC-62/At. 76; EC-65/At. 60.

validated sooner, and a draft measure would also have been submitted to the Regulatory Committee sooner.

7.2270 In our view, since the Commission sought the provision of a detection method on a voluntary basis, the Commission could even have approached the applicant prior to the issuance of the SCF opinion in April 2002. The applicant would then have had the opportunity to make sure that reference material and other documents and materials relevant to the validation of a detection method were available if and when the Commission sought their transmission. Indeed, we note that in the approval procedure concerning NK603 maize (food), work on method validation was undertaken even before the Commission had sought a scientific opinion of the EFSA.[1620]

7.2271 Taking account of the foregoing elements, we consider that for the purposes of exploring the possibility of the applicant undertaking voluntary commitments, the Commission could, and should, have approached the applicant either before or soon after the issuance of the SCF opinion rather than more than a month and a half later.

7.2272 Based on the above considerations, the Panel is of the view that, in the specific circumstances of this procedure, the time taken by the Commission to prepare and forward a draft measure to the Regulatory Committee – and in particular the time taken by the Commission to explore the possibility of the applicant undertaking voluntary commitments – was unjustifiably long.

7.2273 In addition, we recall that the United States claims that the approval procedure concerning Bt-11 sweet maize (food) was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the Commission's failure to submit a draft measure to the Regulatory Committee meeting concerning Bt-11 sweet maize (food) prior to August 2003 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Commission's conduct was a consequence of the general moratorium on approvals.

7.2274 In view of our conclusion with regard to the Commission's failure to submit a draft measure to the Regulatory Committee, we do not go on to examine other arguments put forward by the United States and Argentina in support of their claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.2275 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the Commission to prepare a draft measure to be submitted to the Regulatory Committee – and in particular the time taken to explore the possibility of the applicant undertaking voluntary commitments – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the Commission's conduct was a consequence of the general moratorium on approvals. Based on these

[1620] Exhibit EC-96/At. 34, as well as entries concerning 20 February 2003 and 31 March 2003.

findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning Bt-11 sweet maize (food) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning Bt-11 sweet maize (food), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(iv) LL soybeans (food) (EC-93)

7.2276 Two Complaining Parties, the United States and Argentina, claim that the completion of the approval procedure concerning LL soybeans (food) has been unduly delayed.

7.2277 The **United States** submits that the lead CA (Belgium) refused to forward the application for LL soybeans (food) for consideration at the Community level.

7.2278 The United States also points out that the application concerning LL soybeans (food) is one of four applications identified by the United States which have been pending at the member State level for an average of three and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning LL soybeans (food) is excessive and unjustified and, hence, undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2279 **Argentina** claims that as of the date of Argentina's first written submission the application was delayed at the member State level for 5 years and 8 months without a final decision on its approval. Argentina asserts that the European Communities neither processed the application nor conducted the required risk assessment. Argentina argues that there is no scientific justification for the delay, as the "initial reports" were not prepared.

7.2280 The **European Communities** notes that the application for LL soybean (food) was with the Belgian CA only as of February 1999. The Commission gave notice of the Belgian application to all other member States in March 1999. In April 1999, the Belgium Biosafety Council requested additional information from the applicant in order to proceed with the initial assessment. The request touched upon the issues of substantial equivalence and presence of transgenic PAT DNA and PAT protein.[1621] The applicant did not fully respond to this request for additional information. Greece (June 1999) and Italy (July 1999) also asked for additional information on various points such as nutritional and biochemical characterization and toxicity of the transgenic plant, but did not receive any answer.[1622] In April 2004, the lead CA reminded the applicant to respond to the requests for additional information so that it would be able to finalize the pending assessment report.

7.2281 The European Communities submits that the United States and Argentina choose to ignore the fact that the applicant failed to provide the additional information that was requested by the lead CA in April 1999, and by Greece and Italy in June and July 1999. According to the European Communities, all three requests for additional information remained mostly unanswered. The European Communities also notes that on 6 July 2004, the applicant withdrew its application.

[1621] Exhibit EC-93/At. 11.
[1622] Exhibit EC-93/Ats. 16 and 17.

7.2282 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.2283 We note that contrary to what the European Communities asserts, the application concerning LL soybeans (food) was with the Belgian CA as of early December 1998, and not only as of February 1999.[1623] On 8 December 1998, the Belgian General Food Inspectorate requested the Belgian Biosafety Council to prepare a first evaluation report within 90 days of referral of the file.

7.2284 The record indicates that the Biosafety Council met on the application on 17 December 1998. At that meeting, concerns were raised that while the application focused on animal nutrition, a number of tests concerning possible human consumption impacts were absent. The applicant apparently gave a written undertaking to address these concerns relating to substantial equivalence following instructions from a Belgian expert.[1624]

7.2285 Towards the end of April 1999, the Belgian Biosafety Council responded to a query from the Belgian General Food Inspectorate. The letter notes that the applicant had still not addressed the Biosafety Council's concerns relating to substantial equivalence. The letter further states that the applicant needed to provide additional information regarding the implementation of labelling and, more specifically, the presence of PAT DNA and PAT protein in derived soya products.[1625] The letter of the Biosafety Council concludes by saying that due to the absence of data and information on substantial equivalence and the presence of transgenic PAT DNA and PAT protein it was not possible for the Biosafety Council to issue a final evaluation report with regard to the application concerning LL soybeans (food). We asked the experts advising us whether information regarding substantial equivalence and the presence of transgenic PAT DNA and PAT protein was necessary to ensure that conclusions of the safety assessment were valid. Dr. Nutti responded that these requests were valid.[1626]

7.2286 In May 1999, the lead CA sent a reminder to the applicant informing it that it had yet to reply to the two requests for additional information referred to in the letter of April 1999.[1627] The lead CA also informed the Commission that the deadline for evaluation of this application would not be met due to the lack of response from the applicant to the aforementioned two requests for additional information.[1628] The record indicates that as of August 2003, the applicant had still not fully replied to the first request relating to substantial equivalence.[1629] It appears that the applicant responded to the first request concerning the presence of PAT DNA and PAT protein in derived soya products, but it is not clear when.[1630]

7.2287 Greece (June 1999) and Italy (July 1999) also requested additional information regarding nutritional and biochemical characterization and toxicity of the transgenic plants. We again asked the experts advising us whether the additional information requested by Greece and Italy was necessary to ensure that conclusions of the safety assessment were valid. Dr. Nutti responded that the application did not provide all the information which would be expected in order to comply with the recommended Codex evaluation procedure, and therefore the requests for some of this information

[1623] Exhibit EC-93/Ats. 1 and 3.
[1624] Exhibit EC-93/At. 11.
[1625] *Ibid*.
[1626] Annex H, Dr. Nutti's response to Panel Question 48.
[1627] Exhibit EC-93/At. 14.
[1628] Exhibit EC-93/At. 13.
[1629] Exhibit EC-93/At. 25.
[1630] *Ibid*.

were justified.[1631] In December 2000 and again in July 2001, the applicant apparently provided additional information to the lead CA regarding insert characterization, however this information was not provided to us. In the same correspondence, the applicant indicated that information on compositional analyses would be forthcoming at a later date.[1632] Seven months later, in correspondence dated July 2001, the applicant apparently provided information to satisfy these requests, although this information was not included in the evidence provided to us.[1633]

7.2288 In August 2001, the lead CA requested clarification regarding nutritional composition, stating that the data provided by the applicant in July 2001 had not adequately addressed the lead CA's request of April 1999. We again asked the experts whether this clarification was necessary to ensure that conclusions of the safety assessment were valid. Dr. Nutti noted that the information requested would normally be necessary to judge the safety of the product, however given the incompleteness of the record, it was impossible for her to determine whether or not this information had previously been provided to the lead CA.[1634] The lead CA also inquired about a broiler chicken growth performance study which the applicant had said was already included in the dossier, but which the lead CA could not find. Finally, the lead CA indicated that in accordance with new recommendations by the Biosafety Council on molecular characterization, the lead CA would be requesting some additional information on molecular characterization.

7.2289 The record suggests that the applicant never replied to the August 2001 request for clarification. Indeed, in June 2003, in internal e-mail correspondence concerning a request from the Commission for an update on this dossier, the lead CA highlighted the fact that the applicant had not provided the requested broiler chicken growth study. The lead CA also indicated that it had requested, but not received, additional information on molecular characterization. However, the record does not indicate that such a request was forwarded to the applicant.[1635]

7.2290 It is unfortunate that the evidence provided on this application is incomplete. While the experts indicated that much of the information requested by the lead CA and by other member States was necessary to ensure a valid safety assessment, it was not possible to determine to what extent such information may already have been provided by the applicant. It is also very difficult to determine from the information before us whether particular requests for information were met by the applicant.

7.2291 This said, as noted earlier, it appears that the applicant never fully replied to the lead CA's April 1999 request for additional information. As also noted, the part of the request which remained unresolved, notwithstanding the applicant's undertaking to provide the relevant information, was made known to the applicant already after the December 1998 meeting. It also appears that the responses which were given by the applicant in response to the April 1999 request were not provided in a timely manner. Furthermore, the record suggests that the applicant never responded to the August 2001 request for clarification. In fact, there does not appear to have been any further communication from the applicant until it withdrew its application in July 2004.

7.2292 In the light of the foregoing elements, and in particular the fact that the applicant did not provide information it apparently undertook to provide and otherwise failed to respond to requests for information which were not explicitly challenged, we are not persuaded by the United States' and

[1631] Annex H, Dr. Nutti's response to Panel Question 49.
[1632] Exhibit EC-93/At. 21.
[1633] Exhibit EC-93/At. 22.
[1634] Annex H, Dr Nutti's responses to Panel Question 50.
[1635] Exhibit EC-93/At. 25.

Argentina's assertion that the time taken by Belgium up to August 2003 to assess the application concerning LL soybeans was unjustifiably long.

7.2293 In view of our conclusion with regard to the time taken by Belgium for its assessment, we go on to examine other arguments put forward by the United States and Argentina in support of their claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Total amount of time taken since submission of application

7.2294 The United States and Argentina also put forward the argument that the total amount of time during which the application concerning LL soybeans (food) was pending is excessive and unjustified. The application concerning LL soybeans (food) was first submitted for approval at the end of November 1998. This means that as of August 2003, the approval procedure had been pending for four years and nine months.

7.2295 We agree with the United States and Argentina that, in absolute terms, this is a long period of time for an initial assessment. However, as we have explained earlier, the mere identification of the total amount of time during which an application has been pending does not demonstrate, in and of itself, that the time taken was unjustifiably long.

7.2296 The United States argues that that before there was an EC moratorium, approval procedures used to be completed in less than three years. Even if the United States were correct, however, it must be remembered that the European Communities assesses applications on a case-by-case basis. Thus, the fact that the approval procedure concerning LL soybeans (food) was not completed in less than three years in our view does not demonstrate that it was not justifiable for the European Communities to take more time to process that particular application.

7.2297 The United States further argues that in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, the fact that the application in question lingered at the member State level for well over four years demonstrates the existence of undue delay. We recall in this respect our finding that the record supports the conclusion that the European Communities applied a *de facto* moratorium on approvals as of June 1999. At that time, the application concerning LL soybeans (food) had already been pending for almost seven months. Thus, some of the total time taken cannot be explained by the moratorium. Moreover, the mere fact that a general moratorium was in effect does not necessarily imply that a particular application was affected by it. The United States itself has repeatedly stated that "the moratorium was a decision by the EC not to move products to a *final* decision in the approval process" and that "certain progress in the process, short of a final decision, is not the least bit inconsistent with a moratorium on final approvals".[1636] Therefore, by itself, the fact that a moratorium on approvals was in effect between June 1999 and August 2003 is not sufficient to demonstrate that the period of time during which the application concerning LL soybeans (food) was pending as of August 2003 reflects a failure on the part of the lead CA to complete the relevant approval procedure without undue delay.

7.2298 Accordingly, the Panel is unable to accept the United States' and Argentina's assertion that the total period of time during which the application concerning LL soybeans (food) had been pending as of August 2003 demonstrates that the time taken was unjustifiably long.

[1636] *See, e.g.*, US second written submission, para. 51 (emphasis in original).

Conclusions

7.2299 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that it has not been established that the time taken by the lead CA for its initial assessment of the application concerning LL soybeans (food) was unjustifiably long, or that the total period of time during which the application concerning LL soybeans (food) had been pending as of August 2003 demonstrates that the time taken by the European Communities was unjustifiably long. Based on these findings, the Panel is unable to accept the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning LL soybeans (food) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning LL soybeans (food), the United States has failed to establish that the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, the Panel recalls its findings that it has not been established that the time taken by the lead CA for its initial assessment of the application concerning LL soybeans (food) was unjustifiably long, or that the total period of time during which the application concerning LL soybeans (food) had been pending as of August 2003 demonstrates that the time taken by the European Communities was unjustifiably long. In the light of these findings, the Panel concludes that in respect of the approval procedure concerning LL soybeans (food), Argentina has failed to establish that the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(v) MON810 x GA21 maize (food) (EC-94)

7.2300 One Complaining Party, the United States, claims that the completion of the approval procedure concerning MON810 x GA21 maize (food) has been unduly delayed.

7.2301 The **United States** argues that approval for MON810 x GA21 maize (food), which is produced by conventionally hybridizing two "parental" biotech products, MON810 maize and GA21 maize, has been delayed by the failure of the lead CA to complete its initial assessment. More specifically, the United States argues that at the time of establishment of the Panel, the application had already been under consideration by the lead CA for three and a half years. The United States contends that this lag had two distinct causes.

7.2302 According to the United States, one cause for the lag was the undue delay in the EC approval of GA21 maize under Regulation 258/97. The application for approval of MON810 x GA21 maize (food) submitted under Regulation 258/97 referenced the detailed risk assessments undertaken on the parental biotech products, complemented with confirmatory safety and characterization data on the MON810 x GA21 hybrid. One parent, MON810 maize, was approved under Directive 90/220 in

1998[1637] and was notified in 1998 on the basis of an opinion of substantial equivalence as required under Regulation 258/97 in 1998.[1638] However, the application for the single trait parent GA21 maize (food) under Regulation 258/97 stalled at the Commission level after the Commission requested an opinion from the SCF in May 2000 and then again after the final SCF opinion in February 2002. Therefore, progress on GA21 maize (food) was a limiting step on the progress of the application concerning MON810 x GA21 maize (food) in the regulatory process. In fact, in its comments on the application for MON810 x GA21 maize (food), Italy stated that "examination of the documentation relating to authorization [of MON810 x GA21 maize] should only be carried out after the marketing of GA21 has been authorized [under Regulation 258/97]."[1639] At the time of establishment of the Panel, the approval of GA21 maize (food) under Regulation 258/97 had not yet been granted.

7.2303 The United States contends that the other cause of the lag reflected, in part, the need for the applicant to respond to requests for information that were scientifically unjustified. The United States points out that the lead CA insisted on molecular characterization of the MON810 x GA21 line without regard to the previous data that had been submitted on the parental lines. In particular, the lead CA requested an additional whole food study in mice.[1640] The rationale offered for this request was the need to address hypothetical concerns that unknown pieces of DNA could be scattered over the genome. The impact of any such insertions can be determined by evaluating the compositional analyses of the plant as well as its agronomic performance. If both analyses indicate no unexpected changes, the United States argues, there is no basis on which to hypothesize a food safety concern for food from the plant. In this case, such assessments had been performed on each of the parental lines and no unexpected changes were observed. At no time did the lead CA provide any explanation of the reason it believed that the compositional analyses or feeding studies previously submitted on both the parent lines, as well as the compositional analyses submitted on the hybrid, did not adequately address this issue.

7.2304 The United States notes that, nonetheless, the applicant analysed the composition of the MON810 x GA21 maize, which was found to be comparable to that of the parental lines and other commercial maize varieties.[1641] The applicant also had previously submitted several whole food feeding studies, including a 90-day feeding study in rats using MON810 maize or GA21 maize, and a broiler chicken feeding study using grain from MON810 x GA21 maize. None of these studies revealed any adverse effects.

7.2305 Furthermore, the United States notes, the lead CA requested further information on the levels of EPSPS protein expressed in the hybrid lines, although such information is not relevant to assessing the risks given the known safety information about the EPSPS protein.[1642] The lead CA also requested unnecessary comparisons of compositional data between the new hybrid and non-transgenic control lines. The data submitted in the application analysed the new hybrid in comparison to the

[1637] Commission Decision concerning the placing on the market of genetically modified maize (zea mays L. line MON810) pursuant to Council Directive 90/220/EEC, (98/294/EC), April 22, 1998, Official Journal of the European Communities, L 131/32, May 5, 1998 (Exhibit US-131).

[1638] Exhibit US-132.

[1639] Exhibit EC-94/At. 11.

[1640] Exhibit EC-94/At. 12.

[1641] Exhibit EC-82/At. 9.

[1642] The United States refers to LA Harrison, MR Bailey, MR Naylor, JE Ream, BG Hammond, DL Nida, BL Burnette, TE Nickson, TA Mitsky, ML Taylor, RL Fuchs, and SR Padgette, "The Expressed Protein in Glyphosate-Tolerant Soybean, 5-Enolypyruvylshikimate-3-Phosphate Synthase from Agrobacterium sp. Strain CP4, Is Rapidly Digested in Vitro and Is Not Toxic to Acutely Gavaged Mice", *Journal of Nutrition* 126:728-740 (1996) (Exhibit US-143).

transgenic parental lines.[1643] The transgenic parental lines had already been shown to be substantially equivalent to non-genetically modified maize except for the introduced traits. Given all of the data that had been submitted on both parental lines, the United States argues that the requests for yet further studies lacked any scientific basis.

7.2306 According to the United States, the United Kingdom also insisted that the applicant provide extensive characterization of the new hybrid, rather than rely on the analyses previously carried out on the transgenic parental lines.[1644] As part of this request, the United Kingdom requested molecular characterization to "confirm[] the absence of antibiotic resistance markers and have details regarding the homology between the two constructs introduced as a result of the crosses."[1645] Given that neither parent contained an antibiotic marker gene, there is absolutely no scientific basis, in the United States' view, for theorizing that cross-breeding between the two products would somehow introduce such a gene.

7.2307 Under these circumstances, the United States argues that it was pointless for the applicant to devote resources to pursue the application for MON810 x GA21 maize (food) as long as consideration of the applications for the single trait parent GA21 maize remained suspended under the moratorium. The United States contends that the delay in the application for MON810 x GA21 maize (food) and GA21 maize (food) is thus a direct consequence of the delays in the application for GA21 maize under the moratorium. The United States further points out that because of the delay in the approval procedure concerning GA21 maize (food), that product, as well as MON810 x GA21 maize, have been superseded by a second generation Roundup Ready maize product (NK603 maize and NK603 × MON810 maize, respectively). Nonetheless, the applicant has continued to pursue the necessary regulatory clearance for MON810 x GA21 maize (food).

7.2308 The United States submits, in addition, that the application concerning MON810 x GA21 maize (food) is one of four applications identified by the United States which have been pending at the member State level for an average of three and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning MON810 x GA21 maize (food) is undue. The United States further argues that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2309 The **European Communities** argues that the lead CA requested additional information from the applicant in July 2000, and that that request was only partly answered in February 2002. Contrary to the United States, the European Communities maintains that the lead CA request for a whole food study in mice was necessary to assess unintended effects caused by possible additional DNA fragments. The request was made on valid grounds. Therefore, the delay caused by it cannot be considered "undue." The European Communities adds that issues such as molecular characterization of inserted DNA from transgenic parent lines, the determination of flanking DNA or compositional analysis, still remain unaddressed. Furthermore, the European Communities considers that it is obvious that the assessment of a hybrid cannot be concluded as long as the assessment of one of its parental lines is still open.

7.2310 The **Panel** commences its analysis with the alleged delay at member State level.

[1643] Exhibit EC-94/At. 2.
[1644] Exhibit EC-94/At. 10.
[1645] *Ibid*.

Delay at member State level

7.2311 We recall that although the application was submitted on 29 February 2000, the record shows that the first contact by the lead CA to request additional information from the applicant occurred only on 17 July 2000[1646], *i.e.*, more than four and a half months after receipt of the application. The response to the July 2000 request for information was provided by the applicant only on 15 February 2002. Subsequently, there was a further, five-month delay before the lead CA followed up with the applicant to request additional information on 2 July 2002. Finally, we note that no information has been provided regarding any action on this application between July 2002 and August 2003. It appears that during that period the applicant did not respond to the lead CA's July 2002 request for information.

7.2312 The United States contends that the lengthy delay caused by the applicant due to the time it took to respond to the July 2000 request for information occurred, in part, because there was no justification for requesting the relevant data. In our earlier findings, we observed that the experts expressed the view that whereas some of the information requested by the lead CA was not necessary to ensure the validity of the safety assessment, other requested information was indeed needed. We also previously noted the disagreement of the European Communities with the views expressed by the experts regarding the need for the data requested.

7.2313 Even accepting that contrary to the views of the experts the information requested by the lead CA in July 2000 was necessary to ensure the validity of the safety assessment, this could not provide a justification for the time taken by the lead CA for its assessment of the application both before and after the July 2000 request for information.

7.2314 In examining the issue of the time taken by the lead CA before and after the July 2000 request, we first recall that Regulation 258/97 provides that the lead CA should complete its initial assessment within three months of receipt of an application which contains the necessary information. We recognize that the question of whether or not the lead CA complied with the three-month deadline stipulated in Regulation 258/97 is not dispositive, *per se*, of whether the European Communities met its WTO obligation to complete its approval procedures without undue delay. This said, in the Panel's view, the deadline set forth in Regulation 258/97 provides a useful indicator to guide the Panel's analysis. The three-month deadline is binding and applies to all relevant applications submitted under Regulation 258/97. It may therefore be assumed that the EC legislator set this binding deadline in such a way as to make it possible for the CAs of all member States to assess even complex applications within the prescribed deadline.

7.2315 We first turn to consider the time taken by the lead CA before forwarding its initial request for information of July 2000. We note that when the Commission circulated notice of this application to all member States, it indicated that the initial assessment was to be completed by the lead CA by 16 June 2000 at the latest.[1647] However, by 16 June 2000, the lead CA not only had not completed its initial assessment, but it apparently had not even identified any need for further information. It was not until one full month after the deadline circulated by the Commission that the lead CA forwarded an initial request for information.

7.2316 The European Communities asserts that all of the time taken by the lead CA was necessary to resolve scientific and technical issues, but provides no specific justification for the time taken by the lead CA up to July 2000. Even if it were accepted that in this procedure the lead CA could not have

[1646] Exhibit EC-94/At. 12.
[1647] Exhibit EC-94/At. 5.

met the mid-June deadline circulated by the Commission, this would not imply that the lead CA could not have requested missing information much sooner, rather than a full month after the date on which it should have completed its entire initial assessment.

7.2317 We note that three member States submitted substantive comments or requests for further data prior to July 2000.[1648] However, Regulation 258/97 does not require the lead CA to await comments from other member States, let alone possible responses thereto from the applicant, prior to undertaking its initial assessment.

7.2318 We have previously pointed out that the Netherlands was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, in this instance, we are not convinced that the Dutch CA's conduct reflects a precautionary approach. Indeed, we are not convinced that the Dutch CA could not have identified any need for additional information and forward an appropriate request for information to the applicant sooner than it did even while following a precautionary approach.

7.2319 We now turn to the time taken by the lead CA after it had received the applicant's response to its initial request for information of July 2000. As we indicated above, four and a half months lapsed between the receipt of the information requested in July 2000 and the next request, in July 2002, for additional information. Thus, the lead CA took more time to assess the additional information than it should have used, in accordance with Regulation 258/97, to complete its entire initial assessment.

7.2320 As with the time taken by the lead CA up to the first request for information, the European Communities asserts that the time taken by the lead CA up to the second request for information was necessary to resolve scientific and technical issues. However, the European Communities provides no specific justification for why the lead CA required more than four and a half months to complete its consideration of the responses provided and to identify short-comings. It is pertinent to note in this respect that the information provided by the applicant in response to the July 2000 request was 34 pages long. Given this, and in the absence of a specific justification offered by the European Communities, we are not convinced that the lead CA could not have evaluated much sooner than it did whether additional information was still needed. We also consider that the Dutch CA could have forwarded its July 2002 request for additional information to the applicant at a much earlier date even while following a precautionary approach.

7.2321 In relation to the time taken by the lead CA both before and after the July 2000 request for information, we note, as an additional matter, the European Communities argument that the assessment of a hybrid product such as MON810 x GA21 maize cannot be concluded as long as the assessment of one of its parental lines is still open. Thus, the European Communities appears to argue that the time taken by the lead CA to assess the application concerning MON810 x GA21 maize (food) is justified by the fact that the lead CA was waiting for the result of the Community level assessment of one of the parental lines of this hybrid product, GA21 maize (food).

7.2322 It is correct that between February 2000 and July 2002, the application concerning GA21 maize (food) was still being evaluated at Community level. However, the record does not indicate that the Dutch CA ever stated that it was unable to proceed due to the failure of the European Communities to approve the GA21 maize (food) parent. Moreover, we recall that it was the same Dutch CA which assessed the application concerning GA21 maize (food) and which in late January 2000 forwarded it to the Commission with a favourable assessment. Therefore, we see no reason why

[1648] Exhibit EC-94/Ats. 9-11.

the Dutch CA would not be in a position to reach a conclusion also with regard to the application concerning the hybrid product, *i.e.*, MON810 x GA21 maize.

7.2323 As a general matter, it may be correct to say, as the European Communities does, that "the assessment of a hybrid cannot be concluded as long as the assessment of one of its parental lines is still open". However, it would seem that the assessment of the parental lines could also be made in the context of the assessment of the hybrid. At any rate, the Dutch CA could not have "concluded" the assessment of the application concerning MON810 x GA21 maize (food) completely on its own. If other member States had concerns with the Dutch assessment of the application concerning GA21 maize (food) (even though that assessment was confirmed by the SCP in early 2002), they could have raised an objection on that basis to the Dutch assessment of the application concerning MON810 x GA21 maize (food) and the assessment of that application would then have been "concluded" at Community level.

7.2324 For these reasons, it is not apparent to us that the Dutch CA needed to keep, or would have been justified in keeping, the application at the member State level in order to avoid the possibility of conflicting assessments of MON810 x GA21 maize (food), and we therefore do not consider that the fact that one of the parental lines was still pending justified the Netherlands in not completing its assessment of the application concerning MON810 x GA21 maize (food).

7.2325 Taking account of all of the aforementioned elements, we consider that upon receipt of the original application and subsequently upon on receipt of the information requested by it in July 2000, the lead CA could, and should, have determined more promptly that additional information was needed and could, and should, have forwarded appropriate requests to the applicant more promptly.

7.2326 Based on the above considerations, we therefore conclude that the time taken by the lead CA for its assessment of the application concerning MON810 x GA21 maize (food) was unjustifiably long.

7.2327 In addition, we recall that the United States claims that the approval procedure concerning MON810 x GA21 maize (food) was unduly delayed because, due to the moratorium, the Netherlands failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the time taken by the Netherlands for its initial assessment of MON810 x GA21 maize (food) is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Netherlands' conduct was a consequence of the general moratorium on approvals.

7.2328 In view of our conclusion with regard to the time taken by the Netherlands for its initial assessment, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.2329 In the light of the above, we reach the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning MON810 x GA21 maize was

> unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning MON810 x GA21 maize (food) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning MON810 x GA21 maize (food), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(vi) Bt-1507 maize (food) (EC-95)

7.2330 One Complaining Party, the United States, claims that the completion of the approval procedure concerning Bt-1507 maize (food) has been unduly delayed.

7.2331 The **United States** argues that the lead CA (Netherlands) refused to forward this application to the Commission, thereby unduly delaying its consideration for approval.

7.2332 The United States also points out that the application concerning Bt-1507 maize (food) is one of four applications identified by the United States which have been pending at the member State level for an average of three and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning Bt-1507 maize (food) is undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2333 The **European Communities** observes that after receiving the application in February 2001, the lead CA asked for additional information in June 2001. This information was finally provided in February 2003. Between February 2003 and July 2003, there was ongoing correspondence between the applicant and the lead CA on additional information to be submitted by the applicant, in particular on labelling, monitoring, molecular characterization, and event-specific detection methods. The lead CA finalized the initial assessment report in November 2003 and concluded that the consumption of Bt-1507 maize as well as foods and food ingredients derived from it were as safe for humans as the consumption of the non-genetically modified counterparts.

7.2334 The European Communities further notes that the Commission forwarded the initial assessment report to member States for comments in December 2003, and received comments and reasoned objections against the initial assessment. On 26 March 2004, the complete dossier (including responses to the objections and comments raised by member States) was forwarded to EFSA for consideration under Regulation 1829/2003. In parallel, the applicant undertook the steps to ensure the production of certified reference material and for the validation of a detection method by the JRC.

7.2335 The **Panel** notes that the United States' claim is based on an alleged delay at member State level.

Delay at member State level

7.2336 We recall that the application concerning Bt-1507 maize (food) was submitted on 15 February 2001. However, the first request for additional information from the lead CA was made only on 28 June 2001, *i.e.*, almost four and a half months following receipt of the application. Although the applicant apparently provided a partial response in November 2001, it appears that it did not provide all of the information requested until 12 February 2003. Following the twenty-month period taken by the applicant to provide all the information requested, in March 2003, the lead CA requested further clarifications, which were provided in May 2003. In June 2003, the lead CA posed questions in relation to the applicant's May 2003 reply. The applicant provided answers by 9 July 2003. The information as provided by 9 July 2003 was apparently deemed sufficient by the lead CA to conclude its assessment. As noted, a positive assessment was reported on 4 November 2003.

7.2337 It is clear from the foregoing that the major delay in the assessment of this application is attributable to the time taken by the applicant to provide the information requested in June 2001. We asked the experts advising us for their views on the necessity of the information requested by the lead CA in June 2001 to ensure that the conclusions of the safety assessment were valid. We recall that the experts considered that some of the information requested by the lead CA in June 2001 was not necessary to ensure the validity of the safety assessment for Bt-1507 maize (food). This included some of the information which was not provided by the applicant until February 2003.

7.2338 Even if we were to accept that all of the information requested by the lead CA in June 2001 was necessary to ensure the validity of the safety assessment, this could not provide a justification for the time taken by the lead CA for its assessment of the application before the June 2001 request for information. We recall that the application concerning Bt-1507 maize (food) had been under review in the Netherlands for more than four and a half months before the Dutch CA forwarded its June 2001 request for information.

7.2339 In examining the issue of the time taken by the lead CA before the June 2001 request, we first recall that Regulation 258/97 provides that the lead CA should complete its initial assessment within three months of receipt of an application which contains the necessary information. We recognize that the question of whether or not the lead CA complied with the three-month deadline stipulated in Regulation 258/97 is not dispositive, *per se*, of whether the European Communities met its WTO obligation to complete its approval procedures without undue delay. This said, in the Panel's view, the deadline set forth in Regulation 258/97 provides a useful indicator to guide the Panel's analysis. The three-month deadline is binding and applies to all relevant applications submitted under Regulation 258/97. It may therefore be assumed that the EC legislator set this binding deadline in such a way as to make it possible for the CAs of all member States to assess even complex applications within the prescribed deadline.

7.2340 We note that by the time the lead CA forwarded its first request for information at the end of June 2001, the lead CA had already exceeded the three-month period envisaged in Regulation 258/97 by a month and a half, yet it was far from completing its initial assessment. The European Communities asserts that all of the time taken by the lead CA was necessary to resolve scientific and technical issues, but provides no specific justification for the time taken by the lead CA up to the end of June 2001. Even if it were accepted that in this procedure the lead CA could not have completed its initial assessment within the three-month period provided for in Regulation 258/97, this would not imply that the lead CA could not have requested missing information much sooner. Given the three-month maximum assessment period envisaged in Regulation 258/97, and lacking a specific justification by the European Communities, we are not convinced that the lead CA could not have evaluated much more promptly than it did whether additional information was still needed.

7.2341 We have previously pointed out that the Netherlands was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, in this instance, we are not convinced that the Dutch CA's conduct reflects a precautionary approach. Indeed, we are not convinced that the Dutch CA could not have identified any need for additional information and forwarded an appropriate request for information to the applicant sooner than it did even while following a precautionary approach.

7.2342 Taking account of all of the aforementioned elements, we consider that upon receipt of the original application, the lead CA could, and should, have determined more promptly that additional information was needed and could, and should, have forwarded an appropriate request to the applicant more promptly.

7.2343 Based on the above considerations, we thus conclude that the time taken by the lead CA for its assessment of the application concerning Bt-1507 maize (food) – and in particular the time taken by the lead CA before forwarding its first request for additional information – was unjustifiably long.

7.2344 In addition, we recall that the United States claims that the approval procedure concerning Bt-1507 maize (food) was unduly delayed because, due to the moratorium, the Netherlands failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the failure of the Netherlands to complete the initial assessment of the application concerning Bt-1507 maize (food) by August 2003 is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Netherlands failure to complete its initial assessment by August 2003 was a consequence of the general moratorium on approvals.

7.2345 In view of our conclusion with regard to the time taken by the Netherlands for its initial assessment, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusion

7.2346 In the light of the above, we reach the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning Bt-1507 maize (food) – particularly the time taken prior to the lead CA's initial request for additional information – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning Bt-1507 maize (food) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning Bt-1507 maize (food), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(vii) NK603 maize (food) (EC-96)

7.2347 Two Complaining Parties, the United States and Argentina, claim that the completion of the approval procedure concerning NK603 maize (food) has been unduly delayed.

7.2348 The **United States** argues that although the application concerning NK603 maize (food) eventually received a positive assessment from the lead CA (Netherlands), this product was at the member State level for almost 19 months, instead of the 90 days foreseen by Regulation 258/97. Of this period of time, only three and a half months were used by the applicant to provide additional information; the lead CA used the remaining fourteen and a half months.

7.2349 The United States questions certain requests for additional information from the lead CA, arguing they were scientifically unnecessary. For example, the lead CA requested an additional whole food feeding study in mice or rats, to address concerns about the presence of unintended DNA fragments that the applicant had identified as part of their molecular characterization data.[1649] The lead CA stated that "the presence of additional unintended modifications cannot be excluded with sufficient certainty". The United States argues that the mere fact that an additional insert is present does not necessarily mean that the product presents an additional risk. Rather, the determination turns on the results of all of the other data and information provided by the applicant, which the lead CA failed to take into consideration in making this request. If the results of those tests raise questions, then further examination would be warranted. But in this case, the applicant had conducted compositional analysis and a broiler chicken whole food study with the product containing the additional insert, and in these circumstances would have detected any resulting changes relevant to food safety. The United States observes that the applicant nevertheless conducted the requested test, which identified no adverse effects.

7.2350 The United States further argues that once the application had reached the Community level Austria filed an objection in respect of the application for NK603 maize (food) on the grounds that not only acute but also sub-chronic, mutagenic, reproductive and ecotoxic effects of the protein (EPSPS) should be studied. However, Austria failed to discuss the results of the acute studies, or to provide an explanation of why the proteins in this product would behave differently than all available data indicate is likely. The United States submits that given that EPSPS proteins are commonly found in a wide variety of food sources which have a long history of safe use, the available information regarding the enzyme function of the protein, lack of homology to toxic proteins based on bioinformatics searches, and lack of acute oral toxicity when administered to mice at high doses, the additional toxicological testing for the EPSPS protein that Austria demanded is unfounded and unreasonable. Such testing exceeds Codex Alimentarius guidelines,[1650] as well as the European Communities' own Scientific Committee Guidance Document for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed (March 2003).

7.2351 The United States submits, in addition, that the application concerning NK603 maize (food) is one of five applications identified by the United States which are pending at Commission level and which, as of the date of establishment of the Panel, have been pending for an average of four years and six months. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning NK603 maize (food) is undue. The

[1649] Exhibit EC-96/At. 7.

[1650] The United States refers to Codex Alimentarius, "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants", CAC/GL 45-2003, paras. 37, 38.

United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2352 **Argentina** argues that NK603 maize (food) was stalled at various stages of the approval process under Regulation 258/97. Argentina notes that the assessments performed by the lead CA and subsequently the EFSA concluded that there was no evidence of risk to human health or life. Therefore, it is clear that the delays by the lead CA to complete its initial assessment and forward this application to the Commission were not justified.

7.2353 The **European Communities** notes that the application for food use of the NK603 maize was submitted to the Netherlands in 2001. After the applicant submitted additional information requested by the lead CA, the lead CA completed its evaluation in November 2002 and sent its initial assessment report to the Commission. The eighteen months spent at member State level were due to the incompleteness of the dossier initially submitted by the applicant and the need for further data on molecular characterization and compositional analysis.

7.2354 The European Community further notes that the Commission circulated the dossier to all member States in January 2003. Three member States raised objections and several others requested additional information. The European Communities points out in this connection that Regulation 258/97, in general terms, provided an adequate framework for a risk assessment for GM food products. However, in terms of risk management, it became clear in 1999 that there would have to be new legislation addressing some issues such as labelling and traceability, and also the development and validation of detection methods. The application concerning NK603 maize (food) was partially affected by this situation as it had reached the Community level and the stage of risk management considerations. Thus, it was considered necessary to require the validation of a detection method as a pre-condition for marketing approval. This was done on the basis of a voluntary agreement with the applicant. These detection methods were validated for NK603 maize (food) and the decision-making process was launched immediately after.

7.2355 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.2356 We recall that the applicant first submitted the application to the lead CA in April 2001. Two months later the lead CA requested copies of cited literature and data in order to facilitate the lead CA's work. The applicant provided these documents in July 2001. However, the first request for additional information from the lead CA was made only in December 2001, more than four and a half months later. In August 2002, five months after the applicant supplied the information requested by the lead CA, the lead CA's advisory body, the Dutch Health Council's Committee on the Safety Assessment of Novel Foods, finished its assessment report. It was not until November 2002, however, that the lead CA forwarded its assessment report to the Commission.

7.2357 It is clear from the foregoing that the December 2001 request for information led to delay in the consideration of this application inasmuch as the applicant took more than three months and a half to respond to the request. We asked the experts advising us for their views on the necessity of the information requested by the lead CA in December 2001 to ensure that the conclusions of the safety assessment were valid. We recall the view expressed by one of the experts that the request in question was not necessary to ensure the validity of the safety assessment.

7.2358 However, even accepting that the information requested by the lead CA in December 2001 was appropriate to ensure the validity of the safety assessment, this could not provide a justification

for the time taken by the lead CA to assess the application. Notably, the application concerning NK603 maize (food) had been under review in the Netherlands for more than seven months before the Dutch CA forwarded its December 2001 request for information.[1651] Moreover, once the applicant had provided information in response to the Dutch CA's December 2001 request for information, the Health Council's Committee on the Safety Assessment of Novel Foods still took more than four months to complete its initial assessment report. While this report needed to be adopted by the Dutch CA, the report was not forwarded to the Commission for another two and a half months.

7.2359 In examining the issue of the time taken by the lead CA for its assessment of the application concerning NK603 maize (food), we first recall that Regulation 258/97 provides that the lead CA should complete its initial assessment within three months of receipt of an application which contains the necessary information. We recognize that the question of whether or not the lead CA complied with the three-month deadline stipulated in Regulation 258/97 is not dispositive, *per se*, of whether the European Communities met its WTO obligation to complete its approval procedures without undue delay. This said, in the Panel's view, the deadline set forth in Regulation 258/97 provides a useful indicator to guide the Panel's analysis. The three-month deadline is binding and applies to all relevant applications submitted under Regulation 258/97. It may therefore be assumed that the EC legislator set this binding deadline in such a way as to make it possible for the CAs of all member States to assess even complex applications within the prescribed deadline.

7.2360 We first turn to consider the time taken by the lead CA before forwarding its initial request for information of December 2001. We note that by the time the lead CA forwarded its first request for information, the lead CA had already exceeded the three-month period envisaged in Regulation 258/97 by more than four months, yet it was far from completing its initial assessment.[1652] The European Communities asserts that all of the time taken by the lead CA was necessary to resolve scientific and technical issues, but provides no specific justification for the time taken by the lead CA up to December 2001. Even if it were accepted that in this procedure the lead CA could not have completed its initial assessment within the three-month period provided for in Regulation 258/97, this would not imply that the lead CA could not have requested missing information much sooner. Given the three-month maximum assessment period envisaged in Regulation 258/97, and lacking a specific justification by the European Communities, we are not convinced that the lead CA could not have evaluated much more promptly than it did whether additional information was still needed.

7.2361 We have previously pointed out that the Netherlands was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, in this instance, we are not convinced that the Dutch CA's conduct reflects a precautionary approach. Indeed, we are not convinced that the Dutch CA could not have identified any need for additional information and forwarded an appropriate request for information to the applicant sooner than it did even while following a precautionary approach.

7.2362 Taking account of the aforementioned elements, we consider that upon receipt of the original application, the lead CA could, and should, have determined more promptly that additional information was needed and could, and should, have forwarded an appropriate request to the applicant more promptly.

[1651] The application had been under review for more than four months after receipt of copies of the cited literature and data. These copies were not requested by the lead CA until two months after receipt of the application.

[1652] Even if it were considered that a complete application was only available as of the end of July 2001, the lead CA would still have exceeded the three-month period by more than four and a half months.

7.2363 We now turn to consider the time taken by the lead CA to complete and forward its assessment report. To recall, five months after the applicant supplied the information requested by the lead CA in December 2001, the lead CA's scientific advisory body in August 2002 finished its assessment report. However, the lead CA did not forward its assessment report to the Commission until November 2002, *i.e.*, for more than two and a half months.

7.2364 While accepting that the advisory body's assessment report needed to be adopted by the Dutch CA, we recall that in accordance with Regulation 258/96 the Dutch CA was required to complete its entire initial assessment within no more than three months. Given this, and lacking a specific justification by the European Communities, we are not convinced that the Dutch CA could not have adopted the report in question much sooner than it did in the case of the application concerning NK603 maize (food).

7.2365 Thus, based on the above considerations, we conclude that the time taken by the lead CA for its assessment of the application concerning NK603 maize (food) – and in particular the time taken by the lead CA before forwarding its first request for additional information as well as the time taken by the lead CA to forward its completed assessment report – was unjustifiably long.

7.2366 In addition, we recall that the United States claims that the approval procedure concerning NK603 maize (food) was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the time taken by the Netherlands to complete its initial assessment of the application concerning NK603 maize (food) is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Netherlands' conduct was a consequence of the general moratorium on approvals.

7.2367 In view of our conclusion with regard to the time taken by the Netherlands for its initial assessment, we do not go on to examine other arguments put forward by the United States and Argentina in support of their claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

Conclusions

7.2368 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning NK603 maize (food) – particularly the time taken by the lead CA before forwarding its first request for additional information as well as the time taken by the lead CA to forward its completed assessment report – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning NK603 maize (food) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning NK603 maize (food), the European

Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, the Panel recalls its finding that the time taken by the lead CA for its assessment of the application concerning NK603 maize (food) – particularly the time taken by the lead CA before forwarding its first request for additional information as well as the time taken by the lead CA to forward its completed assessment report – was unjustifiably long. In the light of this finding, the Panel concludes that the European Communities failed to complete the approval procedure concerning NK603 maize (food) without "undue delay", thus breaching its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(viii) RR sugar beet (food) (EC-102)

7.2369 One Complaining Party, the United States, claims that the completion of the approval procedure concerning RR sugar beet (food) has been unduly delayed.

7.2370 The **United States** argues that the lead CA (Netherlands) refused to forward the application to the Commission and that this resulted in undue delay.

7.2371 The United States also points out that the application concerning RR sugar beet (food) is one of four applications identified by the United States which have been pending at the member State level for an average of three and one half years. The United States contends in this respect that although time alone is not dispositive, in the light of the acknowledgement by EC officials of the existence of a moratorium on approvals, this delay in completing the approval procedure concerning RR sugar beet (food) is undue. The United States submits, in addition, that before the European Communities adopted its moratorium, all approval procedures under Directive 90/220 were undertaken and completed in less than three years.

7.2372 The **European Communities** argues that after discussions between the Dutch CA and the applicant, the request was withdrawn on 16 April 2004. As the reason for its withdrawal the applicant pointed to a decision to stop any further development of the RR sugar beet.

7.2373 The **Panel** commences its analysis with the alleged delay at member State level.

Delay at member State level

7.2374 We recall that the applicant submitted the application concerning RR sugar beet (food) to the lead CA on 3 November 1999. However, the first request for additional information from the lead CA was made only on 24 March 2000, almost five months later. The applicant responded one month later. In May 2000, the lead CA requested further information. That information was provided on 7 December 2000. On 16 May 2001, after reviewing the additional information provided by the applicant in December 2000, the lead CA requested further information. The lead CA indicated that it was not yet fully satisfied with the information provided by the applicant concerning the likelihood of specific protein formation. In addition, mentioning recent studies which had shown that "unintended effects on GMOs" were possibly caused by transformation of plant cells, the lead CA also requested a semi-chronic oral toxicity study on rats in order to "to rule out possible undesirable effects [...] with

sufficient certainty".[1653] No specific study was cited in this regard. There is no indication in the evidence before us that the applicant responded to the requests from the lead CA for further information prior to August 2003.

7.2375 We sought the advice of the experts assisting us regarding whether the additional information requested by the lead CA in May 2001 was necessary to ensure that the conclusions of the safety assessment were valid. Dr. Nutti expressed the view that "the information requested by the lead CA regarding the derived proteins and the request for a semi-chronic oral toxicity test on mice or rats with edible parts of sugar beet was not necessary to ensure that the conclusions of the safety assessment were valid". She emphasized that the applicant had already completed an acute toxicity test on rats and conducted studies which confirmed that RR sugar beet "was equivalent in composition and nutrition to the conventional counterpart".[1654]

7.2376 Even accepting that contrary to the views of Dr. Nutti the information requested in May 2001 was necessary to ensure the validity of the safety assessment, this would not provide a justification for the time taken by the lead CA before initially requesting additional information in March 2000 (almost five months), and the time taken to review the information received in December 2000 (five months).

7.2377 In examining the issue of the time taken by the lead CA for its assessment of the application concerning RR sugar beet (food), we first recall that Regulation 258/97 provides that the lead CA should complete its initial assessment within three months of receipt of an application which contains the necessary information. We recognize that the question of whether or not the lead CA complied with the three-month deadline stipulated in Regulation 258/97 is not dispositive, *per se*, of whether the European Communities met its WTO obligation to complete its approval procedures without undue delay. This said, in the Panel's view, the deadline set forth in Regulation 258/97 provides a useful indicator to guide the Panel's analysis. The three-month deadline is binding and applies to all relevant applications submitted under Regulation 258/97. It may therefore be assumed that the EC legislator set this binding deadline in such a way as to make it possible for the CAs of all member States to assess even complex applications within the prescribed deadline.

7.2378 We first turn to consider the time taken by the lead CA before forwarding its initial request for information of March 2000. We note that by the time the lead CA forwarded its first request for information, the lead CA had already exceeded the three-month period envisaged in Regulation 258/97 by almost two months, yet it was far from completing its initial assessment. The European Communities asserts that all of the time taken by the lead CA was necessary to resolve scientific and technical issues, but provides no specific justification for the time taken by the lead CA up to March 2000. Even if it were accepted that in this procedure the lead CA could not have completed its initial assessment within the three-month period provided for in Regulation 258/97, this would not imply that the lead CA could not have requested missing information much sooner. Given the three-month maximum assessment period envisaged in Regulation 258/97, and lacking a specific justification by the European Communities, we are not convinced that the lead CA could not have determined much more promptly than it did whether additional information was still needed.

7.2379 We have previously pointed out that the Netherlands was part of the Group of Seven countries which declared in June 1999 that they would take a thoroughly precautionary approach in dealing with applications for the placing on the market of biotech products. However, in this instance, we are not convinced that the Dutch CA's conduct reflects a precautionary approach. Indeed, we are not

[1653] Exhibit EC-102/At. 32.
[1654] Annex H, paras. 775 and 778.

convinced that the Dutch CA could not have identified any need for additional information and forwarded an appropriate request for information to the applicant sooner than it did even while following a precautionary approach.

7.2380 Taking account of the aforementioned elements, we consider that upon receipt of the original application, the lead CA could, and should, have determined more promptly that additional information was needed and could, and should, have forwarded an appropriate request to the applicant more promptly.

7.2381 We now turn to consider the time taken by the lead CA taken to review the information received in December 2000. To recall, more than five months after the applicant supplied the information requested by the lead CA in May 2000, the lead CA requested further information on protein analysis and a semi-chronic oral toxicity study on rats in order to "to rule out possible undesirable effects". Regarding protein analysis, the lead CA indicated that it was not yet fully satisfied with the information previously provided by the applicant. Regarding the requested toxicity study, the lead CA mentioned recent studies which had shown that "unintended effects on GMOs" were possibly caused by transformation of plant cells. However, as noted, no specific study was cited in this regard.

7.2382 Since it is not clear from the record what recent studies the lead CA was referring to, we have no basis on which to determine whether the lead CA could, and should, have put forward its request for a toxicity study earlier than it did.

7.2383 With regard to protein analysis, we note that the European Communities provides no specific justification for why the lead CA required more than five months to identify a need for yet more information. In the absence of a specific justification by the European Communities, we are not convinced that the lead CA could not have evaluated much sooner than it did whether additional information on protein analysis was still needed. We are also of the view that the Dutch CA could have requested supplementary information on protein analysis at a much earlier date even while following a precautionary approach.

7.2384 Taking account of the aforementioned elements, we consider that the lead CA could, and should, have determined more promptly that additional information was needed on protein analysis and could, and should, have forwarded an appropriate request to the applicant more promptly.

7.2385 Thus, based on the above considerations, we conclude that the time taken by the lead CA for its assessment of the application concerning RR sugar beet (food) – and in particular the time taken by the lead CA before forwarding its first request for additional information as well as the time taken by the lead CA to review the information received in December 2000 and to put forward a new request for information – was unjustifiably long.

7.2386 In addition, we recall that the United States claims that the approval procedure concerning NK603 maize (food) was unduly delayed because, due to the moratorium, the European Communities failed to consider the application in question for final approval. In this respect, we note our earlier findings that (i) a general *de facto* moratorium on approvals was in effect in the European Communities between June 1999 and August 2003 and that (ii) the time taken by the Netherlands to complete its initial assessment of the application concerning RR sugar beet (food) is consistent with the application of such a moratorium. In the light of this, and in the absence of effective rebuttal by the European Communities, we agree with the United States that it is reasonable to infer that the Netherlands' conduct was a consequence of the general moratorium on approvals.

7.2387 In view of our conclusion with regard to the time taken by the Netherlands for its initial assessment, we do not go on to examine other arguments put forward by the United States in support of its claim under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

7.2388 Taking account of the aforementioned elements, we consider that the time taken by the lead CA before initially requesting additional information in March 2000, and the time taken to review the information received in December 2000, is consistent with the United States' view that a general moratorium on final approvals was in effect in the European Communities at that time.

Conclusion

7.2389 In the light of the above, the Panel reaches the following overall conclusion:

(i) DS291 (United States)

With reference to DS291, the Panel recalls its findings that the time taken by the lead CA for its assessment of the application concerning RR sugar beet (food) – particularly the time taken by the lead CA before forwarding its first request for additional information as well as the time taken by the lead CA to review the information received in December 2000 and to put forward a new request for information – was unjustifiably long, and that it can reasonably be inferred from surrounding circumstances that the lead CA's conduct was a consequence of the general moratorium on approvals. Based on these findings, the Panel accepts the United States' contention that, consistent with the general moratorium, the European Communities failed to consider the application concerning RR sugar beet (food) for final approval, and that this resulted in "undue delay" in the completion of the relevant approval procedure. Accordingly, the Panel concludes that in respect of the approval procedure concerning RR sugar beet (food), the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

(d) Summary of the Panel's conclusions

7.2390 In view of the large number of approval procedures reviewed, it is useful to summarize in table form the Panel's conclusions on the Complaining Parties' claim that the European Communities has failed to complete the relevant approval procedures without undue delay and hence has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*.

7.2391 We should recall that most of the conclusions identified in the table are relevant to only one or two of the three complaints we are examining. Our preceding analysis identifies which of these conclusions are applicable to which complaint(s).

	Approval procedures examined by the Panel	Panel's conclusions on asserted "undue delay" (X: unduly delayed, ✓: not unduly delayed)
1	Falcon oilseed rape	X
2	MS8/RF3 oilseed rape	X
3	RR fodder beet	X
4	Bt-531 cotton	X
5	RR-1445 cotton	X
6	Transgenic potato	✓
7	Liberator oilseed rape	X
8	Bt-11 maize (EC-69)	X
9	RR oilseed rape (EC-70)	X
10	LL soybeans (EC-71)	X
11	LL oilseed rape	✓
12	BXN cotton	X
13	Bt-1507 maize (EC-74)	X
14	Bt-1507 maize (EC-75)	X
15	NK603 maize	X
16	GA21 maize (EC-78)	X
17	MON810 x GA21 maize	X
18	RR sugar beet	X
19	MS1/RF1 oilseed rape (EC-89)	X
20	MS1/RF2 oilseed rape	X
21	GA21 maize (food)	X
22	Bt-11 sweet maize (food)	X
23	LL soybeans (food)	✓
24	MON810 x GA21 maize (food)	X
25	Bt-1507 maize (food)	X
26	NK603 maize (food)	X
27	RR sugar beet (food)	X
Total:		X: 24 ✓:3

10. Consistency of the product-specific measures with Article 8 and Annex C(1)(a), second clause, of the *SPS Agreement*

7.2392 Argentina claims that the product-specific measures identified by it are inconsistent with the European Communities' obligations under Article 8 and Annex C(1)(a), second clause, of the *SPS Agreement*.

7.2393 Article 8 of the *SPS Agreement* provides:

> "Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or

> feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement."

7.2394 Annex C(1)(a), second clause, of the *SPS Agreement* provides:

> "Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:
>
> [...]
>
> (a) such procedures are undertaken and completed [...] in no less favourable manner for imported products than for like domestic products[.]"

7.2395 **Argentina** argues that Annex C(1)(a), second clause, establishes an obligation to avoid discriminatory treatment. Members must not differentiate the treatment granted to an imported product and to a like domestic product. Argentina submits that in the present case a comparison should be made between the manner in which the EC approval system has been applied in the case of biotech products and the manner in which it has been applied in the case of novel non-biotech products. Specifically, Argentina points to Regulation 258/97 which it says defines a procedure that does not differ in terms of implementation between the two products. According to Argentina, undue delays have, however, occurred only in the treatment of biotech products. Furthermore, Argentina identifies another instance of less favourable treatment of biotech products. In the view of Argentina, prior to 1998, the European Communities granted approvals for the marketing of biotech products, whereas it has not done so since, as a consequence of the general *de facto* moratorium on approvals.

7.2396 The **European Communities** argues that the differences in treatment alleged by Argentina between biotech products and novel non-biotech products, and between biotech products before and after the "moratorium", have nothing to do with the national treatment obligation set forth in Annex C(1)(a), second clause. According to the European Communities, a national treatment issue would arise if the European Communities in the application of its approval system treated imported biotech products differently from domestic biotech products. The European Communities submits that this is not the case as all products are being treated equally, irrespective of their origin. The European Communities considers, therefore, that Argentina has failed to establish an inconsistency with Annex C(1)(a), second clause.

7.2397 The **Panel** notes that Argentina relies on the alleged inconsistency of the product-specific measures with Annex C(1)(a), second clause, to make consequential claims of inconsistency under Article 8. Accordingly, we will begin our analysis with the claims under Annex C(1)(a), second clause, before turning to Article 8.

(a) Annex C(1)(a), second clause

7.2398 We note that in accordance with the lead-in to Annex C(1) the provisions of Annex C(1)(a) apply "with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures". We have previously found that the procedures set out in Directives 90/220 and 2001/18 as well as Regulation 258/97 (to the extent it is an SPS measure) constitute procedures "to check and ensure the fulfilment of sanitary or phytosanitary measures" within the meaning of Annex C(1) and, as such, are subject to the provisions of Annex C(1), which include those of Annex C(1)(a). Therefore, the European Communities was and is required under the provisions of Annex C(1)(a) to "undertake and complete" the approval procedures set out in Directives 90/220 and 2001/18 as well as

Regulation 258/97 (to the extent it is an SPS measure) "in no less favourable manner for imported products than for like domestic products".

7.2399 Argentina is challenging alleged undue delays in completing the consideration and processing of specified applications. In our view, the type of measure challenged by Argentina could conceivably constitute, or lead to, a breach of the European Communities' obligations under Annex C(1)(a), second clause, and it can therefore be examined in the light of the provisions of Annex C(1)(a), second clause. Since Argentina seeks to establish an inconsistency with Article 8 on the basis of an alleged inconsistency with Annex C(1)(a), second clause, this conclusion applies also to Article 8.

7.2400 In order to establish an inconsistency with Annex C(1)(a), second clause, Argentina must establish (i) that imported products have been treated in a "less favourable manner" than domestic products in respect of the undertaking and completion of approval procedures, and (ii) that the imported products which are alleged to have been treated less favourably are "like" the domestic products which are alleged to have been treated more favourably. If either one of these two elements is not met, that is, if imported products have not been treated "less favourably" than the domestic products to which they are being compared, or if these domestic products are not "like" the relevant imported products, Argentina's claim of inconsistency must fail. In the circumstances of this case, we find it appropriate to begin our analysis with the first element. Thus, we will examine first whether Argentina has demonstrated that imported products have been treated in a "less favourable manner" than domestic products in respect of the undertaking and completion of approval procedures.

7.2401 We note the phrase "in no less favourable manner". It is clear from this phrase that Annex C(1)(a), second clause, lays down a national treatment obligation. National treatment obligations are found in numerous WTO agreements. Moreover, the relevant provisions often use similar language. The Appellate Body has confirmed that, in such circumstances, the jurisprudence on a national treatment provision in one WTO agreement may be useful in interpreting a national treatment provision in another WTO agreement.[1655] In the present case, we find it useful to look to the jurisprudence on Articles III:1 and III:4 of the GATT 1994 for appropriate interpretative guidance.

7.2402 Article III:1 provides:[1656]

> "The contracting parties recognize that internal taxes and other internal charges, and laws, regulations and requirements affecting the internal sale, offering for sale, purchase, transportation, distribution or use of products, and internal quantitative regulations requiring the mixture, processing or use of products in specified amounts or proportions, should not be applied to imported or domestic products so as to afford protection to domestic production."

7.2403 Article III:4 provides in relevant part:

> "The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use."

[1655] Appellate Body Report, *US – Section 211 Appropriations Act*, para. 242.
[1656] *Ad* Note omitted.

7.2404 In *EC – Asbestos*, the Appellate Body had this to say on the term "less favourable treatment" as it appears in Article III:4:

> "[...] there is a second element [in addition to the 'likeness' of the products being 'compared] that must be established before a measure can be held to be inconsistent with Article III:4. [...] A complaining Member must [...] establish that the measure accords to the group of 'like' *imported* products 'less favourable treatment' than it accords to the group of 'like' *domestic* products. The term 'less favourable treatment' expresses the general principle, in Article III:1, that internal regulations 'should not be applied … so as to afford protection to domestic production'. If there is 'less favourable treatment' of the group of 'like' imported products, there is, conversely, 'protection' of the group of 'like' domestic products. However, a Member may draw distinctions between products which have been found to be 'like', without, for this reason alone, according to the group of 'like' *imported* products 'less favourable treatment' than that accorded to the group of 'like' *domestic* products. In this case, we do not examine further the interpretation of the term 'treatment no less favourable' in Article III:4, as the Panel's findings on this issue have not been appealed or, indeed, argued before us."[1657]

7.2405 Subsequently, in *Dominican Republic – Import and Sale of Cigarettes*, the Appellate Body again addressed the meaning of the phrase "less favourable treatment", stating that:

> "[T]he existence of a detrimental [competitive] effect on a given imported product resulting from a measure does not necessarily imply that this measure accords less favourable treatment to imports if the detrimental effect is explained by factors or circumstances unrelated to the foreign origin of the product, such as the market share of the importer in this case."[1658]

7.2406 We recognize that Annex C(1)(a), second clause, does not use the phrase "treatment no less favourable", but the phrase "in no less favourable manner". In our view, there is, however, a close conceptual similarity between these two phrases, and the textual difference between them does not, therefore, render inapposite appropriate reliance on the Appellate Body's interpretation of the phrase "treatment no less favourable" as it appears in Article III:4.

7.2407 We also recognize that Annex C(1) to the *SPS Agreement* does not contain a provision analogous to Article III:1 of the GATT 1994. But the fact that Article III:4 expresses a general principle which is explicitly spelt out in Article III:1 does not necessarily mean that a similar general principle cannot be implicit in Annex C(1)(a), second clause. Indeed, we consider that a central purpose of the provisions of Annex C(1)(a), second clause, is precisely to prevent Members from applying their approval procedures in a manner which would afford protection to domestic production. This view is consistent with Article 2.3 of the *SPS Agreement*, which is part of the context of Annex C(1)(a). The second sentence of Article 2.3, which would appear to be applicable to approval procedures, provides that SPS measures "shall not be applied in a manner which would constitute a disguised restriction on international trade". Thus, we do not think that the absence in Annex C(1) of an analogue to Article III:1 should prevent us from being guided by the Appellate Body's interpretation of the phrase "treatment no less favourable".

[1657] Appellate Body Report, *EC – Asbestos*, para. 100 (emphasis in original).
[1658] Appellate Body Report, *Dominican Republic – Import and Sale of Cigarettes*, para. 96.

7.2408 Reading Annex C(1)(a), second clause, in the light of the jurisprudence on Article III:4, we consider that in undertaking and completing its approval procedures, a Member may, in principle, differentiate between products that have been found to be like because this would not, by itself, mean that the relevant approval procedures have been undertaken or completed in less favourable manner for the group of like imported products than for the group of like domestic products. In particular, a mere showing that a Member has undertaken or completed a particular approval procedure in a manner which is unfavourable for a given imported product would not be sufficient to establish a "less favourable manner" of undertaking or completing approval procedures if the relevant Member's conduct is explained by factors or circumstances unrelated to the foreign origin of the product.

7.2409 With these considerations in mind, we now turn to analyse Argentina's arguments. Argentina's first argument is that the European Communities has undertaken approval procedures under Regulation 258/97 in less favourable manner for the biotech products which are the subject of the product-specific measures challenged by Argentina than for like novel non-biotech products. Argentina asserts that undue delays have occurred only in the processing of applications concerning biotech products.

7.2410 We note that it is not entirely clear from Argentina's submissions which approval procedures are at issue. We understand Argentina to refer to the procedures set out in Articles 4, 6, 7 and 8 of Regulation 258/97. These procedures apply in the same way to biotech products as they do to novel non-biotech products. These procedures also apply equally to imported and domestic products. Finally, we note that we have previously determined that these procedures constitute an approval procedure within the meaning of Annex C. Therefore, in undertaking and completing these procedures, the European Communities must comply with Annex C(1)(a), second clause.

7.2411 Turning to the merits of Argentina's argument, we observe, initially, that Argentina has not provided factual information about the processing of applications concerning those novel non-biotech products which Argentina considers to be like the biotech products at issue. At any rate, even if it were the case, as Argentina seems to assert, that the processing of applications concerning the relevant imported biotech products (*e.g.*, imported biotech maize) has been unduly delayed, while the processing of applications concerning the corresponding domestic non-biotech varieties (*e.g.*, domestic novel non-biotech maize) has not been unduly delayed, this would not be sufficient, in and of itself, to raise a presumption that the procedures envisaged in Regulation 258/97 have been applied in less favourable manner for the group of like imported products than for the group of like domestic products. Argentina does not assert that the processing of applications concerning relevant domestic biotech products (*e.g.*, domestic biotech maize) has not been unduly delayed, or that the processing of applications concerning corresponding imported non-biotech varieties (*e.g.*, imported novel non-biotech maize) has been unduly delayed. In other words, Argentina is not alleging that the manner of processing applications under Regulation 258/97 has differed depending on the origin of the products. In these circumstances, it is not self-evident that the alleged less favourable manner of processing applications concerning the relevant imported biotech products (*e.g.*, imported biotech maize) is explained by the foreign origin of these products rather than, for instance, a perceived difference between biotech products and novel non-biotech products in terms of the required care in their safety assessment, risk for the consumer, etc. Argentina has not adduced argument and evidence sufficient to raise a presumption that the alleged less favourable treatment is explained by the foreign origin of the relevant biotech products.

7.2412 In the light of the above, we find that Argentina has not established that the approval procedures set out in Regulation 258/97 have been undertaken or completed in a less favourable manner for imported products than for domestic products.

7.2413 Argentina's second argument is that after 1998 the European Communities has applied its approval procedures in a less favourable manner for the biotech products which are the subject of the product-specific measures challenged by Argentina than for like biotech products before 1998. More particularly, Argentina submits that after 1998 undue delays have occurred in the processing of applications under the relevant approval procedures. The year 1998 is the year in which, in Argentina's view, the European Communities began applying its general *de facto* moratorium on approvals.

7.2414 We understand Argentina's second argument to relate to the approval procedures contained in Directives 90/220 and 2001/18 as well as Regulation 258/97. Directives 90/220 and 2001/18 as well as Regulation 258/97 apply equally to imported and domestic biotech products. We have previously determined that these pieces of legislation contain approval procedures within the meaning of Annex C. Therefore, in undertaking and completing these approval procedures, the European Communities was and is required to comply with Annex C(1)(a), second clause. We note that Directive 2001/18 is formally and, to some extent, substantively different from Directive 90/220. Argentina appears to assume that the obligation laid down in Annex C(1)(a), second clause, applies not only in situations where imported and domestic products are dealt with under one and the same approval procedure, but also in situations where like products are dealt with under formally or substantively different approval procedures. For the purposes of our analysis of Argentina's argument, we are prepared to proceed on the basis of this assumption, but we do not make a finding in this regard.

7.2415 It seems to us that Argentina wishes to argue, in effect, that approval procedures were applied in less favourable manner for relevant imported biotech products after 1998 than for like domestic biotech products before 1998. Even if this were correct as a factual matter, however, this would not be sufficient, in and of itself, to raise a presumption that the approval procedures at issue have been applied in less favourable manner for the group of like imported products than for the group of like domestic products. Argentina asserts that after 1998 applications concerning the relevant biotech products were processed in less favourable manner, irrespective of whether they were of foreign or domestic origin, and that before 1998 applications concerning biotech products were processed in more favourable manner, irrespective of whether they were of foreign or domestic origin. Thus, it is not Argentina's contention that there has been a difference, before and after 1998, in the manner in which the European Communities has processed applications concerning imported biotech products and the manner in which it has processed applications concerning domestic biotech products. It is therefore not obvious that the alleged less favourable manner of conducting approval procedures for the relevant imported biotech products after 1998 is explained by the foreign origin of these products rather than by other factors or circumstances, such as a different perception of risks associated with biotech products, etc. Argentina has not adduced argument and evidence sufficient to raise a presumption that the alleged less favourable treatment is explained by the foreign origin of the relevant biotech products.

7.2416 Additionally, we note that one of the consequences of accepting Argentina's second argument would be that Members could not consistently with Annex C(1)(a), second clause, elect to conduct their approval procedures in a less favourable manner for all subject products regardless of their origin, *e.g.*, in response to new scientific evidence suggesting that the risks associated with the products subject to the approval requirement had previously been underestimated. In our view, it would be unreasonable to interpret Annex C(1)(a), second sentence, so as to produce such an outcome.

7.2417 In the light of the above, we are not persuaded by Argentina's argument that the European Communities has undertaken and completed its approval procedures in a less favourable manner for

imported products than for domestic products by processing applications concerning biotech products in a less favourable manner after 1998 than before 1998.

7.2418 Since we have found that Argentina has not demonstrated to our satisfaction that imported products have been processed in a "less favourable manner" than domestic products in respect of the undertaking and completion of approval procedures, there is no need to go on to examine whether the imported products which Argentina alleges have been treated less favourably are "like" the domestic products which Argentina alleges have been treated more favourably.

7.2419 Based on all of the above considerations, we conclude that Argentina has failed to establish its product-specific claims under Annex C(1)(a), second clause.

(b) Article 8

7.2420 Turning to Argentina's claims under Article 8, we recall that Argentina seeks to establish an inconsistency with Article 8 on the basis of an alleged inconsistency with Annex C(1)(a), second clause. We have determined that Argentina has failed to establish its claims under Annex C(1)(a), second clause. Under the approach followed by Argentina, this means that its claims under Article 8 have not been established either.

(c) Overall conclusion

7.2421 In the light of the above, the Panel reaches the following conclusion:

(i) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that Argentina has not established that the product-specific measures in respect of which the Panel is making findings have resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(a), second clause, of the *SPS Agreement* and, consequently, with its obligations under Article 8 of the *SPS Agreement*.

11. Consistency of the product-specific measures with Article 8 and Annex C(1)(b) of the *SPS Agreement*

7.2422 The United States and Argentina claim that the product-specific measures identified by them are inconsistent with the European Communities' obligations under Article 8 and Annex C(1)(b) of the *SPS Agreement*.

7.2423 Article 8 of the *SPS Agreement* provides:

> "Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement."

7.2424 Annex C(1)(b) of the *SPS Agreement* provides:

> "Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:
>
> [...]
>
> (b) the standard processing period of each procedure is published or that the anticipated processing period is communicated to the applicant upon request; when receiving an application, the competent body promptly examines the completeness of the documentation and informs the applicant in a precise and complete manner of all deficiencies; the competent body transmits as soon as possible the results of the procedure in a precise and complete manner to the applicant so that corrective action may be taken if necessary; even when the application has deficiencies, the competent body proceeds as far as practicable with the procedure if the applicant so requests; and that upon request, the applicant is informed of the stage of the procedure, with any delay being explained[.]"

7.2425 As we have noted earlier, Annex C(1)(b) essentially sets out five separate, but related, obligations to be observed by Members in the operation of approval procedures. These obligations relate to:

(i) the publication or communication to applicants of the processing period of each procedure;

(ii) the examination of the completeness of the documentation and the communication to applicants of deficiencies;

(iii) the transmission of the results of the procedure;

(iv) the processing of applications which have deficiencies; and

(v) the provision of information about the stage of a procedure and the provision of an explanation of any delay.

7.2426 The **United States** argues that under the relevant product-specific measures – the product-specific moratoria – the European Communities does not allow its approval procedures to proceed to conclusion. As such, the product-specific moratoria are inconsistent with each of the related procedural obligations in Annex C(1)(b) and, consequently, with Article 8 as well.

7.2427 Regarding the *first obligation* (publication or communication of processing period), the United States submits that although the applicable EC approval legislation contains processing periods, under the product-specific moratoria those processing periods are not followed. Instead, the European Communities has imposed an indefinite delay. However, since the European Communities does not acknowledge the product-specific moratoria, the standard processing period is not published, and the anticipated processing period is not communicated to the applicant.

7.2428 Regarding the *second obligation* (completeness of documentation), the United States argues that under the product-specific moratoria the European Communities does not promptly examine documentation and inform the applicant of all deficiencies. To the contrary, applications under the applicable EC legislation are stalled, without explanation. More specifically, the United States

submits that in the Bt-531 cotton, RR-1445 cotton, MS1/RF1 oilseed rape (EC 89) and MS1/RF2 oilseed rape applications, the applicant was not informed in a precise and complete manner of all deficiencies. To the contrary, when the Regulatory Committee fails to approve an application by qualified majority vote, or when the Commission enters into inter-service consultations rather than sending an application on to the Council, the applicant is given no explanation, and thus no opportunity to correct any deficiencies. The same is true when, as for the oilseed rape products, the lead member State fails to take the final step of placing the product on the market.

7.2429 Regarding the *third obligation* (transmission of results), the United States argues that under the product-specific moratoria results of procedures are not promptly communicated to applicants so that corrective action may be taken. Instead, applications are stalled in the approval process without explanation. More specifically, the United States submits that in the Bt-531 cotton, RR-1445 cotton, MS1/RF1 oilseed rape (EC 89) and MS1/RF2 oilseed rape applications, the applicant was not informed in a precise and complete manner of all deficiencies. To the contrary, when the Regulatory Committee fails to approve an application by qualified majority vote, or when the Commission enters into inter-service consultations rather than sending an application on to the Council, the applicant is given no explanation, and thus no opportunity to correct any deficiencies. The same is true when, as for the oilseed rape products, the lead member State fails to take the final step of placing the product on the market.

7.2430 Regarding the *fourth obligation* (processing of deficient applications), the United States argues that under the product-specific moratoria the European Communities does not proceed as far as practicable in the approval process. Instead, applications are stalled in the approval process.

7.2431 Regarding the *fifth obligation* (explanation of delay), the United States argues that under the product-specific moratoria delays are not explained. To the contrary, the European Communities does not even inform applicants of the existence of the general moratorium.

7.2432 **Argentina** argues that Annex C(1)(b) stipulates obligations of publication and notification of the applicant and requires the competent bodies of Members to perform their obligations "promptly" and to explain "any delay". Argentina considers that the undue delay which has been caused by the European Communities in the specific approval procedures identified by it is inconsistent with Article 8 and Annex C(1)(b). Argentina submits that the European Communities has not ensured compliance with the requirements of Annex C(1)(b) because in some cases the relevant EC entity did not promptly determine whether the documentation was complete (second obligation), and in other cases did not inform the applicant of the results of the procedure (third obligation) or of the current stage of the procedure (fifth obligation). Argentina argues in this regard that it has demonstrated that, for instance, in the approval procedure concerning GA21 maize (EC-78) the applicant was still waiting for a definitive answer with respect to its application after more than five years. Finally, Argentina submits that a violation of the provisions of Annex C simultaneously represents a violation of Article 8.

7.2433 The **European Communities** submits that the United States and Argentina have offered a mere assertion that the European Communities has not done what it is required to do under the different obligations contained in Annex C(1)(b). Argentina has offered no evidence in support of its allegations. The United States also considers it sufficient simply to allege that applications were stalled in the approval process and gives no explanations. However, it is a complaining party's burden to establish a prima facie case. In any event, the detailed chronologies of individual approval procedures and other documents submitted by the European Communities demonstrate that the allegations of the United States are unfounded.

7.2434 Regarding the United States' claim that no standard processing periods have been published for the "product-specific moratoria", the European Communities argues that these "moratoria" are individual applications subject to their own particular facts. In the European Communities' view, it is difficult to see how a "standard" processing period other than the one laid down in the legislation could be set out for these applications collectively.

7.2435 The **Panel** notes that in accordance with the lead-in to Annex C(1) the provisions of Annex C(1)(b) apply "with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures". We have previously found that the procedures set out in Directives 90/220 and 2001/18 as well as Regulation 258/97 (to the extent it is an SPS measure) constitute procedures "to check and ensure the fulfilment of sanitary or phytosanitary measures" within the meaning of Annex C(1) and, as such, are subject to the provisions of Annex C(1), which include those of Annex C(1)(b). Therefore, in respect of the approval procedures set out in the aforementioned Directives and Regulation, the European Communities was and is required to comply with the provisions of Annex C(1)(a).

7.2436 We recall that the United States is challenging the alleged failure by the European Communities to consider particular applications for final approval. We have observed in this regard that this is essentially a challenge to the application by the European Communities of a particular way of operating the relevant EC approval procedures. We also recall that Argentina is challenging alleged undue delays in completing the consideration and processing of specified applications.

7.2437 In our view, the type of measure challenged by the United States and Argentina could conceivably constitute, or lead to, a breach of EC obligations under Annex C(1)(b), and it can therefore be examined in the light of the provisions of Annex C(1)(b). Since the United States and Argentina seek to establish an inconsistency with Article 8 on the basis of an alleged inconsistency with Annex C(1)(b), this conclusion applies also to Article 8.

7.2438 In view of the fact that the United States' and Argentina's claim under Article 8 is in the nature of a consequential claim, we will begin our analysis with the claims under Annex C(1)(b).

(a) First obligation in Annex C(1)(b) (publication or communication of processing period)

7.2439 Only the United States has presented arguments in relation to the first obligation contained in Annex C(1)(b). Specifically, the United States puts forward two main arguments. The first argument is that as a result of the European Communities' failure to consider the relevant applications for approval, the European Communities did not follow the standard processing periods which are published in the applicable EC approval legislation. The United States appears to infer from this that the effective standard processing period was not published.

7.2440 We agree with the European Communities that the first obligation in Annex C(1)(b) does not, and logically cannot, require the European Communities to publish a "standard" processing period for every individual approval procedure undertaken by it. The processing period to be published is the period which is intended to be the norm for all approval procedures of a particular type, *e.g.*, the approval procedures envisaged in Directive 2001/18 for the placing on the market of biotech products. This follows from the word "standard", which in the specific context of the first obligation should be understood as meaning "normal".[1659] However, we do not understand the United States to argue that

[1659] The dictionary defines "standard" as "[o]f a prescribed or normal size, amount, quality, etc.". *The New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. II, p. 3028. The French

the European Communities should have published a standard processing period for each individual approval procedure conducted by it.

7.2441 We understand the United States to argue that the failure by the European Communities to consider a particular application for final approval meant that it was not following the published standard processing period for the relevant type of procedure and that the effective standard processing period for the relevant type of procedure was no longer published. Even if we were to accept that what has to be published in accordance with the first obligation in Annex C(1)(b) is the "effective" standard processing period, the mere fact that the European Communities in one particular approval procedure might not have followed the published standard processing period would not, by itself, justify the conclusion that there was a new and unpublished effective "standard" processing period. A single departure from the published standard processing period in our view does not demonstrate the existence of a new "standard" processing period.[1660] In any event, even if there was a new standard processing period, the fact that it was unpublished would not be a consequence of the failure by the European Communities to consider the relevant application for final approval. In other words, it would not be a consequence of the product-specific measure at issue. Rather, it would be a consequence of a separate and independent failure by the European Communities to publish the new standard processing period.

7.2442 In the light of this, we conclude that the United States has failed to establish its product-specific claims under the first obligation contained in Annex C(1)(b), insofar as these claims are based on the requirement to publish the standard processing period of each procedure.

7.2443 The United States' second argument in support of its claim under Annex C(1)(b) is that since the European Communities does not acknowledge its failure to consider the relevant applications for approval, the anticipated processing period is not communicated to the applicants. We note that pursuant to Annex C(1)(b) the anticipated processing period is to be communicated to the applicant "upon request". The United States has provided no evidence to show (i) that an applicant requested that the anticipated processing period be communicated to it, (ii) that the request was denied by a relevant EC entity, and (iii) that this was because of a deliberate failure to consider the relevant applications for approval. Moreover, we do not think that the failure by the European Communities to consider particular applications for final approval necessarily resulted in the European Communities not communicating to applicants the anticipated processing periods upon request. Indeed, in our view, the fact that the European Communities may have prevented a particular approval procedure from proceeding to conclusion would not have made it impossible for the European Communities to communicate to the applicant the anticipated processing period upon request, as required by Annex C(1)(b).

7.2444 In the light of this, we conclude that the United States has failed to establish its product-specific claims under the first obligation contained in Annex C(1)(b), insofar as these claims are based on the requirement to communicate to applicants the anticipated processing period.

(b) Second obligation in Annex C(1)(b) (completeness of documentation)

7.2445 Concerning the second obligation contained in Annex C(1)(b), both the United States and Argentina have presented arguments. We begin our analysis with the United States' arguments.

("la durée normale") and Spanish ("el período normal de tramitación") versions of the *SPS Agreement* support this interpretation.

[1660] We recall that the measures at issue are individual product-specific measures, and not the product-specific measures collectively or the general moratorium on approvals.

7.2446 The United States argues that as a result of the European Communities' failure to consider the relevant applications for approval, the European Communities did not promptly examine the completeness of documentation and inform applicants of any deficiencies. The United States has identified individual approval procedures which it believes support its claim under the second obligation.

7.2447 Among the applications referred to by the United States are those concerning MS1/RF1 oilseed rape (EC 89) and MS1/RF2 oilseed rape. We have determined above that there are twenty-five product-specific measures on which the United States is seeking findings. However, the applications concerning MS1/RF1 oilseed rape (EC 89) and MS1/RF2 oilseed rape are not part of these twenty-five measures. We are therefore not entitled to make product-specific findings on these two applications concerning oilseed rape.

7.2448 The United States also refers to the applications concerning Bt-531 cotton and RR-1445 cotton. They are among the applications which are the subject of product-specific claims put forward by the United States. In relation to these applications, the United States argues that when the Regulatory Committee failed to approve them by a qualified majority vote, or when the Commission entered into inter-service consultations after the Regulatory Committee vote, the applicant was given no explanation, and thus no opportunity to correct any deficiencies. As an initial matter, we note that the second obligation in Annex C(1)(b) applies when a "competent body" "receives" an application. In our view, the competent body receiving the applications concerning Bt-531 and RR-1445 cotton was the lead member State to which these applications were submitted for initial assessment, not the Regulatory Committee or the Commission at the post-Regulatory Committee stage.

7.2449 In any event, the United States has not demonstrated that either the Regulatory Committee or the Commission identified deficiencies in the documentation submitted by the applicant and did not inform the applicant thereof in a precise and complete manner. We recall that in the case of the application concerning Bt-531 cotton, three member States made written statements in support of their votes in the Regulatory Committee in February 1999, and that the applicant provided additional information more than two years after the Regulatory Committee meeting and the launching by the Commission of inter-service consultations. The United States has not shown that any of the member State statements identified deficiencies in the documentation submitted by the applicant. We have found earlier that none of the member State statements specifically called for the provision of the additional information and that there is no indication that the applicant submitted the additional information in response to the written statements. We also recall our earlier finding that there is no evidence to suggest that the Commission was waiting for the additional information provided by the applicant and for that reason did not submit a draft measure to the Council. We therefore do not consider that the additional information provided by the applicant addressed "deficiencies" which had been identified by the Regulatory Committee or the Commission.

7.2450 Regarding the application concerning RR-1445 cotton, we note that as in the case of the application concerning Bt-531 cotton, a number of member States made written statements in support of their votes in the Regulatory Committee in February 1999. The United States has not shown that any of these statements identified deficiencies in the documentation submitted by the applicant. Moreover, we have found earlier that the record of the consultation of the Regulatory Committee does not contain any indication of a request to the applicant for further information. In fact, no further information was provided subsequent to the Regulatory Committee vote. Finally, the United States itself points out in a different context that nothing in the record indicates that the Commission communicated any scientific concerns to the applicant or identified any shortcomings in the application following the Regulatory Committee vote. We therefore consider that the United States has not demonstrated that either the Regulatory Committee or the Commission identified deficiencies

in the documentation submitted by the applicant and did not inform the applicant thereof in a precise and complete manner.

7.2451 By way of an additional consideration, we note that the failure by the European Communities to consider particular applications for final approval did not necessarily result in the European Communities not examining promptly the completeness of documentation and not informing applicants of any deficiencies. Indeed, in our view, the fact that the European Communities may have prevented a particular approval procedure from proceeding to conclusion would not have made it impossible for the European Communities to examine the completeness of the documentation or inform the applicant of deficiencies in the documentation submitted, as required by Annex C(1)(b).[1661]

7.2452 In the light of the above considerations, we conclude that the United States has failed to establish its product-specific claims under the second obligation contained in Annex C(1)(b).

7.2453 Argentina submits that the European Communities has not ensured compliance with the requirements of Annex C(1)(b) because in some cases the relevant EC entity did not promptly determine whether the documentation was complete. Argentina has failed specifically to identify these "cases" and has not demonstrated that in these cases the competent body found deficiencies in the documentation submitted by the applicant and did not inform the applicant thereof in a precise and complete manner.

7.2454 In the light of this, we conclude that Argentina has failed to establish its product-specific claims under the second obligation contained in Annex C(1)(b).

(c) Third obligation in Annex C(1)(b) (transmission of results)

7.2455 With regard to the third obligation contained in Annex C(1)(b), both the United States and Argentina have presented arguments. We begin our analysis with the United States' arguments.

7.2456 The United States argues that as a result of the European Communities' failure to consider the relevant applications for approval, the European Communities did not promptly communicate the results of procedures to applicants so that corrective action could be taken if necessary. The United States has identified individual approval procedures which it believes support its claim under the third obligation. Among the applications referred to by the United States are those concerning MS1/RF1 oilseed rape (EC 89) and MS1/RF2 oilseed rape. We have already determined that we are not entitled to make product-specific findings on the two applications concerning oilseed rape.

7.2457 The United States also refers to the applications concerning Bt-531 cotton and RR-1445 cotton. They are among the product-specific measures challenged by the United States. In relation to these approval procedures, the United States argues that when the Regulatory Committee failed to approve them by a qualified majority vote, or when the Commission entered into inter-service consultations after the Regulatory Committee vote, the applicant was given no explanation, and thus no opportunity to correct any deficiencies.

7.2458 We note at the outset that when the applications concerning Bt-531 and RR-1445 cotton reached the Regulatory Committee stage, they were subject to Directive 90/220. It is clear from Article 21 of Directive 90/220 that the role of the Regulatory Committee is to assist the Commission in its decision-making by delivering opinions on draft measures proposed by the Commission. The

[1661] We note in this regard that certain progress in the approval process is not inconsistent with a deliberate failure by the European Communities to move a particular application to final decision.

Regulatory Committee cannot by itself take decisions on applications. Moreover, Directive 90/220 does not provide for the applicant to be given an explanation of the vote.[1662] Indeed, we have noted earlier that there is no publicly available record of Regulatory Committee votes. The European Communities has pointed out in this regard that Regulatory Committee votes have no external legal effect and cannot, therefore, be challenged under EC law.[1663] Thus, there is no "corrective action" which can be taken by the applicant in response to an unfavourable Regulatory Committee vote. For all these reasons, we are not persuaded that a vote in the Regulatory Committee can be considered a "result of the procedure" within the meaning of the third obligation contained in Annex C(1)(b). In our view, the Regulatory Committee vote is rather a "stage of the procedure" of which the applicant must be informed upon request in accordance with the fifth obligation in Annex C(1)(b).

7.2459 We believe that the same is true for inter-service consultations held by the Commission prior to the submission of a draft measure to the Council. Such consultations are a "stage of the procedure", not a "result of the procedure". At any rate, the outcome of such consultations is a draft measure to be transmitted to the Council for action, not a decision on an application.

7.2460 Based on the preceding considerations, we find that the Regulatory Committee votes and the opening of inter-service consultations by the Commission in the approval procedures concerning Bt-531 and RR-1445 cotton were not "results" which the European Communities was required to transmit to the applicant.

7.2461 More generally, we note that the failure by the European Communities to consider particular applications for final approval meant that no final results were achieved. Thus, there were no final results which could have been communicated to applicants as required by the third obligation in Annex C(1)(b).[1664]

7.2462 In the light of the above, we conclude that the United States has failed to establish its product-specific claims under the third obligation contained in Annex C(1)(b).

7.2463 Argentina submits that the European Communities has not ensured compliance with the requirements of Annex C(1)(b) because in some cases the relevant EC entity did not inform the applicant of the results of the procedure. Argentina has failed specifically to identify these "cases" and has not demonstrated that in these cases there were "results" which needed to be transmitted to the applicants. We note that Argentina has referred to the fact that in the approval procedure concerning GA21 maize (EC-78), the applicant was still waiting for a definitive answer regarding its application after more than five years. We recall in this regard that the third obligation in Annex C(1)(b) requires the competent body to "transmit" as soon as possible "the results of the procedure" in a precise and complete manner to the applicant so that corrective action may be taken if necessary. Thus, the third obligation applies in situations where results have been reached.[1665] Argentina's example is one where no final results have been reached yet. Since no results have been reached, none could be transmitted

[1662] It is important to recall in this context that the United States is not alleging that Directive 90/220 is, as such, WTO-inconsistent.

[1663] In support of its statement, the European Communities refers to the jurisprudence of the European Court of First Instance, case T-326/99, *Nancy Fern Olivieri v. Commission and EMEA*, decision of 18 December 2003, paras. 51 *et seq*.

[1664] As is clear from the discussion of the approval procedures concerning Bt-531 and RR-1445 cotton, the United States has failed to establish that "results" other than the final results of the relevant procedures had to be transmitted to the relevant applicants and that those results were not transmitted to them.

[1665] We note that the requirement in Annex C(1)(a), first clause, that approval procedures be "completed" without undue delay serves to ensure that "results" are reached.

to the applicant. In our view, the example of the approval procedure concerning GA21 maize (EC-78) does not, therefore, assist Argentina in establishing an inconsistency with the third obligation.

7.2464 In the light of this, we conclude that Argentina has failed to establish its product-specific claims under the third obligation contained in Annex C(1)(b).

(d) Fourth obligation in Annex C(1)(b) (processing of deficient applications)

7.2465 Only the United States has presented arguments in relation to the fourth obligation contained in Annex C(1)(b). The United States argues that as a result of the European Communities' failure to consider the relevant applications for approval, the European Communities did not proceed as far as practicable in the approval process.

7.2466 We note that pursuant to Annex C(1)(b) the competent body is to proceed as far as practicable with the procedure "if the applicant so requests". The United States has provided no evidence of an applicant making such a request and of a relevant EC entity denying that request because of a decision by the European Communities not to consider the relevant application for final approval. Moreover, we do not think that the failure by the European Communities to consider particular applications for final approval necessarily resulted in the European Communities not proceeding as far as practicable with procedures if applicants so requested. Indeed, in our view, the fact that the European Communities may have prevented a particular approval procedure from proceeding to conclusion would not have made it impossible for the European Communities to proceed as far as practicable with that procedure upon request, as required by Annex C(1)(b).[1666]

7.2467 In the light of this, we conclude that the United States has failed to establish its product-specific claims under the fourth obligation contained in Annex C(1)(b).

(e) Fifth obligation in Annex C(1)(b) (explanation of delay)

7.2468 Regarding the fifth obligation contained in Annex C(1)(b), both the United States and Argentina have presented arguments. We begin our analysis with the United States' arguments.

7.2469 The United States argues that as a result of the European Communities' failure to consider the relevant applications for approval, delays were not explained. The fifth obligation states that "upon request", the applicant is to be informed of the stage of the procedure, with any delay being explained. The United States has provided no evidence of an applicant making such a request, or of a relevant EC entity denying an explanation of any delay because of a deliberate failure by the European Communities to consider the relevant application for approval. Moreover, we do not think that the failure by the European Communities to consider particular applications for final approval necessarily resulted in the European Communities not informing applicants of the stage of procedures and not explaining any delays, if applicants so requested. Indeed, in our view, the fact that the European Communities may have prevented a particular approval procedure from proceeding to conclusion would not have made it impossible for the European Communities to inform applicants of the stage of procedures and explain any delays, as required by Annex C(1)(b).

7.2470 In the light of this, we conclude that the United States has failed to establish its product-specific claims under the fifth obligation contained in Annex C(1)(b).

[1666] We note in this regard that certain progress in the approval process is not inconsistent with a deliberate failure by the European Communities to move a particular application to final decision.

7.2471 Argentina submits that the European Communities has not ensured compliance with the requirements of Annex C(1)(b) because in some cases the relevant EC entity did not inform the applicant of the current stage of the procedure. Argentina has failed specifically to identify these "cases" and has not demonstrated that the relevant applicants requested information about the stage of the procedure and were denied such information.

7.2472 In the light of this, we conclude that Argentina has failed to establish its product-specific claims under the fifth obligation contained in Annex C(1)(b).

(f) Article 8

7.2473 Turning now to the United States' and Argentina's claims under Article 8, we recall that the United States and Argentina seek to establish an inconsistency with Article 8 on the basis of an alleged inconsistency with Annex C(1)(b). We have determined that the United States and Argentina have failed to establish their claims under Annex C(1)(b). Under the approach followed by the United States and Argentina, this means that their claims under Article 8 have not been established either.

(g) Overall conclusions

7.2474 In the light of the above, the Panel reaches the following conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence submitted by the United States and the European Communities, the Panel concludes that the United States has not established that the product-specific measures in respect of which the Panel is making findings have resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(b) of the *SPS Agreement* and, consequently, with its obligations under Article 8 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that Argentina has not established that the product-specific measures in respect of which the Panel is making findings have resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(b) of the *SPS Agreement* and, consequently, with its obligations under Article 8 of the *SPS Agreement*.

12. Consistency of the product-specific measures with Article 8 and Annex C(1)(c) of the *SPS Agreement*

7.2475 Argentina claims that the product-specific measures identified by it are inconsistent with the European Communities' obligations under Article 8 and Annex C(1)(c) of the *SPS Agreement*.

7.2476 Article 8 of the *SPS Agreement* provides:

> "Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or

> feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement."

7.2477 Annex C(1)(c) of the *SPS Agreement* provides:

> "Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:
>
> [...]
>
> (c) information requirements are limited to what is necessary for appropriate control, inspection and approval procedures, including for approval of the use of additives or for the establishment of tolerances for contaminants in food, beverages or feedstuffs[.]"

7.2478 **Argentina** submits that the European Communities acted inconsistently with the provisions of Annex C(1)(c) by delaying the examination of the relevant applications and by requiring excessive submissions under the terms of subsequent legislation. Regarding the submission of information under the terms of subsequent legislation, Argentina points out that the European Communities has invoked requirements contained in subsequent legislation as grounds for not processing applications. According to Argentina, this is clear from the fact that applications submitted under Directive 90/220 had to be resubmitted under Directive 2001/18 even in cases where the procedures had already been in progress under the old Directive for three years. Argentina also points out that there were numerous requests for additional information in the approval procedures which are the subject of its product-specific claims under Annex C(1)(c). Finally, Argentina argues that a violation of the provisions of Annex C simultaneously represents a violation of Article 8.

7.2479 The **European Communities** argues that delays do not fall within the scope of application of Annex C(1)(c). Regarding information requirements, the European Communities submits that the question of which information requirements are necessary is a question of standards set forth in the *SPS Agreement* itself. The European Communities also argues that Argentina should have attacked Directive 2001/18 if it considered the requirement to resubmit an updated dossier upon entry into force of Directive 2001/18 to be inconsistent with the *SPS Agreement*.

7.2480 The **Panel** notes that in accordance with the lead-in to Annex C(1) the provisions of Annex C(1)(c) apply "with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures". We have previously found that the procedures set out in Directives 90/220 and 2001/18 as well as Regulation 258/97 (to the extent it is an SPS measure) constitute procedures "to check and ensure the fulfilment of sanitary or phytosanitary measures" within the meaning of Annex C(1) and, as such, are subject to the provisions of Annex C(1), which include those of Annex C(1)(c). Therefore, in respect of the approval procedures set out in the aforementioned Directives and Regulation, the European Communities was and is required to comply with the provisions of Annex C(1)(c).

7.2481 We note that Argentina relies on the alleged inconsistency of the relevant product-specific measures with Annex C(1)(c) to make consequential claims of inconsistency under Article 8. Accordingly, we will begin our analysis with the claims under Annex C(1)(c).

(a) Annex C(1)(c)

7.2482 We recall that the product-specific measures which Argentina says give rise to an inconsistency with Annex C(1)(c) are undue delays caused by the European Communities in the consideration of particular applications. Argentina asserts that the European Communities has breached its obligations under Annex C(1)(c) by delaying the completion of the relevant approval procedures. We are not persuaded by this assertion. In our view, the failure by the European Communities to complete particular approval procedures without undue delay did not itself impose, or lead to the imposition of, information requirements which were not necessary. We therefore fail to see how the measures challenged by Argentina could be considered to give rise to an inconsistency with Annex C(1)(c). At any rate, Argentina has not identified specific information requirements which were imposed on applicants in the relevant approval procedures, nor has it explained why any such requirements were not necessary for appropriate approval procedures.

7.2483 Argentina also asserts that the European Communities has breached its obligations under Annex C(1)(c) by requiring excessive submissions under the terms of subsequent legislation. Here again, we must recall that the product-specific measures which Argentina is challenging are undue delays caused by the European Communities in the consideration of particular applications. The failure by the European Communities to complete particular approval procedures without undue delay did not impose a requirement on applicants to provide information based on legislation not yet in force, nor did it cause such a requirement to be imposed. Likewise, the European Communities' failure to complete particular approval procedures without undue delay did not require applicants to update their applications in accordance with the provisions of Directive 2001/18 once that Directive had entered into force. Nor did that failure cause such a requirement to be imposed.[1667] We are therefore unable to agree with Argentina that the European Communities has breached its obligations under Annex C(1)(c) by requiring excessive submissions under the terms of subsequent legislation. In any event, Argentina has not explained why the submissions it referred to were "excessive" and thus not necessary.

7.2484 We note Argentina's argument that there were numerous requests for additional information in the approval procedures which are the subject of its claims under Annex C(1)(c). It is sufficient to note in this regard that if Argentina was of the view that some or all of these requests for additional information constitute information requirements and that these requirements were not limited to what was necessary, it should have challenged these requests.

7.2485 In the light of the above, we conclude that Argentina has failed to establish its product-specific claims under Annex C(1)(c).

(b) Article 8

7.2486 Turning to Argentina's claims under Article 8, we recall that Argentina seeks to establish an inconsistency with Article 8 on the basis of an alleged inconsistency with Annex C(1)(c). We have determined that Argentina has failed to establish its claims under Annex C(1)(c). Under the approach followed by Argentina, this means that its claims under Article 8 have not been established either.

[1667] As pointed out by the European Communities, the requirement to update applications in accordance with the provisions of Directive 2001/18 flows from Article 35 of that Directive. Argentina does not challenge Article 35 as such.

(c) Overall conclusion

7.2487 In the light of the above, the Panel reaches the following conclusion:

(i) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that Argentina has not established that the product-specific measures in respect of which the Panel is making findings have resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(c) of the *SPS Agreement* and, consequently, with its obligations under Article 8 of the *SPS Agreement*.

13. Consistency of the product-specific measures with Article 8 and Annex C(1)(e) of the *SPS Agreement*

7.2488 Argentina claims that the product-specific measures identified by it are inconsistent with the European Communities' obligations under Article 8 and Annex C(1)(e) of the *SPS Agreement*.

7.2489 Article 8 of the *SPS Agreement* provides:

> "Members shall observe the provisions of Annex C in the operation of control, inspection and approval procedures, including national systems for approving the use of additives or for establishing tolerances for contaminants in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement."

7.2490 Annex C(1)(e) of the *SPS Agreement* provides:

> "Members shall ensure, with respect to any procedure to check and ensure the fulfilment of sanitary or phytosanitary measures, that:
>
> [...]
>
> (e) any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary[.]"

7.2491 **Argentina** argues that the detailed requirements of Directive 2001/18 and of its predecessor, Directive 90/220, as well as of Regulation 258/97 do not seem to meet the criteria of "reasonableness and necessity". Moreover, the European Communities has failed to exercise the authority granted to it by the aforementioned legislation, and that failure to act cannot be deemed reasonable or necessary. Furthermore, when Directive 2001/18 came into force, no consideration was given to the newly submitted applications, nor were those applications approved which had already been submitted under the predecessor Directive. Argentina further submits that the application of the European Communities' approval procedures is not limited to what is reasonable and necessary for the approval of biotech products.

7.2492 The **European Communities** argues that to the extent that Argentina's argument relates to the EC approval legislation itself, there is no reason to respond as the legislation is not a measure at issue. Furthermore, Argentina offers no support for its assertion that the application of the European Communities' approval procedures is not limited to what is reasonable and necessary for the approval

of biotech products. The European Communities submits, therefore, that Argentina has not established a prima facie case.

7.2493 The **Panel** notes that Argentina relies on the alleged inconsistency of the relevant product-specific measures with Annex C(1)(e) to make consequential claims of inconsistency under Article 8. Accordingly, we will begin our analysis with the claims under Annex C(1)(e).

(a) Annex C(1)(e)

7.2494 We note that Annex C(1)(e) imposes limitations on any requirements for approval of "*individual specimens* of a product" (emphasis added). The product-specific measures challenged by Argentina do not concern "individual specimens" of biotech products. They concern specific biotech products for which marketing approval has been sought. We also recall that the product-specific measures which Argentina says give rise to an inconsistency with Annex C(1)(e) are undue delays caused by the European Communities in the consideration of particular applications. It is not apparent to us that the European Communities' failure to complete approval procedures concerning particular biotech products without undue delay imposed, or led to the imposition of, any requirements for the approval of individual specimens of the relevant biotech products. We therefore fail to see how the measures challenged by Argentina could be considered to give rise to an inconsistency with Annex C(1)(e).

7.2495 In the light of this, we conclude that Argentina has failed to establish its product-specific claims under Annex C(1)(e).

7.2496 To the extent Argentina is seeking to challenge requirements contained in the EC approval legislation, we agree with the European Communities that the relevant legislation is not a measure within our terms of reference.

(b) Article 8

7.2497 Turning to Argentina's claims under Article 8, we recall that Argentina seeks to establish an inconsistency with Article 8 on the basis of an alleged inconsistency with Annex C(1)(e). We have determined that Argentina has failed to establish its claims under Annex C(1)(e). Under the approach followed by Argentina, this means that its claims under Article 8 have not been established either.

(c) Overall conclusion

7.2498 In the light of the above, the Panel reaches the following conclusion:

(i) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence submitted by Argentina and the European Communities, the Panel concludes that Argentina has not established that the product-specific measures in respect of which the Panel is making findings have resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(e) of the *SPS Agreement* and, consequently, with its obligations under Article 8 of the *SPS Agreement*.

14. Consistency of the product-specific measures with Article III:4 of the GATT 1994

7.2499 Canada and Argentina claim that the European Communities has acted inconsistently with its obligations under Article III:4 of the GATT 1994 in respect of the product-specific measures they are challenging. We recall that the United States did not present claims under the GATT 1994.

7.2500 Article III:4 of the GATT 1994 provides in relevant part:

> "The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use."

7.2501 **Canada** argues that the failure of the European Communities to consider or approve, without undue delay, the four applications of specific interest to Canada falls within the scope of the GATT 1994 and is inconsistent with the European Communities' obligations under Article III:4. According to Canada, the measures at issue are "laws, regulations or requirements laws, regulations or requirements affecting the internal sale, offering for sale, purchase, and distribution" of the biotech products concerned; the biotech products subject to the product-specific measures are "like" domestically-grown non-biotech counterparts in the light of the criteria put forth by the Appellate Body; and the imported biotech products concerned are accorded treatment less favourable than that accorded like non-biotech products of national origin. Canada submits that, for these reasons, the measures at issue constitute a violation of the European Communities' national treatment obligations under Article III:4.

7.2502 **Argentina** argues that the suspension of consideration of, or the failure to consider, the particular applications of interest to Argentina is inconsistent with Article III:4 of the GATT 1994, because it gives less favourable treatment to biotech products than to non-biotech products. Argentina argues that the inconsistencies result from the fact that (i) biotech and non-biotech products are "like products", (ii) the suspension of consideration of, or the failure to consider, the particular applications are "requirements affecting the sale, offering sale, purchase, transport, distribution and use of products on the domestic market", and (iii) the suspension of consideration of, or the failure to consider, the particular applications has modified the conditions of competition in the relevant market to the detriment of imported products.

7.2503 The **European Communities** argues that there is no violation of Article III:4 of the GATT 1994 with regard to the product-specific measures challenged by Canada and Argentina. This is because: (i) the measures challenged by Canada and Argentina are alleged delays in dealing with specific requests for approval within a specified timeframe, and these measures are not in themselves "laws, regulations or requirements" as provided for by Article III:4 of the GATT 1994; (ii) imported products are not accorded less favourable treatment than like domestic products, as there is no discrimination between relevant imported biotech products and same biotech products cultivated or processed domestically, which are the only "like products" to the imported biotech products concerned.

7.2504 The **Panel** will analyse Canada's and Argentina's claim separately.

(a) DS292 (Canada)

7.2505 In relation to DS292, we recall that we have already reached the conclusion that the failure by the European Communities to consider or approve, without undue delay, the four particular applications identified by Canada has given rise to a breach of the European Communities' obligations under Annex C(1)(a), first clause, of the *SPS Agreement* and, consequently, its obligations under Article 8 of the *SPS Agreement*. In these circumstances, we see no need to examine, and offer additional findings on, whether the relevant measures are also inconsistent with Article III:4. Accordingly, we exercise judicial economy with regard to Canada's claim under Article III:4.

(b) DS293 (Argentina)

7.2506 In relation to DS293, we begin our analysis with the applications concerning Bt-531 cotton and RR-1445 cotton which Argentina says have yet to be approved under Regulation 258/97.

(i) Product-specific measures affecting the approval of Bt-531 cotton and RR-1445 cotton under Regulation 258/97

7.2507 Argentina challenges under Article III:4 the suspension of consideration of, or failure to consider, applications concerning Bt-531 cotton and RR-1445 cotton which were allegedly submitted for "approval"[1668] under Regulation 258/97.

7.2508 We recall that in respect of the same alleged product-specific measures Argentina presented a claim under Article 5.1 of the *SPS Agreement*. In the context of our analysis of that claim, we have pointed out that we have seen no evidence that applications concerning Bt-531 cotton and RR-1445 cotton were submitted for approval under Regulation 258/97, and we therefore found that Argentina has failed to meet its burden of demonstrating the existence of a suspension of consideration of, or failure to consider, Bt-531 cotton and RR-1445 cotton for approval under Regulation 258/97. As the existence of these product-specific measures has not been demonstrated, we cannot but reject Argentina's claim that the European Communities has acted inconsistently with its obligations under Article III:4 in relation to these alleged measures.

(ii) Other product-specific measures challenged by Argentina

7.2509 We now turn to address the remaining eight product-specific measures in respect of which the Panel has decided to make findings.

7.2510 Argentina claims that the alleged suspension of consideration of, or the failure to consider, the relevant eight applications is inconsistent with Article III:4 of the GATT 1994 because it resulted in less favourable treatment being accorded to the biotech products which are the subject of the eight applications than to like non-biotech products.

7.2511 Argentina submits that the alleged suspension of consideration of, or the failure to consider, an application for the approval of a biotech product constitutes a "requirement" affecting the sale, offering for sale, etc. within the meaning of Article III:4. For the purposes of our analysis, we are willing to proceed on the assumption that the alleged suspension of consideration of, or the failure to consider, an application constitutes a "requirement" within the meaning of Article III:4. Moreover, we initially focus our analysis on the "no less favourable treatment" obligation contained in Article III:4, rather than on the "like products" element. We recall in this connection that the

[1668] Argentina's first written submission, paras. 201-202.

Appellate Body in *EC – Asbestos* and *Dominican Republic – Import and Sale of Cigarettes* made statements in relation to the meaning of the phrase "no less favourable treatment" in Article III:4.[1669] We find these statements to be relevant to the type of measures challenged by Argentina under Article III:4.

7.2512 Argentina contends that, as a result of the alleged suspension of consideration of, or the failure to consider, the relevant eight applications, the European Communities has accorded "less favourable treatment" to the biotech products which are the subject of the eight applications than to like non-biotech products. More particularly, Argentina considers that the measures at issue have modified the conditions of competition in the EC market to the detriment of imported biotech products. Argentina notes in this regard that as a result of the alleged suspension of consideration of, or the failure to consider, the relevant eight applications the biotech products which are the subject of these applications were not approved.

7.2513 In considering Argentina's contention, the first thing to be observed is that Argentina has not provided specific factual information about the treatment accorded by the European Communities to the non-biotech products which Argentina considers to be like the biotech products at issue. It appears to be Argentina's contention, however, that these non-biotech products may be marketed in the European Communities, whereas the relevant biotech products may not be marketed.

7.2514 At any rate, even if it were the case that, as a result of the measures challenged by Argentina, the relevant imported biotech products cannot be marketed, while corresponding domestic non-biotech products can be marketed, in accordance with the aforementioned statements by the Appellate Body this would not be sufficient, in and of itself, to raise a presumption that the European Communities accorded less favourable treatment to the group of like *imported* products than to the group of like *domestic* products. We note that Argentina does not assert that domestic biotech products have not been less favourably treated in the same way as imported biotech products, or that the like domestic non-biotech varieties have been more favourably treated than the like imported non-biotech varieties. In other words, Argentina is not alleging that the treatment of products has differed depending on their origin. In these circumstances, it is not self-evident that the alleged less favourable treatment of imported biotech products is explained by the foreign origin of these products rather than, for instance, a perceived difference between biotech products and non-biotech products in terms of their safety, etc. In our view, Argentina has not adduced argument and evidence sufficient to raise a presumption that the alleged less favourable treatment is explained by the foreign origin of the relevant biotech products.

7.2515 In the light of the above, we find that Argentina has not established that, as a result of the alleged suspension of consideration of, or the failure to consider, the relevant eight applications, the European Communities has accorded "less favourable treatment" to imported products than to domestic products.

7.2516 Since we have found that Argentina has not demonstrated to our satisfaction that imported products have been treated "less favourably" than domestic products, there is no need to go on to determine whether the challenged measures in fact constitute "requirements" within the meaning of Article III:4, and whether the imported products which Argentina alleges have been treated less favourably are "like" the domestic products which Argentina alleges have been treated more favourably. Our finding on the "no less favourable treatment" obligation necessarily implies that Argentina has failed to establish its claim under Article III:4 with regard to the eight product-specific measures in question.

[1669] We have reproduced the relevant statements at paras. 7.2404 and 7.2405 above.

(c) Conclusions

7.2517 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that it is not necessary to make findings on whether the product-specific measures which are being challenged by Canada are inconsistent with Article III:4 of the GATT 1994. Accordingly, the Panel offers no findings under Article III:4.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that Argentina has not established that the product-specific measures in respect of which the Panel is making findings have resulted in the European Communities acting inconsistently with its obligations under Article III:4 of the GATT 1994.

15. Consistency of the product-specific measures with the *TBT Agreement*

7.2518 The Panel now turns to address Canada's and Argentina's claims of inconsistency under the *TBT Agreement*. We recall that the United States did not present claims under the *TBT Agreement*.

7.2519 **Canada** considers that the product-specific measures it is challenging are SPS measures and that, as such, they are not subject to the requirements of the *TBT Agreement*. Canada argues, however, that if the Panel decides that the product-specific measures at issue are not SPS measures, then Canada submits, in the alternative, that these measures are subject to the requirements of the *TBT Agreement*. More particularly, Canada's alternative claim is that the relevant measures are inconsistent with Articles 2.1, 2.2, 5.1.2 and 5.2.1, first part, of the *TBT Agreement.*

7.2520 Furthermore, Canada states that to the extent that the Panel determines that parts of the measures at issue are covered by the *TBT Agreement* in addition to the *SPS Agreement*, Canada's TBT claims are to be considered cumulative rather than alternative, *vis-à-vis* its SPS claims.

7.2521 **Argentina** considers that the Panel should examine the product-specific measures Argentina is challenging under the *SPS Agreement*. However, if the Panel concludes that it should not analize Argentina's claim under the *SPS Agreement*, Argentina submits, in the alternative, that the product-specific measures at issue are subject to the requirements of the *TBT Agreement*. More particularly, in Argentina's view the relevant measures are inconsistent with Articles 2.1, 2.2, 5.1.1, 5.1.2, 5.2.1, 5.2.2 and 12 of the *TBT Agreement*.

7.2522 The **European Communities** considers that, given the reasons on which the relevant product-specific measures are based, they fall in part within the scope of the *SPS Agreement* and in part outside the scope of the *SPS Agreement*. However, the European Communities rejects the alternative claims by Canada and Argentina that the relevant product-specific measures they are challenging are inconsistent with the *TBT Agreement*.

7.2523 The **Panel** will analyse Canada's and Argentina's claims separately.

(a) DS292 (Canada)

7.2524 Canada has stated that if the Panel determines that parts of the relevant product-specific measures are covered by the *TBT Agreement* in addition to the *SPS Agreement*, Canada's claims under the *TBT Agreement* are to be considered cumulative rather than alternative. We note that each of the four product-specific measures challenged by Canada concerns an approval procedure which was conducted under Directive 90/220. In two cases, the relevant procedure was continued under Directive 2001/18 after the repeal of Directive 90/220. We have found that the relevant approval procedures set out in these Directives are SPS measures within the meaning of Annex A(1) of the *SPS Agreement*. We did not determine that parts of the approval procedures set out in the Directives are not covered by the *SPS Agreement*. In the light of this, and in view of Article 1.5 of the *TBT Agreement*[1670], we have no basis for finding that parts of the relevant approval procedures are covered by the *TBT Agreement* in addition to the *SPS Agreement*. Consequently, we should treat Canada's claims under Articles 2.1, 2.2, 5.1.2 and 5.2.1, first part, of the *TBT Agreement* as alternative claims. Since Canada's alternative claims are relevant only in the event that we decide that the relevant product-specific measures are not subject to the *SPS Agreement*, and since we have found that these measures are subject to the *SPS Agreement* (notably Annex C(1)(a) and Article 8), we see no need to address Canada's alternative claims under Articles 2.1, 2.2, 5.1.2 and 5.2.1, first part, of the *TBT Agreement* further.

(b) DS293 (Argentina)

7.2525 Argentina's claim that the product-specific measures it is challenging are inconsistent with the *TBT Agreement* is presented in the alternative, in the event the Panel "considers that it should not analyse Argentina's claim under the *SPS Agreement*".[1671]

7.2526 Regarding the product-specific measures described by Argentina as the undue delays in finalizing consideration of particular applications, we found above that the European Communities has breached its obligations under Annex C(1)(a), first clause, of the *SPS Agreement* and Article 8 of the *SPS Agreement* in respect of each of the eight measures concerned. Accordingly, in respect of these measures, we found that we *should* analyse Argentina's claim under the *SPS Agreement*. Since Argentina's alternative claim under the *TBT Agreement* is relevant only in the event that we consider that the relevant product-specific measures should *not* be analysed under the *SPS Agreement*, we see no need to address Argentina's alternative claim under the *TBT Agreement* further.

7.2527 Regarding the product-specific measures described by Argentina as the suspension by the European Communities of consideration of, or the failure to consider, particular applications, we found above that Argentina has not established that the European Communities acted inconsistently with its obligations under Articles 5.1, 5.5, 5.6 or 2.2 of the *SPS Agreement* in respect of the ten measures concerned. Thus, we found that the ten measures are not inconsistent with the provisions of the *SPS Agreement* identified by Argentina. However, the relevant findings do not imply that Argentina's claim that the relevant product-specific measures are WTO-inconsistent should not be analysed under the *SPS Agreement*. As we have said earlier, the second type of measures challenged by Argentina in our view is conceptually the same as the type of product-specific measures challenged by the United States. Our findings above show that the measures challenged by the United States could, and in many cases did, give rise to an inconsistency with the provisions of Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement*. Hence, we consider that Argentina's claim *could* be

[1670] We recall that Article 1.5 states that the provisions of the *TBT Agreement* do not apply to SPS measures within the meaning of Annex A(1) of the *SPS Agreement*.

[1671] Argentina's first written submission, paras. 374 and 450.

properly analysed under the *SPS Agreement*. Since Argentina's alternative claim under the *TBT Agreement* is relevant only in the event that we consider that the relevant product-specific measures should *not* be analysed under the *SPS Agreement*, we see no need to address Argentina's alternative claim under the *TBT Agreement* further.

(c) Conclusions

7.2528 In the light of the above, the Panel reaches the following conclusions:

(i) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that it is not necessary to make findings on whether the product-specific measures which are being challenged by Canada are inconsistent with Articles 2.1, 2.2, 5.1.2 and 5.2.1, first part, of the *TBT Agreement*. Accordingly, the Panel offers no findings under Articles 2.1, 2.2, 5.1.2 or 5.2.1, first part, of the *TBT Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that it is not necessary to make findings on whether the relevant ten product-specific measures challenged by Argentina are inconsistent with Articles 2.1, 2.2, 5.1.1, 5.1.2, 5.2.1, 5.2.2 and 12 of the *TBT Agreement*. Accordingly, the Panel offers no findings under Articles 2.1, 2.2, 5.1.1, 5.1.2, 5.2.1, 5.2.2 or 12 of the *TBT Agreement*.

F. EC MEMBER STATE SAFEGUARD MEASURES

1. Introduction

7.2529 The Complaining Parties have made a series of claims concerning measures adopted by EC member States which allegedly prohibit the import, use of, or marketing of certain biotech products. These measures (hereafter "safeguard measures" or "member State measures") were adopted by EC member States on the basis of Article 16 of Directive 90/220[1672] (later replaced by Article 23 of Directive 2001/18[1673]) and Article 12 of Regulation 258/97.[1674]

(a) Safeguard measures in the context of the relevant EC approval procedures

7.2530 Where a biotech product has been approved for Community-wide marketing under Directives 90/220 or 2001/18, or Regulation 258/97, member States ordinarily may not prohibit or restrict trade in, or use of, that product on their respective territories, provided the conditions attached to the marketing approval are being met. Exceptionally, however, member States may provisionally adopt safeguard measures which prohibit or restrict trade in, or use of, biotech products which have been granted Community-wide marketing approval.

[1672] Exhibits US-25; CDA-18; ARG-4.
[1673] Exhibits US-24; CDA-17; ARG-3.
[1674] Exhibits US-26; CDA-19; ARG-5.

7.2531 Pursuant to Article 16 of Directive 90/220, a member State may provisionally restrict or prohibit the use and or sale of a product in its territory where it has "justifiable reasons to consider that a product which has been properly notified and has received written consent [...] constitutes a risk to human health or the environment".[1675] Safeguard measures adopted pursuant to Article 16 of Directive 90/220 have been maintained and reviewed on the basis of Article 23 of Directive 2001/18 since the entry into force of that Directive. Article 23 provides that a safeguard measure may be adopted where, "as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge", a member State has "detailed grounds for considering that a GMO as or in a product [...] constitutes a risk to human health or the environment [...]".[1676] Finally, Article 12 of Regulation 258/97 provides that a safeguard measure may be adopted where, "as a result of new information or a reassessment of existing information", a member State has "detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment [...]".[1677]

7.2532 The safeguard measures taken pursuant to Directives 90/220 and 2001/18, or Regulation 258/97, can be maintained only on a provisional basis, pending a full assessment at EC level.[1678] The member State adopting a safeguard measure must immediately inform the Commission and other member States of its measure.[1679] Upon notification of the safeguard measure, the Commission must take a decision with respect to that measure. Such decision will result either in the modification of the Community-wide marketing approval, or in the termination of the measure.[1680]

7.2533 According to the procedure laid down in the relevant provisions of Directives 90/220 and 2001/18, and Regulation 258/97[1681], the Commission, when making a decision on a safeguard measure which has been notified, is assisted for this purpose by the Regulatory Committee[1682] or by the Standing Committee on Foodstuffs, respectively.[1683] The Commission must submit a draft of the measure to be taken to the Regulatory Committee or the Standing Committee on Foodstuffs, which shall deliver their opinion on the draft within a time-limit which the chairman may lay down according to the urgency of the matter.[1684] If the draft measure is in accordance with the opinion of the Regulatory Committee or the Standing Committee on Foodstuffs, the Commission must adopt the draft measure. However, if the measure is not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission must submit without delay a proposal to the Council of

[1675] *See supra*, footnote 1672.
[1676] *See supra*, footnote 1673.
[1677] *Supra*, footnote 1674.
[1678] Article 16(1) of Directive 90/220; Article 23(1), 3rd paragraph of Directive 2001/18; and Article 12(1) of Regulation 258/97.
[1679] Article 16(1) of Directive 90/220; Article 23(1), 3rd paragraph of Directive 2001/18; and Article 12(1) of Regulation 258/97.
[1680] Article 21 of Directive 90/220. Under Directive 90/220, such a decision by the Commission must be taken within a period of three months from the time of notification of the measure. We note that there is no similar timeframe pursuant to Regulation 258/97.
[1681] Details of the procedures for Directives 90/220 and 2001/18, and Regulation 258/97 are described in section C.
[1682] Articles 21 of Directive 90/220 and 30(2) of Directive 2001/18.
[1683] Article 13 of Regulation 258/97.
[1684] Article 21 of Directive 90/220; Article 30(2) of Directive 2001/18; and Article 13 of Regulation 258/97. While Article 30(2) of Directive 2001/18 refers to Articles 5, 7 and 8 of Decision 1999/468, the European Communities notes that these provisions are similar to Article 21 of Directive 90/220 (EC reply to Panel question No. 84, para. 229).

Ministers on the measure to be taken. The Council must act on the proposal within a period of three months, failing which the Commission must adopt the proposed measure.[1685]

(b) Overview of the specific measures at issue

7.2534 The Complaining Parties make claims with respect to nine different safeguard measures, which they allege prohibit the importation or marketing of various biotech products. The nine measures were taken by six different member States, namely Austria, France, Germany, Greece, Italy and Luxembourg. For ease of reference, the safeguard measures are identified hereinafter by the name of the member State which has adopted the measure and the product(s) affected by such measure. Accordingly, the following safeguard measures are at issue in this dispute:

(1) *Austria – T25 maize*;
(2) *Austria – Bt-176 maize*;
(3) *Austria – MON810 maize*;
(4) *France – MS1/RF1 oilseed rape (EC-161)*;
(5) *France – Topas oilseed rape*;
(6) *Germany – Bt-176 maize*;
(7) *Greece – Topas oilseed rape*;
(8) *Italy – Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25 maize*; and
(9) *Luxembourg – Bt-176 maize.*

7.2535 The safeguard measures at issue have all been taken pursuant to Article 16 of Directive 90/220, with the exception of the measure by Italy on Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25 maize, which was adopted on the basis of Article 12 of Regulation 258/97.

7.2536 Each safeguard measure was notified to the Commission by the relevant member State with evidence allegedly supporting the adoption of the measure. On the basis of the information provided by the member State, the Commission requested in each case the opinion of the relevant EC scientific committee on whether this information constituted relevant scientific evidence that would cause the committee to consider that the product(s) at issue constituted a risk for human health or the environment. For each safeguard measure at issue, the relevant EC scientific committee reaffirmed its earlier assessment, or that of another EC scientific committee that the relevant products did not present any risks to human health or the environment. However, the Panel understands that as of the date of establishment of this Panel, no decision had been taken at Community level with regard to any of the safeguard measures at issue in this dispute. That is to say, no decision had been taken with regard to whether the Community-wide marketing approval for the relevant products should be modified, or whether the safeguard measures at issue should be terminated.[1686]

7.2537 The safeguard measures at issue in this dispute were still in force at the time of establishment of this Panel.[1687] However, the European Communities asserts that the safeguard measure adopted by Italy was repealed by a Decree adopted in October 2004.[1688]

[1685] Article 21 of Directive 90/220; Article 30 of Directive 2001/18; and Article 13(4)(b) of Regulation 258/97.

[1686] According to Canada, the Commission indicated that it had called upon all EC member States with national measures in place restricting or prohibiting the marketing of EC-approved biotech products to lift or withdraw those measures. *See* Exhibits CDA-33 and -34.

[1687] EC reply to Panel question No. 101.

(c) Overview of Parties' claims and Panel's approach

7.2538 The **United States** is challenging all nine safeguard measures at issue in this case, as mentioned in paragraph 6 above. According to the United States, these safeguard measures are covered by the *SPS Agreement*. The United States argues that the safeguard measures violate various provisions of the *SPS Agreement*. In particular, the member States have failed to base their measures on a risk assessment and on scientific principles pursuant to Articles 5.1 and 2.2 of the *SPS Agreement*. Moreover, the member States have applied arbitrary or unjustifiable distinctions in their levels of protection against risks that have resulted in discrimination or a disguised restriction on international trade pursuant to Articles 5.5 and 2.3 of the *SPS Agreement*. The United States further argues that the safeguard measure prohibiting the importation of Topas oilseed rape adopted by Greece, in addition to violating various provisions of the *SPS Agreement*, violates Article XI:1 of the GATT 1994.

7.2539 **Canada** is challenging five safeguard measures, namely:

(1) *Austria – T25 maize*;
(2) *France – MS1/RF1 oilseed rape (EC-161)*;
(3) *France – Topas oilseed rape*;
(4) *Greece – Topas oilseed rape*; and
(5) *Italy – Bt-11 maize (EC-163), MON809 maize, MON810 maize and T25 maize*.

7.2540 Canada argues that the safeguard measures are SPS measures pursuant to Annex A of the *SPS Agreement*, and also affect international trade. Canada argues that the safeguard measures are not based on a risk assessment, as required by Article 5.1 of the *SPS Agreement*. Canada further argues that the safeguard measures violate Article 5.6, since the European Communities' own regulatory regime constitutes another measure, reasonably available taking into account technical and economic feasibility. Canada argues that the safeguard measures fail to meet any of the three requirements of Article 2.2, namely that they 1) be applied to the extent necessary to protect human, animal or plant life or health; 2) be based on scientific principles; and 3) not be maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5. Consequently Canada argues that these measures violate Article 2.2. Finally, Canada argues that the safeguard measures are inconsistent with the European Communities' obligations under Article 5.5 of the *SPS Agreement*, and thus by implication, also violate Article 2.3.

7.2541 With respect to the Greek safeguard measure, Canada considers that it violates Article XI:1 of the GATT 1994. Canada further argues that the safeguard measures are inconsistent with Article III:4 of the GATT 1994. Canada also makes cumulative claims under the *TBT Agreement* arguing that the measures constitute technical regulations because they establish product specifications. In particular, Canada argues that the safeguard measures are inconsistent with Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.

7.2542 **Argentina** makes claims with respect to six member State measures, as follows:

(1) *Austria – T25 maize*;
(2) *Austria – Bt-176 maize*;
(3) *Austria – MON810 maize*;
(4) *Germany – Bt-176 maize*;

[1688] *See* EC reply to Panel question No. 160 and Exhibit EC-166. This was contested by Canada in their comments on other Parties' responses to Panel question 160, paras. 52-53.

(5) *Italy – MON810 maize, T25 maize, Bt-11 maize (EC-163)*[1689]; and
(6) *Luxembourg – Bt-176 maize.*

7.2543 Argentina argues that the safeguard measures are SPS measures pursuant to Annex A of the *SPS Agreement*, and also affect international trade. Argentina argues that the safeguard measures are not based on a risk assessment, as required by Article 5.1 of the *SPS Agreement*. Argentina further argues that the safeguard measures violate Article 5.6, since the European Communities' own regulatory regime constitutes another measure, reasonably available taking into account technical and economic feasibility. Argentina argues that the safeguard measures fail to meet the requirements of Article 2.2, which requires that a measure be applied "only to the extent necessary," while also requires that it be based on "sufficient scientific evidence." Consequently, the safeguard measures conflict with Article 2.2, and cannot be justified under the exception of Article 5.7. Finally, Argentina argues that the safeguard measures are inconsistent with the European Communities' obligations under Article 5.5 of the *SPS Agreement*, and thus by implication, also violate Article 2.3.

7.2544 Argentina argues that the safeguard measures are inconsistent with Article III:4 of the GATT 1994. Argentina also makes alternative claims under the *TBT Agreement* arguing that the measures constitute technical regulations because they establish product specifications. In particular, Argentina argues that the safeguard measures are inconsistent with Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.

2. Analysis of the safeguard measures in the light of the *SPS Agreement*

7.2545 Before examining whether the relevant safeguard measures are inconsistent with the *SPS Agreement*, as claimed by the Complaining Parties, we must determine whether the *SPS Agreement* is applicable to these measures.

(a) Applicability of the *SPS Agreement*

7.2546 We begin our examination of whether the *SPS Agreement* is applicable to the relevant safeguard measures by summarizing the Parties' general positions. In the light of these, we will outline how we will approach this issue, and subsequently address the applicability of the *SPS Agreement* measure-by-measure.

(i) General

7.2547 The **United States** argues that all the safeguard measures fall within the scope of the *SPS Agreement*. The general purpose of the member State measures can be inferred from the text of the EC legislation on which the measures are based. The overall objective set out in Article 16 of Directive 90/220 and Article 12 of Regulation 258/97 is the protection of human health and the environment. Since all measures were based on one of these provisions, it can be inferred that the measures were enacted for the purpose of protecting human health and the environment. Moreover, the sanitary or phytosanitary purpose of the member State measures can be found in the measures themselves, as well as in the justifications offered by the member States when the measures were adopted.

[1689] In respect of the safeguard measure imposed by Italy, while the complaints by the United States and Canada refer to four products, *i.e.*, Bt-11 maize (EC-163), MON809 maize, MON810 maize and T25 maize, the complaint by Argentina refers to only three products, *i.e.*, Bt-11 maize (EC-163), MON810 maize and T25 maize.

7.2548 The United States notes that the European Communities has not contested the fact that each of the member State measures was adopted at least for some reasons that fall within the scope of the *SPS Agreement*. It considers that the fact that the measures were adopted for some reasons covered by the *SPS Agreement* is sufficient to bring those measures within the scope of that Agreement. Annex A of the *SPS Agreement* makes it clear that "any measure" applied to protect against one of the enumerated risks falls within the scope of the Agreement. Annex A does not state that the measure needs to be exclusively applied to protect against only the enumerated risks, nor does the *SPS Agreement* state that a measure addressing one of the risks enumerated in Annex A loses its status as an SPS measure if the adoption of the measure is also supported by other rationales. The United States notes that in the *EC - Hormones* case, all parties agreed that the relevant EC Directives fell within the scope of the *SPS Agreement*, even though the Directives were not adopted solely to address alleged effects on human health.

7.2549 **Canada** argues that the safeguard measures it is challenging fall within the scope of paragraph 1(a) to (d) of Annex A of the *SPS Agreement*. Canada notes that the member State measures are intended to "protect" "human", "animal" or "plant" "life or health", or "to prevent or limit other damage" within their territories, as can be inferred from the relevant provisions of EC law on which the measures are based. According to Canada, this can also be inferred from the measures themselves, as well as from official statements made by government officials in relation to the passage or adoption of the measures. This evidence also supports the conclusion that these measures are designed to protect against "risks arising from" "the entry, establishment or spread" of "pests" or "disease-causing organisms" or "additives, contaminants, toxins or disease-causing organisms" in "food" or "feedstuffs". Although these terms are not defined in the *SPS Agreement*, their ordinary meaning, when read in context and in light of the object and purpose of the *SPS Agreement*, falls within the scope of the types of concerns intended to be addressed by the safeguard measures. More importantly, the text of the measures themselves, as well as the supporting documentation provided at the time the measures were adopted, demonstrate that the measures are SPS measures.

7.2550 **Argentina** argues that the purpose of the safeguard measures may be inferred from the Community legislation under which the measures were adopted. The relevant provisions of EC Directive 90/220 and Regulation 258/97 clearly indicate that the purpose of the EC legislation is the "protection of human health and the environment". Since the EC member States have taken their measures explicitly on the basis of this legislation, it can be inferred that the measures were imposed for the purpose of protecting human health or the environment. The safeguard measures are, therefore, SPS measures as defined in the *SPS Agreement*.

7.2551 The **European Communities** notes that each of the safeguard measures was adopted for some reasons that fall within the scope of the *SPS Agreement*, and some reasons that fall outside the scope of that Agreement. According to the European Communities, if a WTO Member acts on the basis of two different objectives, one of which falls within the scope of the *SPS Agreement* and the other of which does not, these two measures are in effect different for WTO purposes. Therefore, the measure or part of the measure adopted for reasons that fall outside the scope of the *SPS Agreement* cannot be inconsistent with that Agreement. Only the measure, or part of the measure, adopted for reasons that fall within the scope of the *SPS Agreement* require further analysis. This is so even if the two different objectives sought to be achieved by a measure are reflected in a single document.

7.2552 The **Panel** recalls that pursuant to Article 1.1 of the *SPS Agreement*, the Agreement applies to "all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade".

7.2553 We recall once again that the term "SPS measures" is defined in Annex A(1) of the *SPS Agreement* as any measure applied:

> (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
>
> (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
>
> (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
>
> (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.
>
> Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures [...].

7.2554 In order to determine whether the *SPS Agreement* applies to the safeguard measures, the Panel must therefore determine (1) whether such measures are "sanitary or phytosanitary measures", or "SPS measures", as defined in Annex A of the *SPS Agreement*; and (2) whether these measures may, directly or indirectly, affect international trade.

7.2555 It is clear from the definition contained in Annex A(1) that one of the elements which determines whether a particular measure is an SPS measure is the purpose of the measure.[1690] A measure is an SPS measure if it is applied "to protect" life or health from certain enumerated risks, or if it is applied "to prevent or limit" certain other damage.

7.2556 In the case at hand, the Complaining Parties are challenging the maintenance in August 2003 of the relevant safeguard measures. We must therefore determine whether at that time each of the relevant safeguard measures served at least one of the purposes identified in the definition contained in Annex A of the *SPS Agreement*. In our view, a determination as to whether a particular safeguard measure was applied in August 2003 for one of the purposes enumerated in Annex A(1) must be made in the light of the specific circumstances of each case.

7.2557 We note that applicable EC legislation required the member States in question to provide justification for the adoption of their safeguard measures. We think that documents submitted by these member States by way of justification for the adoption of their measures are relevant to ascertaining the purposes of these measures.

7.2558 However, we consider that it would not be appropriate in this case to limit our inquiry to determining the purposes for which the safeguard measures were adopted. To begin with, we recall that our task in this case is to determine the purposes for which the relevant safeguard measures were maintained in August 2003. Furthermore, Annex A(1) does not refer to measures "adopted" for one of the enumerated purposes, but, more broadly, to measures "applied" for one of the enumerated purposes. Moreover, we see nothing in the *SPS Agreement* which would bar a panel from considering purposes which were not articulated by the member States when they adopted their safeguard

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[1690] As we have noted above in the context of our discussion of the general *de facto* moratorium on approvals, there are other elements which must be met for a measure to constitute an "SPS measure". *See supra*, para. 7.456.

measures.[1691] Finally, our approach is consistent with the view expressed by the Appellate Body that in identifying the purposes of a measure, panels need not seek to determine the subjective intent of the legislators or regulators who adopted the measure. According to the Appellate Body, the purposes of a measure may and should rather be ascertained on the basis of objective considerations, for instance by examining whether there is an objective relationship between the stated purposes and the text and structural features of the relevant measure.[1692]

7.2559 We recall that the safeguard measures were originally adopted on the basis of Article 16 of Directive 90/220 and Article 12 of Regulation 258/97. Both provisions make it clear that safeguard measures may be taken in case of a risk, or danger, to human health or the environment.[1693] The Complaining Parties argue that it can be inferred from this that the purpose of the safeguard measures is to protect against risks to human health or the environment. We note that the provisions of the *SPS Agreement* reflect similar objectives.[1694] We agree that the fact that the member States have invoked Article 16 of Directive 90/220 and Article 12 of Regulation 258/97 in support of their measures may, together with other elements, support the conclusion that these measures are applied to protect against risks to human health or the environment. However, the mere invocation of, and reference to, the aforementioned articles does not demonstrate, in and of itself, that a particular measure is in fact being applied for the purpose of protecting human health or the environment. Thus, we think it is necessary to make a separate assessment of the applicability of the *SPS Agreement* for each of the nine safeguard measures at issue.

7.2560 With these considerations in mind, we now turn to examine individually the nine safeguard measures at issue in this case.

[1691] This does not mean, however, that we need to accept at face value assertions of purposes which are implausible in the light of all relevant circumstances.

[1692] *See, e.g.*, Appellate Body Reports, *Japan – Alcoholic Beverages II*, pp. 27-28 (including the statement that "[i]t is irrelevant that protectionism was not an intended objective if the particular tax measure in question is nevertheless, to echo Article III:1 [of the GATT 1994], "applied to imported or domestic products so as to afford protection to domestic production. This is an issue of how the measure in question is applied"); *Chile – Alcoholic Beverages*, paras. 62 and 71-72; and *US – Offset Act* (*Byrd Amendment*), para. 259. While these Appellate Body reports discussed claims under WTO agreements other than the *SPS Agreement*, the logic followed by the Appellate Body in these reports is applicable, in our view, to the issue we are considering here.

[1693] Article 16 of Directive 90/220: "1. Where a Member State has justifiable reasons to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision. 2. A decision shall be taken on the matter within three months in accordance with the procedure laid down in Article 21."

Article 12 of Regulation 258/97: "1. Where a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment, that Member State may either temporarily restrict or suspend the trade in and use of the food or food ingredient in question in its territory. It shall immediately inform the other Member States and the Commission thereof, giving the grounds for its decision. 2. The Commission shall examine the grounds referred to in paragraph 1 as soon as possible within the Standing Committee for Foodstuffs; it shall take the appropriate measures in accordance with the procedure laid down in Article 13. The Member State which took the decision referred to in paragraph 1 may maintain it until the measures have entered into force."

[1694] *See* e.g. Preamble for protection of human health; relevant ecological and environmental conditions to be taken into account in assessment of risks pursuant to Article 5.2 of the *SPS Agreement*.

(ii) Austria – T25 maize

7.2561 We begin with the safeguard measure applied by Austria on T25 maize. We recall that the product at issue was approved by the Commission for placing on the market in April 1998.[1695] In April 2000, Austria adopted an ordinance to prohibit commercialisation of T25 maize on its territory.[1696] Austria's safeguard measure, which was taken on the basis of Article 16 of Directive 90/220, was notified to the Commission in May 2000.[1697]

Is the Austrian safeguard measure on T25 maize an SPS measure?

7.2562 We start with the issue of whether the Austrian safeguard measure on T25 maize is an SPS measure. In order to make this determination, we need to consider two distinct elements, namely: (1) the purpose of the measure; and (2) the form and nature of the measure.

Purpose of the safeguard measure

7.2563 We first consider the issue of the purpose of the safeguard measure. Before turning to the arguments of the Parties on this issue, we recall that we must determine whether the purpose of the safeguard measure falls within one of the categories of purposes set out in Annex A(1) of the *SPS Agreement*.

7.2564 The **United States** notes that among the reasons set out to prohibit T25 maize, Austria cited the failure by the European Commission, at the time it approved the product, to set forth "protection for ecologically sensitive regions." According to the United States, a measure based on such justification is an SPS measure because it is applied "to protect animal life or health" from "disease-causing organisms"; or "to prevent or limit [...] damage" from the "spread of pests".

7.2565 **Canada** notes that Austria sought to justify its ban on T25 maize on the grounds that pollen from the genetically modified variety could spread to fields containing non-biotech maize, giving rise to a risk of genetic transfer and the development of herbicide resistance in other species. Austria also cited the absence of a monitoring programme on the long-term effects of genetically altered plants, particularly in relation to the protection of ecologically sensitive regions, and the need for further testing of possible long-term ecological effects. Since these concerns relate to potential risks arising from T25 maize acting as a "pest" in relation to its surrounding environment, Canada argues that the Austrian safeguard measure is an SPS measure within the meaning of Annex A(1) of the *SPS Agreement*.

7.2566 **Argentina** argues that the purpose of the safeguard measures may be inferred from the Community legislation under which the bans were adopted, and that the relevant provisions of EC Directive 90/220 and Regulation 258/97 clearly indicate that the purpose of the EC legislation is the "protection of human health and the environment". Since the EC member States have taken their measures explicitly on the basis of this legislation, it can be inferred that the measures were imposed

[1695] Commission Decision 98/293.

[1696] We note that the text of the ordinance provides for an exception in cases where the product is to be immediately re-exported after handling and repackaging. Regulation No. 120, Federal Ministry for Social Protection and Generations, Ordinance issued on 28 April 2000 prohibiting the commercialization of the genetically altered corn Zea Mays L. T25 in Austria, approved by the European Commission on 22 April 1998 under Decision 98/293, Federal Gazette, vol. 2000, 28 April 2000 (Exhibits EC-160/At. 3_trans; CDA-76; US-53).

[1697] Exhibit EC-160/At. 3_trans.

for the purpose of protecting human health or the environment. The safeguard measures are, therefore, SPS measures as defined in the *SPS Agreement*.

7.2567 The **European Communities** asserts that the main reasons for which the Austrian measure affecting T25 maize was adopted and maintained include, *inter alia*, horizontal gene transfer; antibiotic resistance; effects on non-target organisms; persistence and invasiveness in agricultural and natural habitats; development of resistance; out-crossing; undesirable effects on management practices; biodiversity; monitoring; labelling; co-existence; and human and animal health.[1698]

7.2568 In examining the purposes for which Austria's safeguard measure on T25 maize is applied, the **Panel** will first consider the documents notified by Austria to the Commission in support of its safeguard measure. We note that Austria provided a justification for its safeguard measure in a document entitled "*Reasons for the decision of the Republic of Austria to prohibit the placing on the market of GM maize line T25* [...]" (hereafter the "Reasons document").

7.2569 In the Reasons document, Austria argued that the product had not been examined under realistic conditions of the use of the herbicide and of corresponding agricultural practices. [1699] Austria noted in this regard that neither the applicant's application seeking approval for the placing on the market of T25 maize nor the approval decision of the Commission foresaw a monitoring programme. In particular, Austria considered that special measures monitoring the spread of pollen to surrounding fields cultivated with conventional maize were missing. Austria further criticized the lack of a monitoring programme regarding the long-term effects of biotech plants and herbicides especially because of the fact that the conditions attached to the approval of T25 maize for Community-wide marketing did not foresee the protection of environmentally sensitive areas. An additional reason cited by Austria in support of its safeguard measure was that regional ecological aspects were not differentiated. Austria pointed out in this regard that the use of herbicide resistant plants such as T25 maize in areas of unavoidable applications of herbicides seemed to be useful, if good agricultural practices minimized the danger of the development of resistance in other species. Austria argued, however, that since mountain ecosystems are susceptible to accelerated soil erosion and rapid loss of habitat and genetic diversity, the use of herbicide resistant plants such as T25 maize in these areas should only take place after further investigations of possible long-term and secondary ecological effects.

7.2570 A document submitted by Austria to the Commission for an Experts Meeting held in Brussels in January 2004 (hereafter the "January 2004 document") also sheds light on the reasons for which Austria is applying its safeguard measure on T25 maize.[1700] In this document, Austria states that it adopted a safeguard measure because: (a) the environmental risk assessment was considered as insufficient, as it had not taken into account an integrated point of view of the use of herbicides under realistic conditions[1701]; and (b) possible long term effects and ecological aspects had not been scientifically assessed. In addition to these reasons, Austria cited other, more general concerns which in its view justify the precautionary approach embodied in Austria's safeguard measure. Specifically, Austria pointed out that the allergological and toxicological risk assessment concerning EC-approved biotech products such as T25 maize had been inadequate. Austria also noted that pending the report of the Working Group on antibiotic resistance marker genes set up by the European Communities in

[1698] Exhibit EC-155.
[1699] Exhibit EC-160/At. 3_trans.
[1700] Exhibit EC-158/At. 30.
[1701] It is not clear to the Panel if Austria is referring to a specific environmental risk assessment, and if so, which assessment.

accordance with Directive 2001/18, products containing such genes, including T25 maize, should not be placed on the market.

7.2571 Finally, we note that Austria's reasons for adopting the safeguard measure on T25 maize are also discussed in a letter addressed to the Commission in February 2004 by the Austrian Federal Minister for Health and Women. In that letter, Austria rejected a request by the Commission for the withdrawal of Austria's safeguard measure. In this context, Austria recalled that "[t]he crucial factors in the case of [the decision concerning] maize T25 were the absence of a supervisory programme and of an examination of the use of herbicide and agricultural practice. Both are related to the consideration of regional ecological characteristics and the protection of ecologically sensitive areas."[1702] Austria also reiterated its concern about inadequacies in the allergological and toxicological risk assessment concerning biotech products, such as T25 maize, which were submitted for approval under Directive 90/220[1703] and/or Regulation 258/97. Furthermore, Austria noted that it could not withdraw its safeguard measure on T25 maize in view of the fact that a coherent regulatory solution to the problem of coexistence had not yet been found.

7.2572 Based on the foregoing, we consider that at the time of review by the Panel, Austria applied its safeguard measure on T25 maize to address concerns about:[1704]

(1) the spread of pollen to cultivated surrounding fields (co-existence);
(2) long-term ecological effects in environmentally sensitive areas;
(3) allergenicity and toxicity; and
(4) the development of antibiotic resistance.

7.2573 The European Communities asserts that Austria's safeguard measure on T25 maize is also applied in view of concerns about labelling**.** This concern was not articulated by Austria in the documents discussed by us above. Furthermore, the European Communities has neither substantiated nor explained its assertion. In the light of this, we are not persuaded that Austria is applying its safeguard measure also to address the additional concern identified by the European Communities.

7.2574 Having determined the purposes for which Austria applied its safeguard measure at the time of review by the Panel, we now go on to assess whether these purposes fall within one of the categories of purposes which according to Annex A(1) characterize an SPS measure. To that end, we will consider one by one each of the above-noted purposes of Austria's safeguard measure.

Spread of pollen to cultivated surrounding fields (co-existence)

7.2575 We begin with the purpose of preventing the spread of pollen to surrounding areas cultivated with conventional maize. We observe that Austria does not claim that its safeguard measure on T25 maize is intended to prevent environmental effects associated with out-crossing between T25 maize and conventional maize. Rather, Austria emphasizes the need for "special measures monitoring the possible – mostly regarded as safe – spread of pollen to fields in the surroundings cultivated with conventional maize".[1705] As Austria in this statement explicitly notes the lack of compelling safety

[1702] Exhibit EC-158/At. 31_trans.

[1703] The document submitted by Austria actually refers to Regulation 2001/18, which appears to be an error.

[1704] We note that some of these concerns were articulated by Austria in documents which post-date the date of establishment of this Panel. However, we see no grounds for considering that these plausible concerns did not underlie the safeguard measure at issue already in August 2003.

[1705] Exhibit EC-160/At. 3, p. 4.

concerns, we understand this statement to refer to concerns over the possible loss of economic value to farmers, who due to the existence of unwanted, out-crossed plants in their fields, can no longer market their crops as non-GM crops.

7.2576 In Section VII.C we have found that the term "other damage" as it appears in Annex A(1)(d) includes economic damage which arises from the entry, establishment or spread of pests and which is not a consequence of damage to the life or health of animals or plants. We also found that plants growing where they are undesired can be considered as "pests". This includes cross-breeds between GM maize and conventional maize which grow in a conventional maize field.

7.2577 In view of these findings, we consider that Austria's safeguard measure on T25 maize, to the extent it is applied to prevent economic damage resulting from the entry, establishment or spread of cross-breeds between T25 and conventional maize in cultivated surrounding maize fields, falls within the scope of Annex A(1)(d) of the *SPS Agreement.*

Long-term ecological effects in environmentally sensitive areas

7.2578 The Panel turns now to the next objective stated by Austria for prohibiting the placing on the market of T25 maize, namely, Austria's concerns over long-term ecological effects. Austria includes in this category of concerns secondary ecological effects. The Panel understands the term "secondary ecological effects" to refer to indirect environmental effects which might be caused by the cultivation of T25 maize.

7.2579 In Section VII.C we have addressed concerns that GM plants might crowd out or eliminate other plants, due to a potential competitive advantage, invasiveness or persistence, thus affecting the genetic diversity of remaining plant populations and putting at risk the survival of certain plant species. In relation to these concerns, we stated that to the extent a measure is applied to avoid this kind of adverse effect, it can be considered a measure covered by Annex A(1)(a), as it would be applied "to protect [...] plant life or health […] from risks arising from the entry, establishment or spread" of GM plants *qua* "pests".

7.2580 We further found that to the extent that GM plants may result in changes in plant populations, this may increase or decrease the food available for particular animal populations and thus enhance, or detract from, the fitness and health of these animal populations, which in turn may have a deleterious effect on the life or health of plants, *e.g.*, by affecting their ability to reproduce. We stated that, by causing harm to the health of animals or other plants in this way, GM plants would act as "pests" within the meaning of Annex A(1)(a), and that to the extent a measure is applied to avoid this kind of adverse effect, it can be considered a measure covered by Annex A(1)(a).

7.2581 We also found that Annex A(1)(a) covers measures applied to protect animal or plant life or health from risks arising directly or indirectly from the entry, establishment or spread of cross-breeds with undesired traits (such as herbicide resistance) resulting from transfer of genetic material from a GM plant.

7.2582 Moreover, we addressed potential risks to the environment, including to farmland wildlife, resulting from a change in weed control practices (the application of a herbicide where none was used before the increased application of a herbicide, or the application of a different, more harmful herbicide). We said that to the extent a measure is applied to avoid adverse effects on the life or health of animals or plants which arise from the management techniques associated with GMOs, such a measure falls within the scope of Annex A(1)(a), in that it can be viewed as a measure applied to

protect the life or health of animals or plants from risks arising indirectly from the entry, establishment or spread of weeds *qua* "pests".

7.2583 Finally, we found that to the extent a measure seeks to avoid adverse effects of GMOs on the environment other than adverse effects on animal or plant life or health, including on geochemical processes, such a measure can be considered to be covered by Annex A(1)(d), inasmuch as it can be viewed as a measure which is applied to prevent or limit "other damage" from the entry, establishment or spread of "pests". As noted earlier, the GMOs themselves or cross-breeds of GM plants might qualify as the relevant pests, or other plants or animals might become pests as a result of the release of GMOs into the environment. Furthermore, we said that to the extent that a measure is applied to avoid adverse effects arising from the management techniques associated with GMOs other than damage to the life or health of animals or plants, that measure can be considered as a measure applied to prevent or limit "other damage" resulting indirectly from the entry, establishment or spread of weeds *qua* "pests".

7.2584 In view of the above findings, we consider that Austria's safeguard measure on T25 maize, to the extent it is applied to avoid potential long-term ecological effects of the release into the environment of T25 maize, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

Allergenicity and toxicity

7.2585 We turn now to Austria's stated concern regarding potential risks of allergenicity and toxicity associated with T25 maize.

7.2586 In Section VII.C we have found that Annex A(1)(b) covers measures applied to protect the life or health of humans or animals (not including target organisms) from risks arising from toxins produced in GM plants which are foods or feedstuffs. Furthermore, we found that to the extent that a measure seeks to protect humans and animals from allergenic effects of GM plants used as or in foods, that measure can be considered to be a measure applied to protect human or animal life or health from risks arising from toxins produced in GM plants which are foods or feedstuffs and, as such, would fall within the scope of Annex A(1)(b).

7.2587 We also recall our view that if interaction with, and exposure to, GMOs other than as or in a food produced allergenic effects in persons, the GMOs in question could be considered "pests" within the meaning of Annex A(1). We therefore found that to the extent that a measure seeks to avoid the entry, establishment or spread of allergenic GM plants, that measure can be considered to be a measure applied to protect human life or health from risks arising from the entry, establishment or spread of GM plants *qua* "pests". As such, it would fall within the meaning of Annex A(1)(c).

7.2588 In view of the above findings, we consider that Austria's safeguard measure on T25 maize, to the extent it is applied to protect from potential allergenic and toxicologic effects associated with T25 maize, falls within the scope of Annex A(1)(b) and (c) of the *SPS Agreement*.

Development of antibiotic resistance

7.2589 We turn finally to the purpose of managing potential risks associated with the transfer of the *bla*-ampicillin resistance gene to bacteria of the intestine of humans or animals due to consumption of T25 maize. We recall our discussion in Section VII.C regarding antibiotic resistance marker genes (ARMG). More particularly, we recall that in our view, the concern relates to the potential transfer to pathogens of ARMG present in certain GMOs, and the possible resulting decrease in effectiveness of

medical treatments involving specific antibiotics which might pose a risk to the life or health of animals infected with the resistant pathogen.

7.2590 In Section VII.C we have found that Annex A(1)(a) covers measures applied to protect animal life or health from risks arising from the entry, establishment or spread of disease-causing organisms which have or might become resistant to antibiotics due to the transfer of ARMG from a GM plant. Similarly, we found that Annex A(1)(a) covers measures applied to protect animal life or health from risks arising from the entry, establishment or spread of diseases due to the reduced effectiveness of antibiotics used to treat the pathogens which have become resistant to these antibiotics through gene transfer. Furthermore, we found that Annex A(1)(b) covers measures applied to protect human or animal life or health from risks arising indirectly, namely *via* the potential transfer to humans or animals of marker genes conferring resistance to antibiotics used in human or veterinary medicine, from additives in foods or feedstuffs. We recall in this respect that, in our view, ARMGs can be considered to be additives for the purposes of Annex A(1)(b).

7.2591 In view of the above findings, we consider that Austria's safeguard measure on T25 maize, to the extent it is applied to avoid risks associated with the transfer of the *bla*-ampicillin resistance gene to bacteria of the intestine of humans or animals due to consumption of T25 maize, falls within the scope of Annex A(1)(a) and (b) of the SPS Agreement.

Conclusion with regard to the purpose of the safeguard measure

7.2592 In the light of the above considerations, we conclude that the safeguard measure applied by Austria with respect to T25 maize qualifies as an SPS measure within the meaning of Annex A(1) as far as its purpose is concerned.

Form and nature of the safeguard measure

7.2593 We now turn to the issue of the form and nature of the Austrian safeguard measure on T25 maize. We start by recalling the Parties' arguments on this matter.

7.2594 The **United States** notes that the Austrian measure is in the form of an "ordinance", which is defined as "an authoritative decree or command"[1706]. The United Stated further notes that a decree is among the types of measures explicitly mentioned in Annex A(1) of the *SPS Agreement*.

7.2595 **Canada** argues that the measure falls within the scope of "laws, decrees, regulations, requirements and procedures." As indicated by the use of the word "include", Annex A provides a non-exhaustive list of the forms that an SPS measure can take. The Austrian measure takes the form of an "ordinance", a type of measure which is not among those expressly enumerated in Annex A, but which is nonetheless legally binding and lawfully promulgated by the central government authorities. The term ordinance is also defined as synonymous to the word "decree", which is specifically referred to in Annex A(1).

7.2596 **Argentina** notes that an "ordinance" is defined as an "authoritative decree or command", and that a decree is one of the types of measures specifically mentioned in Annex A of the *SPS Agreement*.

[1706]*The New Shorter Oxford English Dictionary*, L. Brown (ed.) (Clarendon Press, 1993), Vol. I, p. 2017.

7.2597 The **Panel** recalls that the second paragraph of Annex A(1) addresses the form and nature of measures which may qualify as SPS measures. In respect of the form of SPS measures, we have indicated earlier in this report that the reference in the second paragraph to "laws, decrees [and] regulations" should not be taken to prescribe a particular legal form and that SPS measures may in principle take many different legal forms. Furthermore, in respect of the nature of SPS measures, we have indicated earlier that the reference in the same paragraph to "requirements" is broad and unqualified. Hence, both an authorization to market a particular product and a ban on the marketing of a particular product may be considered as "requirements". The second example would constitute a negative requirement.

7.2598 We note that the Austrian safeguard measure on T25 maize was implemented by Austria through an ordinance to prohibit commercialization of T25 maize on its territory. Annex A(1) does not specifically refer to "ordinances". As we have pointed out, this fact alone does not necessarily mean that Austria's safeguard measure is not an SPS measure, since no specific legal form is prescribed. Austria's ordinance clearly is a measure attributable to the Austrian Government. It is also not in dispute that the ordinance is legally binding. We therefore consider that, for the purposes of Annex A(1), the Austrian ordinance may be assimilated to measures adopted in the form of "laws", "decrees" or "regulations".

7.2599 In respect of the nature of the Austrian measure, we note that the ordinance prohibits the marketing of T25 maize. As indicated above, we are of the view that a prohibition on the marketing of a particular product (within a particular territory) may be considered a "requirement" for the purposes of Annex A(1).

7.2600 We therefore conclude that the safeguard measure taken by Austria with respect to T25 maize qualifies as an SPS measure within the meaning of Annex A(1) as far as its form and nature are concerned.

Conclusion

7.2601 We have now considered Austria's safeguard measure on T25 maize in terms of its purpose, its form and its nature. In relation to each of these issues, we have found that Austria's measure satisfies the definition of the term "SPS measure" set out in Annex A(1). In the light of this, we come to the conclusion that the safeguard measure taken by Austria with respect to T25 maize constitutes an "SPS measure" within the meaning of Annex A(1).

7.2602 At this juncture, we could go on and address the question of whether, in view of its multiple purposes, the Austrian safeguard measure could be considered to embody more than one SPS measure. However, neither the Complaining Parties nor the European Communities have argued that to the extent any of the safeguard measures at issue falls to be assessed under the *SPS Agreement*, it should be deemed to constitute more than one SPS measure. In their submissions to the Panel, the Parties treated the relevant safeguard measures as constituting one SPS measure each. In the light of this, like the Parties, we will treat the Austrian safeguard measure as constituting one single SPS measure. We will revisit this issue, however, if our disposition of the relevant claims under the *SPS Agreement* (and, where appropriate, any implementing action to be taken in view of our disposition of particular claims) were to depend on, and be affected by, whether we treat the Austrian safeguard measure as constituting a single SPS measure or as embodying more than one SPS measure.

Effect on international trade

7.2603 We now turn to the issue of whether Austria's safeguard measure on T25 maize is a measure that may affect international trade, and that is therefore subject to the provisions of the *SPS Agreement*. We recall that according to Article 1.1 of the *SPS Agreement*, the *SPS Agreement* applies to all SPS measures which "may, directly or indirectly, affect international trade." Accordingly, for Austria's safeguard measure on T25 maize to be subject to the *SPS Agreement*, it must be a measure which may, directly or indirectly, affect international trade. We recall the Parties' arguments on this matter.

7.2604 The **United States** argues that the measure adopted by Austria prohibits the "placing on the market" of T25 maize, thereby effectively blocking the importation of the product.

7.2605 **Canada** argues that the measure prohibits commercialization of T25 maize and bans its importation, except where the imported product is "immediately" exported "after possible handling and repackaging" in Austria. Since the measure effectively blocks market access for the targeted biotech product, it clearly affects international trade.

7.2606 **Argentina** notes that since the safeguard measure prevents access of T25 maize to Austria, resulting in the absence of imports of this product, the measure can be said to affect international trade.

7.2607 The **Panel** notes that pursuant to Article 1.1 of the *SPS Agreement*, it is not necessary to demonstrate that an SPS measure has an actual effect on trade. Article 1.1 merely requires that an SPS measure "may, directly or indirectly, affect international trade".

7.2608 Austria's decision to apply a safeguard measure on T25 maize is contained in the text of the Ordinance that entered into force on 29 April 2000.[1707] According to the text of the Ordinance, Austria's decision prohibits the placing on the Austrian market of T25 maize. In our understanding, the prohibition applies also to imports of T25 maize from outside the European Communities.[1708]

7.2609 In view of the fact that Austria's safeguard measure prohibits imports of T25 maize, we have no difficulty concluding that the safeguard measure by Austria is an SPS measure which may affect international trade within the meaning of Article 1.1 of the *SPS Agreement* and, as such, is subject to the provisions of the *SPS Agreement*.

Overall conclusions

7.2610 In the light of the above, the Panel reaches the following overall conclusions:

(a) DS291 (United States)

(b) With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that the Austrian safeguard measure on T25 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement.*

[1707] Exhibit EC-160/At. 3.

[1708] We note that this is subject to an exception for imported T25 maize that is immediately exported after handling and repackaging in Austria.

(c) DS292 (Canada)

(d) With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that the Austrian safeguard measure on T25 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(e) DS293 (Argentina)

(f) With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that the Austrian safeguard measure on T25 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(iii) Austria – Bt-176 maize

7.2611 We now turn to the safeguard measure applied by Austria on Bt-176 maize. We recall that the application for placing on the market of this product was initially submitted to France.[1709] The product was authorized by the EC Commission in 1996.[1710] Austria adopted an Ordinance to prohibit the sale of Bt-176 maize on its territory in February 1997 on the basis of Article 16 of Directive 90/220.[1711] Austria notified its Decision to the Commission on 14 February 1997.

Is the Austrian safeguard measure on Bt-176 maize an SPS measure?

7.2612 We start with the issue of whether the Austrian safeguard measure on Bt-176 maize is an SPS measure. In order to make this determination, we need to consider two distinct elements, namely: (1) the purpose of the measure; and (2) the form and nature of the measure.

Purpose of the safeguard measure

7.2613 We first consider the issue of the purpose of the safeguard measure. Before turning to the arguments of the Parties on this issue, we recall that we must determine whether the purpose of the safeguard measure falls within one of the categories of purposes set out in Annex A(1) of the *SPS Agreement*.

7.2614 The **United States** recalled that in its decision to adopt the measure, Austria noted its concern with regard to the effect of Bt toxin on non-target organisms and the potential transfer of antibiotic resistant genes to humans and animals. According to the United States, a measure based on such justification is an SPS measure because it is applied "to protect animal life or health" from "disease-causing organisms"; "to protect human life or health" from "toxins" or "disease-causing organisms in foods"; or "to prevent or limit [...] damage" from the "spread of pests".

7.2615 **Argentina** argued that the purpose of the safeguard measures may be inferred from the Community legislation under which the bans were adopted, and that the relevant provisions of EC Directive 90/220 and Regulation 258/97 clearly indicate that the purpose of the EC legislation is the "protection of human health and the environment". Since the EC member States have taken their measures explicitly on the basis of this legislation, it can be inferred that the measures were imposed

[1709] C/F/94/11-03.
[1710] Commission Decision 97/98 (Exhibits US–97; ARG–37).
[1711] Regulation No. 45 of the Federal Ministry for Consumer Health and Protection, 13 February 1997.

for the purpose of protecting human health or the environment. The safeguard measures are, therefore, SPS measures as defined in the *SPS Agreement*.

7.2616 The **European Communities** argues that the main reasons for which the measure was adopted and maintained include, *inter alia*, horizontal gene transfer; antibiotic resistance; effects on non-target organisms; toxicity or allergenicity; persistence and invasiveness in agricultural and natural habitats; development of resistance; out-crossing; undesirable effects on management practices; biodiversity; monitoring; labelling; co-existence; and human and animal health.[1712]

7.2617 In examining the purposes for which Austria's safeguard measure on Bt-176 maize is applied, the **Panel** will first consider the document notified by Austria to the Commission in support of its safeguard measure in February 1997, hereafter referred to as Austria's "Reasons document".[1713] In the Reasons' document, Austria stated that "new scientific results have questioned the present scientific possibility of a conclusive evaluation of the mechanism of gene transfer, as well as the development of resistance to Bt toxin. Accordingly, possible risks are very hard to assess and should be avoided at the present state of the scientific discussion."[1714] Austria considered that, in the case of Bt-176 maize, approving the product despite the uncertainties regarding both the ampicillin resistance as well as the resistance against the Bt toxin without any legally binding resistance management programme was in conflict with the principle of precaution.[1715] In particular, Austria noted that evidence on "the impact of a potential gene transfer of the *bla*-gene/b-lactamase and potential induction of resistance in bacteria on the therapy of humans and animals with antibiotics remains not fully conclusive."[1716]

7.2618 We note that Austria also notified the Commission in May 1997 of the results of two studies concerning the possible adverse effects on the environment due to the cultivation of Bt maize.[1717] In the cover letter, Austria states that "[...] these studies prove that pests may evolve (*sic*) resistance against *Bt* toxins much faster than previously expected, due to the fact that transgenic crops producing insecticidal proteins from *Bt* [...] are being grown commercially."[1718]

7.2619 Furthermore, in the cover letter addressed to the Commission at the time of notification of the measure, Austria indicated that it maintained its position that "the labelling laid down in the Commission's decision is insufficient", and that "[c]onsumers should be informed precisely about the fact that this product has been genetically modified."[1719]

7.2620 The January 2004 document submitted by Austria to the Commission also sheds light on the reasons for which Austria is applying its safeguard measure on Bt-176 maize.[1720] In this document, Austria states that it adopted its safeguard measure regarding Bt-176 maize because: "(a) [t]he transgenic maize line contains the ampicillin-resistance gene including its bacterial regulatory sequences. The probability of gene transfer of a functional *bla*-construct into bacteria – even though it is considered low – has to be taken into account for the risk assessment, because the spreading of antibiotic resistance is unacceptable; and (b) [t]he environmental risk assessment has been considered

[1712] Exhibit EC-155.
[1713] Exhibit EC-158/At. 7.
[1714] *Ibid*, p. 5.
[1715] *Ibid.*
[1716] Exhibit EC-158/At. 7 p. 6.
[1717] Exhibit EC-158/At. 10. The two studies referred to by Austria are contained in Exhibits EC-158/At. 11-12.
[1718] Exhibit EC-158/At. 10.
[1719] Exhibit EC-158/At. 7.
[1720] Exhibit EC-158/At. 30.

as insufficient: the possible unintended effects of the Bt-toxin on non-target organisms and the possible resistance-development in insects, *e.g*. the European corn borer, has not been thoroughly assessed".[1721] In addition to these reasons, Austria cited other, more general concerns which in its view justify the precautionary approach embodied in Austria's safeguard measure. Specifically, Austria pointed out that the allergological and toxicological risk assessment concerning EC-approved biotech products such as Bt-176 maize had been inadequate. Austria also noted that pending the report of the EC working group on antibiotic resistance marker genes established pursuant to Directive 2001/18, products containing such genes, including Bt-176 maize, should not be placed on the market.

7.2621 We note that Austria's concerns for adopting a safeguard measure on Bt-176 maize are also discussed in a letter addressed to the Commission in February 2004 by the Austrian Federal Minister for Health and Women. In that letter, Austria rejected a request by the Commission for the withdrawal of Austria's safeguard measure. In this context, Austria recalled that "[t]he Austrian decision concerning Bt-176 maize was based on health doubts regarding the ampicillin-resistant gene (*bla*) with a bacterial promoter and the possible resistance formation of insects to the bacillus thuringiensis (Bt) protein. There was also a lack of clarity regarding the ecological effects of herbicide resistance and inadequate designation."[1722] Austria also reiterated its concern about inadequacies in the allergological and toxicological risk assessment concerning biotech products, such as Bt-176 maize, which were submitted for approval under Directive 90/220 and/or Regulation 258/97. Furthermore, Austria noted that it could not withdraw its safeguard measure on T25 maize in view of the fact that a coherent regulatory solution to the problem of co-existence had not yet been found. The Austrian letter notes in this respect that in June 2003 a resolution had been approved in the Austrian parliament calling on the Austrian Federal Government to refrain from approving new GM plants, especially in relation to their cultivation, until a coherent solution was found on this issue.

7.2622 Based on the foregoing, we consider that at the time of review by the Panel, Austria applied its safeguard measure on Bt-176 maize to address concerns about:[1723]

(1) the transfer of the *bla*-ampicillin resistance gene to bacteria of the intestine of humans and animals;
(2) the development of resistance to Bt toxin in insects;
(3) effects on non-target organisms;
(4) environmental effects of herbicide resistance;
(5) co-existence;
(6) allergenicity and toxicity; and
(7) insufficient labelling.

7.2623 Having determined the purposes for which Austria applied its safeguard measure at the time of review by the Panel, we now go on to assess whether these purposes fall within one of the categories of purposes which according to Annex A(1) characterize an SPS measure. To that end, we will consider one by one each of the above-noted purposes of Austria's safeguard measure.

[1721] Exhibit EC-158/At. 30, p. 2.
[1722] Exhibit EC-158/At. 31_trans.
[1723] We note that some of these concerns were articulated by Austria in documents which post-date the date of establishment of this Panel. However, we see no grounds for considering that these plausible concerns did not underlie the safeguard measure at issue already in August 2003.

Transfer of the bla-ampicillin resistance gene to bacteria of the intestine of humans or animals

7.2624 The Panel begins with Austria's stated concern regarding the potential transfer of the *bla*-ampicillin resistance gene to bacteria of the intestine of humans or animals due to consumption of Bt-176 maize. The concern identified by Austria with regard to Bt-176 is similar to that identified by Austria with regard to its safeguard measure on T25 maize, discussed above. We recall our discussion in Section VII.C regarding antibiotic resistance marker genes, and in particular our view that the concern relates to the potential transfer to pathogens of ARMG present in certain GMOs, and the possible resulting decrease in effectiveness of medical treatments involving specific antibiotics which might pose a risk to the life or health of animals infected with the resistant pathogen.

7.2625 In Section VII.C we have found that Annex A(1)(a) covers measures applied to protect animal life or health from risks arising from the entry, establishment or spread of disease-causing organisms which have or might become resistant to antibiotics due to the transfer of ARMG from a GM plant. Similarly, we found that Annex A(1)(a) covers measures applied to protect animal life or health from risks arising from the entry, establishment or spread of diseases due to the reduced effectiveness of antibiotics used to treat the pathogens which have become resistant to these antibiotics through gene transfer. Furthermore, we found that Annex A(1)(b) covers measures applied to protect human or animal life or health from risks arising indirectly, namely *via* the potential transfer to humans or animals of marker genes conferring resistance to antibiotics used in human or veterinary medicine, from additives in foods or feedstuffs. We recall in this respect that, in our view, ARMGs can be considered to be additives for the purposes of Annex A(1)(b).

7.2626 Thus, consistent with the Panel's reasoning above in the context of Austria's safeguard measure on T25 maize, we consider that Austria's safeguard measure on Bt-176 maize, to the extent it is applied to avoid potential risks associated with the transfer of the *bla*-ampicillin resistance gene to bacteria of the intestine of humans or animals, falls within the scope of Annex A(1)(a) and (b) of the *SPS Agreement*.

Development of resistance to Bt toxin in insects

7.2627 We turn now to another objective stated by Austria for prohibiting the placing on the market of Bt-176 maize, namely the managing of potential risks associated with the development of resistance to Bt toxin in both target and non-target insects. We understand the concern identified by Austria to be that resistance in insects to Bt toxin may develop due to frequent exposure to this pesticide (the Bt toxin) and that the development of high levels of resistance in insect populations might require the application of a pesticide where none was used before, the increased application of a pesticide, or the application of more harmful pesticides, to control the resistant populations and that this might have adverse effects on the environment.

7.2628 We recall our analysis in Section VII.C regarding the development of pesticide-resistance in target organisms. We found that resistant target organisms (insects) could be regarded as "pests" within the meaning of Annex A(1), inasmuch as they present a risk to animal, plant or human life or health or result in other damage. We further determined that risks to animal or plant life or health, or other damage to the environment, resulting from a change in pesticide use may be viewed as arising indirectly from the entry, establishment or spread of resistant target organisms *qua* relevant pest. We found that to the extent that a measure seeks to avoid such risks and damage, it can be considered to be covered by Annex A(1)(a) and (d) of the *SPS Agreement*.

7.2629 In view of the above findings, we consider that Austria's safeguard measure on Bt-176 maize, to the extent it is applied to protect from potential risks associated with the development of resistance to Bt toxin in insects due to the cultivation of Bt-176 maize, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

Effects on non-target organisms

7.2630 We now consider Austria's stated objective of managing risks associated with potential effects on non-target organisms, other than risks associated with the development of resistance in insects as addressed above. As we noted earlier, we understand "non-target" organisms to mean plants and animals (including insects) which are not themselves the organisms farmers seek to control or eliminate through the cultivation of GM crops, but which are affected by the cultivation of the GM crop, including through consumption of the GM plants or components thereof (*e.g.*, pollen).

7.2631 We recall our conclusions in Section VII.C that a GM crop that is eaten by animals can be considered to be a "food" for that animal. This would include, for example, pollen of the GM crop which is consumed by insects and GM plants consumed by non-target insects, deer, rabbits or other wild fauna. As we previously noted, a poisonous substance, such as the Bt toxin, which is produced by a GM crop could qualify as a "toxin" within the meaning of Annex A(1)(b). We determined on that basis that measures applied to protect the life or health of animals (not including target organisms) from risks arising from toxin produced in GM plants are covered by Annex A(1)(b).

7.2632 Moreover, we indicated in Section VII.C our view that if a GM plant produces a poisonous substance which could adversely affect the health of non-target organisms, even if the non-target organisms do not eat the GM plant, *e.g.* through exposure other than through ingestion of food, the GM plant could be considered a "pest" within the meaning of Annex A(1)(a). Thus, a measure applied to protect from risks arising from such exposure to GM plants would, in our view, fall within the scope of Annex A(1)(a).

7.2633 In addition, in Section VII.C we concluded that to the extent that GM plants may result in changes in animal or plant populations, this may increase or decrease the food available for particular non-target animal populations and thus alter the fitness and health of these animal populations, which may in turn lead to further deleterious effects on the life or health of animals or other plants. We also recall our conclusion that by causing harm to the health of animals or other plants in this way, GM plants would act as "pests" within the meaning of Annex A(1), and that to the extent a measure is applied to avoid this kind of adverse effect, it can be considered a measure covered by Annex A(1)(a). Furthermore, we found that Annex A(1)(a) covers measures applied to protect animal or plant life or health from risks arising directly or indirectly from the entry, establishment or spread of cross-breeds with undesired traits (such as insecticidal traits) resulting from transfer of genetic material from a GM plant.

7.2634 In view of these findings, we consider that Austria's safeguard measure on Bt-176 maize, to the extent it is applied to avoid potential risks to the health of non-target organisms from the consumption of Bt-176 maize, falls within the scope of Annex A(1)(b) of the *SPS Agreement*. Furthermore, to the extent that Austria's safeguard measure is applied to avoid other potential risks to the life or health of non-target organisms arising directly or indirectly from Bt-176 maize (*i.e.*, risks unrelated to the ingestion of Bt-176 maize as food), it falls within the scope of Annex A(1)(a) of the *SPS Agreement*.

Environmental effects of herbicide resistance

7.2635 Another concern raised by Austria concerns the environmental effects of herbicide resistance. We understand this to be a concern about the environmental effects of Bt-176 maize which contains a herbicide resistance marker gene.

7.2636 In Section VII.C we have found that cross-breeds between conventional and GM plants, including herbicide-resistant plants, could be regarded as "pests" for the purposes of Annex A(1), to the extent they have undesired introduced traits (such as herbicide resistance) and harm animal or plant life or health or result in other damage. We have determined on that basis that measures applied to protect animal or plant life or health from risks arising directly (*e.g.*, through changes in selective advantage) from the entry, establishment or spread of cross-breeds with undesired traits resulting from the transfer of genetic material from a GM plant fall within the scope of Annex A(1)(a), while measures applied to prevent "other damage" to the environment from the entry, establishment or spread of cross-breeds fall within the scope of Annex A(1)(d).

7.2637 In addition, we recall that one possible concern arising from cross-breeds that have acquired herbicide resistance is that they may lead to the need for an increased use of the same herbicides, or different, more toxic herbicides, to control the resistant weeds. We determined that risks to animal or plant life or health, or other damage to the environment, resulting from a change in pesticide use may be viewed as arising indirectly from the entry, establishment or spread of cross-breeds *qua* relevant pest. We deduced from this that measures applied to avoid such indirect adverse effects on the environment fall within the scope of Annex A(1)(a) and (d).

7.2638 Furthermore, in Section VII.C we have found that to the extent a measure is applied to avoid adverse effects on the life or health of animals or plants which arise from particular management (weed control) practices associated with GMOs, including herbicide resistant GMOs, such a measure falls within the scope of Annex A(1)(a), in that it can be viewed as a measure applied to protect the life or health of animals or plants from risks arising indirectly from the entry, establishment or spread of weeds *qua* "pests". Similarly, we said that to the extent that a measure is applied to avoid adverse environmental effects arising from management (weed control) practices associated with GMOs other than damage to the life or health of animals or plants, that measure can be considered as a measure applied to prevent or limit "other damage" resulting indirectly from the entry, establishment or spread of weeds *qua* "pests" and would thus also be covered by Annex A(1)(d).

7.2639 In view of our findings above, we consider that Austria's safeguard measure on Bt-176 maize, to the extent it is applied to avoid risks to the environment arising from herbicide resistance, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

Co-existence

7.2640 We now turn to Austria's stated concern about co-existence. We understand this to be a concern that farmers cultivating conventional maize might experience a loss of economic value of their crop due to the existence of unwanted genetically modified maize plants in their fields (contamination). The loss would result from the circumstance that the farmers might no longer be able to market their crops as non-GM crops.

7.2641 In Section VII.C we have found that the term "other damage" as it appears in Annex A(1)(d) includes economic damage which arises from the entry, establishment or spread of pests and which is not a consequence of damage to the life or health of animals or plants. We also found that plants growing where they are undesired can be considered as "pests". Such plants include cross-breeds

between GM maize and conventional maize which grow in a conventional maize field as a result of pollen dispersal. Such plants further include GM maize plants growing in a conventional maize field as a result of unintentional dispersal of GM seed. Thus, we consider that to the extent Austria's safeguard measure on Bt-176 maize is applied to prevent economic damage resulting from the contamination of conventional maize due to the entry, establishment or spread of Bt-176 maize (via dispersal of GM seed), or of cross-breeds between Bt-176 maize and conventional maize (via dispersal of GM pollen), in cultivated conventional maize fields, it falls within the scope of Annex A(1)(d) of the *SPS Agreement.*

7.2642 In view of the above findings, we consider that Austria's safeguard measure on Bt-176 maize, to the extent it is applied to prevent or limit damage from the possible contamination of conventional maize by Bt-176 maize, falls within the scope of Annex A(1)(d) of the *SPS Agreement*.

Allergenicity and toxicity

7.2643 We now turn to Austria's stated concern regarding the potential risks of allergenicity and toxicity associated with Bt-176 maize. We recall our analysis related to allergens and toxins in Section VII.C and our analysis of this concern in the context of Austria's safeguard measure on T25 maize.

7.2644 In particular, we recall that in Section VII.C we have found that to the extent that a measure seeks to protect humans and animals from allergenic effects of GM plants used as or in foods or feedstuffs, that measure can be considered to be a measure applied to protect human or animal life or health from risks arising from toxins produced in GM plants which are foods or feedstuffs and, as such, would fall within the scope of Annex A(1)(b). We furthermore recall our view that if interaction with, and exposure to, GMOs other than as or in a food or feedstuff produced allergenic effects in persons, the GMOs in question could be considered "pests" within the meaning of Annex A(1)(c).

7.2645 Consistent with our reasoning above, we consider that Austria's safeguard measure on Bt-176 maize, to the extent it is applied to avoid potential allergenic or toxic effects, falls within the scope of Annex A(1)(b) and (c) of the *SPS Agreement*.

Insufficient labelling

7.2646 Finally, we turn to Austria's stated concern regarding insufficient labelling of Bt-176 maize. We recall that Austria considered that "the labelling laid down in the Commission's decision is insufficient" and that "[c]onsumers should be informed precisely about the fact that this product has been genetically modified."[1724] The Commission's decision to which Austria refers stipulates that the label of each package of seeds of Bt-176 maize is to indicate that the product "protects itself against corn borers", and that it "has increased tolerance to the herbicide glufosinate-ammonium".[1725] The preamble to the decision further notes that there were no safety grounds for mentioning on the label that the product has been obtained by genetic modification techniques. Thus, it appears that contrary to the Commission, Austria wanted the label to indicate the presence of GMOs, in addition to providing the information the Commission required to be indicated on the label of each package of seeds.

[1724] Exhibit EC-158/At. 7.
[1725] Exhibits US-97; ARG-37.

7.2647 We note that Austria stated that the explicit identification of the presence of GMOs which it was seeking would be for the information of consumers of Bt-176 maize. We also note, however, that Austria's letter to the Commission states that Austria's safeguard measure on Bt-176 maize is taken in accordance with Article 16 of Directive 90/220. To recall, Article 16 provides that member States may take safeguard measures in cases where there are justifiable reasons to consider that an approved biotech product constitutes a risk to human health or the environment. Article 16 does not authorize a member State to restrict or prohibit the use and/or sale of an approved biotech product merely because a labelling requirement specified in the written consent for the placing on the market of that biotech product does not ensure consumers' freedom of choice (with regard to the consumption of GM products *vs*. non-GM products).

7.2648 Since Austria specifically claimed to be acting in accordance with the provisions of Article 16 of Directive 90/220, we consider that Austria's reference to consumer information should be read in the light of, and together with, Austria's reference to Article 16. Indeed, in our view, Austria's argument that consumers should be explicitly informed about the presence of GMOs can be understood as an argument that identification of the presence of a GMO would help protect notably from unanticipated adverse effects on human health which might arise from the consumption of Bt-176 maize.[1726] As we have indicated in Section VII.C, explicit identification of the presence of a GMO alerts and sensitises users of a product containing or consisting of a GMO to the possibility that any observed adverse effects of the product on human health might be attributable to the presence of a GMO as opposed to other factors. In view of the foregoing elements, we consider that Austria's concern about insufficient labelling reflects a concern about risks to consumer health arising from the consumption of Bt-176 maize.

7.2649 This interpretation of Austria's labelling concern is consistent with the provisions of Directive 90/220. While Directive 90/220 does not require a statement on a label to the effect that a GMO is present in a product, it does not state that such a requirement may not be imposed as part of the conditions attached to the written consent to placing on the market. Furthermore, we recall that Directive 2001/18 requires labelling to indicate the presence of GMOs. We find in Section VII.C that this requirement could be presumed to be applied to protect human health and the environment from possible unanticipated effects of GMOs. Thus, our interpretation of Austria's labelling concern is consistent with the kind of general labelling requirement which was subsequently imposed by Directive 2001/18.

7.2650 We refer to our analysis in Section VII.C of labelling to indicate the presence of GMOs. As noted in that section, we are of the view that labelling to indicate the presence of GMOs imposed for the purpose of protecting human health from unanticipated effects of GMOs falls within the scope of Annex A(1)(b) or (c) of the *SPS Agreement*, depending on what the adverse effects would be.

7.2651 In view of our findings above, we consider that Austria's safeguard measure on Bt-176 maize, to the extent it is applied to avoid adverse effects on human health (due to the potential transfer of ARMG to gut bacteria and possible allergenicity and toxicity) which in Austria's view were not adequately avoided by the labelling requirements imposed by the Commission, falls within the scope of Annex A(1)(b) and (c) of the *SPS Agreement*.

[1726] In view of Austria's reference to "consumers", we are assuming that Austria was concerned with unanticipated adverse effects on human health from consumption of Bt-176 maize, and not with other adverse effects on human health, on animals or on the environment.

Conclusion with regard to the purpose of the safeguard measure

7.2652 In the light of the above considerations, we conclude that the safeguard measure applied by Austria with respect to Bt-176 maize qualifies as an SPS measure within the meaning of Annex A(1) as far as its purpose is concerned.

Form and nature of the measure

7.2653 We now turn to the issue of the form and nature of Austria's safeguard measure on Bt-176 maize.

7.2654 We note that the arguments presented by the United States and Argentina regarding the form and nature of Austria's safeguard measure on Bt-176 maize are the same as for Austria's safeguard measure on T25 maize.

7.2655 Thus, as in the case of Austria's safeguard measure on T25 maize we conclude that the safeguard measure applied by Austria with respect to Bt-176 maize qualifies as an SPS measure within the meaning of Annex A(1) as far as its form and nature are concerned.

Conclusion

7.2656 We have now considered Austria's safeguard measure on Bt-176 maize in terms of its purpose, its form and its nature. In relation to each of these issues, we have found that Austria's measure satisfies the definition of the term "SPS measure" set out in Annex A(1). In the light of this, we come to the conclusion that the safeguard measure taken by Austria with respect to Bt-176 maize constitutes an "SPS measure" within the meaning of Annex A(1).

7.2657 At this juncture, we could go on and address the question of whether, in view of its multiple purposes, the Austrian safeguard measure could be considered to embody more than one SPS measure. However, neither the United States, nor Argentina or the European Communities have argued that to the extent any of the safeguard measures at issue falls to be assessed under the *SPS Agreement*, it should be deemed to constitute more than one SPS measure. In their submissions to the Panel, the Parties treated the relevant safeguard measures as constituting one SPS measure each. In the light of this, like the Parties, we will treat the Austrian safeguard measure as constituting one single SPS measure. We will revisit this issue, however, if our disposition of the relevant claims under the *SPS Agreement* (and, where appropriate, any implementing action to be taken in view of our disposition of particular claims) were to depend on, and be affected by, whether we treat the Austrian safeguard measure as constituting a single SPS measure or as embodying more than one SPS measure.

Effect on international trade

7.2658 We now turn to the issue of whether Austria's safeguard measure on Bt-176 maize is a measure that may affect international trade, and that is therefore subject to the provisions of the *SPS Agreement*. We recall that according to Article 1.1 of the *SPS Agreement*, the *SPS Agreement* applies to all SPS measures which "may, directly or indirectly, affect international trade." Accordingly, for Austria's safeguard measure on Bt-176 maize to be subject to the *SPS Agreement*, it must be a measure which may, directly or indirectly, affect international trade. We recall the Parties' arguments on this matter.

7.2659 The **United States** argues in this regard that the measure adopted by Austria prohibits the "placing on the market" of Bt-176 maize, thereby effectively blocking the importation of the product.

7.2660 **Argentina** notes that since the safeguard measure prevents access of Bt-176 maize to Austria, resulting in the absence of imports of this product, the measure can be said to affect international trade.

7.2661 The **Panel** notes that the arguments of the parties regarding the effects on trade of Austria's safeguard measure on Bt-176 maize are essentially the same as their arguments with respect to Austria's measure on T25 maize. We recall our reasoning and conclusions with respect to Austria's safeguard measure on T25 maize in paragraphs 7.2603-7.2609 above. In view of the fact that Austria's measure prohibits imports of Bt-176 maize, we have no difficulty concluding that Austria's safeguard measure is an SPS measure which may affect international trade within the meaning of Article 1.1 of the *SPS Agreement* and, as such, is subject to the provisions of the *SPS Agreement*.

Overall conclusions

7.2662 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that the Austrian safeguard measure on Bt-176 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that the Austrian safeguard measure on Bt-176 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(iv) Austria – MON810 maize

7.2663 We now turn to the safeguard measure applied by Austria on MON810 maize. We recall that the application for placing on the market of this product was initially submitted to France.[1727] The product was authorized for all uses by the European Commission in 1998.[1728] In June 1999, Austria adopted an Ordinance to prohibit the sale of MON810 maize on its territory pursuant to Article 16 of Directive 90/220.[1729]

Is the Austrian safeguard measure on MON810 maize an SPS measure?

7.2664 We start with the issue of whether the Austrian safeguard measure on MON810 maize is an SPS measure. In order to make this determination, we need to consider two distinct elements, namely: (1) the purpose of the measure; and (2) the form and nature of the measure.

[1727] C/F/95/12-02.
[1728] Commission Decision 98/294.
[1729] Regulation No. 175, Federal Ministry for Women's Issues and Consumer Protection, Ordinance issued on 10 June 1999 prohibiting the entry of MON810 maize into Austria.

Purpose of the safeguard measure

7.2665 We first consider the issue of the purpose of the safeguard measure. Before turning to the arguments of the parties on this issue, we recall that we must determine whether the purpose of the safeguard measure falls within one of the categories of purposes set out in Annex A(1) of the *SPS Agreement*.

7.2666 The **United States** notes that in its decision to adopt a safeguard measure to prohibit MON810 maize, Austria referred to the adverse effects of Bt toxin on non-target organisms. Austria also expressed a concern that insects could develop resistance to the Bt toxin, thus becoming more difficult to manage and control.[1730] According to the United States, a measure based on such justification is an SPS measure because it is applied "to protect animal life or health" from "disease-causing organisms"; "to protect human life or health" from "toxins" or "disease-causing organisms in foods"; or "to prevent or limit [...] damage" from the "spread of pests".

7.2667 **Argentina** argued that the purpose of the safeguard measures may be inferred from the Community legislation under which the bans were adopted, and that the relevant provisions of EC Directive 90/220 and Regulation 258/97 clearly indicate that the purpose of the EC legislation is the "protection of human health and the environment". Since the EC member States have taken their measures explicitly on the basis of this legislation, it can be inferred that the measures were imposed for the purpose of protecting human health or the environment. The safeguard measures are, therefore, SPS measures as defined in the *SPS Agreement*.

7.2668 The **European Communities** argues that the main reasons for which the measure was adopted and maintained include, *inter alia*, horizontal gene transfer; antibiotic resistance; effects on non-target organisms; toxicity or allergenicity; development of resistance; biodiversity; monitoring; labelling; co-existence; and human and animal health.[1731]

7.2669 In examining the purposes for which Austria's safeguard measure on MON810 maize is applied, the **Panel** will first consider the document notified by Austria to the Commission in support of its safeguard measure, hereafter referred to as Austria's Reasons document. In this document, Austria notes that its objections regarding the assessment of MON810 maize concern the possible unintended effects of the Bt toxin on non-target organisms, and the possible development of Bt resistance in insects, such as the European corn borer.[1732]

7.2670 The concerns of Austria with respect to MON810 maize are further identified in a January 2004 document as follows: "(a) [a] risk assessment on indirect and long term effects of the Bt toxin is missing; and (b) [t]he environmental risk assessment has been considered as insufficient: the possible unintended effects of the Bt-toxin on non-target organisms and the possible resistance-development in insects [...] has not been thoroughly assessed".[1733] In addition to these reasons, Austria cited other, more general concerns which in its view justify the precautionary approach embodied in Austria's safeguard measure. Specifically, Austria pointed out that the allergological and toxicological risk assessment concerning EC-approved biotech products such as MON810 maize had been inadequate. Austria also noted that pending the report of the EC Working Group on antibiotic resistance marker genes (ARMG), biotech products containing such genes, such as MON810 maize, should not be placed on the market.

[1730] US first written submission, para. 157.
[1731] Exhibit EC-155.
[1732] Exhibit EC-159/At. 3_trans., pages 5-6.
[1733] Exhibit EC-159/At. 30, p. 2.

7.2671 We note that Austria's concerns for adopting a safeguard measure with regard to MON810 maize are also discussed in a letter addressed to the Commission in February 2004 by the Austrian Federal Minister for Health and Women. In this letter, Austria rejected a request by the Commission that Austria withdraw its safeguard measure. In this context, Austria recalled that "[t]his prohibition on cultivation was issued in the light of scientific discoveries concerning the effects of the *bacillus thuringiensis* (Bt) protein, which is directed at insects, on monarch butterflies in the US and other non-target organisms. In addition, Austria referred to the question of resistance formation, as in the case of Bt-176 maize."[1734] Austria also reiterated its concern about inadequacies in the allergological and toxicological risk assessment concerning biotech products, such as MON810 maize, which were submitted for approval under Directive 90/220 and/or Regulation 258/97. Furthermore, Austria noted that it could not withdraw its safeguard measure on MON810 maize in view of the fact that a coherent regulatory solution to the problem of co-existence had not yet been found. The Austrian letter notes in this respect that in June 2003 a resolution had been approved in the Austrian parliament calling on the Austrian Federal Government to refrain from approving new GM plants, especially in relation to their cultivation, until a coherent solution was found on this issue.

7.2672 Based on the foregoing, we consider that at the time of review by the Panel, Austria applied its safeguard measure on MON810 maize to address concerns about:[1735]

(1) the effects on non-target organisms, including indirect and long-term effects;
(2) the development of resistance to Bt toxin in insects, including indirect and long-term effects of insect resistance;
(3) allergenicity and toxicity;
(4) the development of antibiotic resistance; and
(5) co-existence.

7.2673 The European Communities asserts that Austria's safeguard measure on MON810 maize is also applied in view of concerns about labelling. This concern was not articulated by Austria in the documents discussed by us above. Furthermore, the European Communities has neither substantiated nor explained its assertion. In the light of this, we are not persuaded that Austria is applying its safeguard measure to address this concern asserted by the European Communities.

7.2674 Having determined the purposes for which Austria applied its safeguard measure at the time of review by the Panel, we now go on to assess whether these purposes fall within one of the categories of purposes which according to Annex A(1) characterize an SPS measure. To that end, we will consider one by one each of the above-noted purposes of Austria's safeguard measure.

Effects on non-target organisms, including indirect and long-term effects

7.2675 We turn first to Austria's stated concern regarding the potential effects on non-target organisms associated with MON810 maize. We recall our analysis related to effects on non-target organisms in Section VII.C and our analysis of this concern in the context of Austria's safeguard measure on Bt-176 maize.

[1734] Exhibit EC-158/At. 31.
[1735] We note that some of these concerns were articulated by Austria in documents which post-date the date of establishment of this Panel. However, we see no grounds for considering that these plausible concerns did not underlie the safeguard measure at issue already in August 2003.

7.2676 We recall our conclusions in Section VII.C that a GM crop that is eaten by animals can be considered to be a "food" for that animal. This would include, for example, pollen of the GM crop which is consumed by insects and GM plants consumed by non-target insects, deer, rabbits or other wild fauna. As we previously noted, a poisonous substance, such as the Bt toxin, which is produced by a GM crop could qualify as a "toxin" within the meaning of Annex A(1)(b). We determined on that basis that measures applied to protect the life or health of animals (not including target organisms) from risks arising from toxin, produced in GM plants are covered by Annex A(1)(b).

7.2677 Moreover, in Section VII.C we indicated our view that if a GM plant produces a poisonous substance which could adversely affect the health of non-target organisms, even if the non-target organisms do not eat the GM plant, *e.g.* through exposure other than through ingestion of food (such as contact with the leaves of a GM plant), the GM plant could be considered a "pest" within the meaning of Annex A(1)(a). Thus, a measure applied to protect from risks arising from such exposure to GM plants would, in our view, fall within the scope of Annex A(1)(a).

7.2678 In addition, in Section VII.C we concluded that to the extent that GM plants may result in changes in animal or plant populations, this may increase or decrease the food available for particular non-target animal populations and thus alter the fitness and health of these animal populations, which may in turn lead to further deleterious effects on the life or health of animals or other plants. We also recall our conclusion that by causing harm to the health of animals or other plants in this way, GM plants would act as "pests" within the meaning of Annex A(1), and that to the extent a measure is applied to avoid this kind of adverse effect, it can be considered a measure covered by Annex A(1)(a). Furthermore, we found that Annex A(1)(a) covers measures applied to protect animal or plant life or health from risks arising directly or indirectly from the entry, establishment or spread of cross-breeds with undesired traits (such as insecticidal traits) resulting from transfer of genetic material from a GM plant.

7.2679 In view of the above findings, we consider that Austria's safeguard measure on MON810 maize, to the extent it is applied to avoid potential adverse effects on non-target organisms of MON810 maize, falls within the scope of Annex A(1)(a) and (b) of the *SPS Agreement*.

Development of resistance to Bt toxin in insects, including indirect and long-term effects of insect resistance

7.2680 We turn now to Austria's stated concern regarding the potential development of resistance to Bt toxin in insects associated with MON810 maize. We understand the concern identified by Austria to be that resistance in insects to Bt toxin may develop due to frequent exposure to this pesticide (the Bt toxin) and that the development of high levels of resistance in insect populations might require the application of a pesticide where none was used before, the increased application of a pesticide, or the application of more harmful pesticides to control the resistant populations.

7.2681 We recall our analysis in Section VII.C regarding the development of pesticide-resistance in insects. We found that resistant target organisms (insects) could be regarded as "pests" within the meaning of Annex A(1), inasmuch as they present a risk to animal, plant or human life or health or result in other damage. We further determined that risks to animal or plant life or health, or other damage to the environment, resulting from a change in pesticide use may be viewed as arising indirectly from the entry, establishment or spread of resistant target organisms *qua* relevant pest. We found that to the extent that a measure seeks to avoid such risks and damage, it can be considered to be covered by Annex A(1)(a) and (d) of the *SPS Agreement*.

7.2682 In view of the above findings, we consider that Austria's safeguard measure on MON810 maize, to the extent it is applied to avoid potential risks associated with the development of resistance to Bt toxin in insects due to the cultivation of MON810 maize, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

Allergenicity and toxicity

7.2683 We turn now to Austria's stated concern regarding the potential risks of allergenicity and toxicity associated with MON810 maize. We recall our analysis related to allergens and toxins in Section VII.C and our analysis of this concern related to Austria's safeguard measures on T25 maize and Bt-176 maize.

7.2684 In particular, we recall that in Section VII.C we have found that to the extent a measure seeks to protect humans and animals from allergenic effects of GM plants used as or in foods, that measure can be considered to be a measure applied to protect human or animal life or health from risks arising from toxins produced in GM plants which are foods or feedstuffs and, as such, would fall within the scope of Annex A(1)(b). We furthermore recall our view that if interaction with, and exposure to, GMOs other than as or in a food produced allergenic effects in persons, the GMOs in question could be considered "pests" within the meaning of Annex A(1)(c).

7.2685 Consistent with our reasoning above, in the context of the case before us, we consider that Austria's safeguard measure on MON810 maize, to the extent it is applied to avoid potential allergenic or toxic effects of MON810 maize, falls within the scope of Annex A(1)(b) and (c) of the *SPS Agreement*.

Development of antibiotic resistance

7.2686 We turn finally to Austria's stated concern regarding the presence in MON810 maize of an antibiotic resistance marker gene (ARMG) and the possible development of antibiotic resistance. We understand this to be a concern about a potential transfer of the ARMG present in MON810 maize to bacteria of the intestine of humans or animals due to consumption of MON810 maize. We recall our discussion in Section VII.C regarding ARMG, and in particular our view that this concern relates to the potential transfer to pathogens of ARMG present in certain GMOs, and the possible resulting decrease in effectiveness of medical treatments involving specific antibiotics which might pose a risk to the life or health of animals infected with the resistant pathogen.

7.2687 In Section VII.C we have found that Annex A(1)(a) covers measures applied to protect animal life or health from risks arising from the entry, establishment or spread of disease-causing organisms which have or might become resistant to antibiotics due to the transfer of ARMG from a GM plant. Similarly, we found that Annex A(1)(a) covers measures applied to protect animal life or health from risks arising from the entry, establishment or spread of diseases due to the reduced effectiveness of antibiotics used to treat the pathogens which have become resistant to these antibiotics through gene transfer. Furthermore, we found that Annex A(1)(b) covers measures applied to protect human or animal life or health from risks arising indirectly, namely *via* the potential transfer to humans or animals of marker genes conferring resistance to antibiotics used in human or veterinary medicine, from additives in foods or feedstuffs. We recall in this respect that, in our view, ARMGs can be considered to be additives for the purposes of Annex A(1)(b).

7.2688 Thus, in view of our findings above, we consider that Austria's safeguard measure on MON810 maize, to the extent it is applied to avoid potential risks associated with the presence in MON810 maize of an ARMG, falls within the scope of Annex A(1)(a) and (b) of the *SPS Agreement*.

Co-existence

7.2689 We now turn to Austria's stated concern about co-existence. We understand this to be a concern that farmers cultivating conventional maize might experience a loss of economic value of their crop due to the existence of unwanted genetically modified maize plants in their fields (contamination). The loss would result from the circumstance that the farmers might no longer be able to market their crops as non-GM crops.

7.2690 In Section VII.C we have found that the term "other damage" as it appears in Annex A(1)(d) includes economic damage which arises from the entry, establishment or spread of pests and which is not a consequence of damage to the life or health of animals or plants. We also found that plants growing where they are undesired can be considered as "pests". Such plants include cross-breeds between GM maize and conventional maize which grow in a conventional maize field as a result of pollen dispersal. Such plants further include GM maize plants growing in a conventional maize field as a result of unintentional dispersal of GM seed. Thus, we consider that to the extent Austria's safeguard measure on MON810 maize is applied to prevent economic damage resulting from the contamination of conventional maize due to the entry, establishment or spread of MON810 maize (via dispersal of GM seed), or of cross-breeds between MON810 maize and conventional maize (via dispersal of GM pollen), in cultivated conventional maize fields, it falls within the scope of Annex A(1)(d) of the *SPS Agreement.*

7.2691 In view of the above findings, we consider that Austria's safeguard measure on MON810 maize, to the extent it is applied to prevent or limit damage from the possible contamination of conventional maize by MON810, falls within the scope of Annex A(1)(d) of the *SPS Agreement*.

Conclusion with regard to the purpose of the safeguard measure

7.2692 In the light of the above considerations, we conclude that the safeguard measure applied by Austria with respect to MON810 maize qualifies as an SPS measure within the meaning of Annex A(1) as far as its purpose is concerned.

Form and nature of the measure

7.2693 We now turn to the issue of the form and nature of Austria's safeguard measure on MON810 maize.

7.2694 We note that the arguments presented by the United States and Argentina regarding the form and nature of Austria's safeguard measure on MON810 maize are the same as for Austria's safeguard measure on T25 maize.

7.2695 Thus, as in the case of Austria's safeguard measure on T25 maize we conclude that the safeguard measure applied by Austria with respect to MON810 maize qualifies as an SPS measure within the meaning of Annex A(1) as far as its form and nature are concerned.

Conclusion

7.2696 We have now considered Austria's safeguard measure on MON810 maize in terms of its purpose, its form and its nature. In relation to each of these issues, we have found that Austria's measure satisfies the definition of the term "SPS measure" set out in Annex A(1). In the light of this, we come to the conclusion that the safeguard measure taken by Austria with respect to MON810 maize constitutes an "SPS measure" within the meaning of Annex A(1).

7.2697 At this juncture, we could go on and address the question of whether, in view of its multiple purposes, the Austrian safeguard measure could be considered to embody more than one SPS measure. However, neither the United States nor Argentina or the European Communities have argued that to the extent any of the safeguard measures at issue falls to be assessed under the *SPS Agreement*, it should be deemed to constitute more than one SPS measure. In their submissions to the Panel, the Parties treated the relevant safeguard measures as constituting one SPS measure each. In the light of this, like the Parties, we will treat the Austrian safeguard measure as constituting one single SPS measure. We will revisit this issue, however, if our disposition of the relevant claims under the *SPS Agreement* (and, where appropriate, any implementing action to be taken in view of our disposition of particular claims) were to depend on, and be affected by, whether we treat the Austrian safeguard measure as constituting a single SPS measure or as embodying more than one SPS measure.

Effect on international trade

7.2698 We now turn to the issue of whether Austria's safeguard measure on MON810 maize is a measure that may affect international trade, and that is therefore subject to the provisions of the *SPS Agreement*. We recall that according to Article 1.1 of the *SPS Agreement*, the *SPS Agreement* applies to all SPS measures which "may, directly or indirectly, affect international trade." Accordingly, for Austria's safeguard measure on MON810 maize to be subject to the *SPS Agreement*, it must be a measure which may, directly or indirectly, affect international trade. We recall the Parties' arguments on this matter.

7.2699 The **United States** argues that the measure adopted by Austria prohibits the "placing on the market" of MON810 maize, thereby effectively blocking the importation of the product.

7.2700 **Argentina** notes that since the safeguard measure prevents access of MON810 maize to Austria, resulting in the absence of imports of this product, the measure can be said to affect international trade.

7.2701 The **Panel** notes that the arguments of the parties regarding the effects on trade of Austria's safeguard measure on MON810 maize are essentially the same as their arguments with respect to Austria's safeguard measure on T25 maize. We recall our reasoning and conclusions with respect to Austria's measure on T25 maize in paragraphs 7.2603-7.2609 above. In view of the fact that Austria's safeguard measure prohibits imports of MON810 maize, we have no difficulty concluding that the safeguard measure by Austria is an SPS measure which may affect international trade within the meaning of Article 1.1 of the *SPS Agreement* and, as such, is subject to the provisions of the *SPS Agreement*.

Overall conclusions

7.2702 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that the Austrian safeguard measure on MON810 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that the Austrian safeguard measure on MON810 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(v) France – MS1/RF1 oilseed rape (EC-161)

7.2703 We now turn to the safeguard measure applied by France on MS1/RF1 oilseed rape (EC-161). We recall that the application for placing on the market, growing and obtaining seeds of this oilseed rape was initially submitted to the United Kingdom.[1736] The product was authorized by the Commission in February 1996 for cultivation and placing on the market.[1737] In November 1998, France adopted a Decree suspending commercialization of MS1/RF1 oilseed rape (EC-161) on its territory for a period of two years.[1738] The period of application of the French safeguard measure on MS1/RF1 oilseed rape (EC-161) was extended twice, namely in July 2001[1739] and July 2003.[1740]

Is the French safeguard measure on MS1/RF1 oilseed rape (EC-161) an SPS measure?

7.2704 We start with the issue of whether the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is an SPS measure. In order to make this determination, we need to consider two distinct elements, namely: (1) the purpose of the measure; and (2) the form and nature of the measure.

Purpose of the safeguard measure

7.2705 We first consider the issue of the purpose of the safeguard measure. Before turning to the arguments of the Parties on this issue, we recall that we must determine whether the purpose of the safeguard measure falls within one of the categories of purposes set out in Annex A(1) of the *SPS Agreement*.

7.2706 The **United States** notes that according to the SCP, France justified the ban based on its "concern over the environmental impact of genetic escape" and the "spread of herbicide tolerance" to other plants. This justification indicates that the French measures are sanitary and phytosanitary measures as they are applied "to protect [...] plant life or health" from the "spread of pests" and "prevent or limit other damage" from the "spread of pests".

[1736] C/UK/94/M1/1.

[1737] Commission Decision 96/158, 6 February 1996.

[1738] France, Ministry of Agriculture and Fishing, Decree of 16 November 1998 involving suspension of the commercialisation of genetically modified colza by virtue of Article 16 of Directive 90/220/European Communities of 23 April 1990, pursuant to Decision 96/158 of 6 February 1996, Official Journal, No. 267, 18 November 1998, at 17379 (Exhibits US-60; CDA-68).

[1739] France, Ministry of Agriculture and Fishing, Decree of 26 July 2001 regarding suspension of the sale of genetically modified colza by virtue of Article 16 of Directive 90/220/European Communities of 23 April 1990, pursuant to Decision 96/158/European Communities of 6 February 1996, Official Journal, 30 August 2001 at 13903 (Exhibit CDA-70).

[1740] France, Ministry of Agriculture, Food, Fisheries and Rural Affairs, Order of 25 July 2003 suspending the marketing of genetically modified rapeseed pursuant to Article 23 of Directive 2001/18/European Communities of 12 March 2001, Official Journal, 14 August 2003 at 14061 (Exhibit CDA-71).

7.2707 **Canada** notes that the French safeguard measure against MS1/RF1 oilseed rape (EC-161) is predicated on concerns that its release into the environment may have detrimental effects on the surrounding plant life or health. More specifically, France indicated that it was concerned about genetic escape from the biotech varieties, leading to the transfer of herbicide resistance through hybridization with wild oilseed rape varieties. In essence, the concerns of France were related to potential risks arising from the release into the environment of the biotech oilseed rape varieties because of their alleged potential to function as a pest in relation to the surrounding environment, and in particular, to out-cross with wild species of oilseed rape.

7.2708 The **European Communities** argues that the main reasons for which the measure was adopted and maintained include, *inter alia*, persistence and invasiveness in agricultural and natural habitats; development of resistance; out-crossing; undesirable effects of management practices; biodiversity; monitoring; labelling; co-existence; and human and animal health.

7.2709 In examining the purposes for which France's measure on MS1/RF1 oilseed rape (EC-161) is applied, the **Panel** will first consider the document notified by France to the Commission in November 1998 which sets out the reasons for suspending the placing on the market of MS1/RF1 oilseed rape (EC-161) for an initial period of two years (hereafter the "Reasons document").[1741]

7.2710 In the Reasons document, France justifies its safeguard measure on MS1/RF1 oilseed rape (EC-161) on the basis of alleged risks to the environment. In particular, France was concerned with the potential dissemination of the herbicide-tolerance gene into the environment through hybridisation with other plant species, as well as among different varieties of oilseed rape. France notes that while experimental platforms have been set up to measure and quantify on an agronomic scale the extent and consequences of gene flows in various species, including oilseed rape, knowledge in this area is still fragmented. It further notes that the agricultural practices at issue must be considered in the broader context of their global impact on the environment.

7.2711 We note that France's decision to extend the application of its safeguard measure suspending the placing on the market of MS1/RF1 oilseed rape (EC-161) in July 2001[1742] and July 2003[1743] was based on opinions from the French "Commission du Génie biomoléculaire" (hereafter the "Biomolecular Engineering Committee" or "BEC"), delivered in February 2001[1744] and July 2003[1745] respectively, at the request of the French authorities. In its February 2001 opinion, the BEC invokes the need to pursue scientific experiments with a view to complete current scientific knowledge and to validate risk management options for the cultivation of GM oilseed rape that could limit potential adverse effects on the environment. In particular, the BEC opinion points to the need to obtain additional information on the effects of pollen dispersal from oilseed rape plants and the role of

[1741] The document entitled "*Motivation du moratoire, pour une période de deux ans, relative à la mise en marché sur le territoire français de colza génétiquement modifié tolérant aux herbicides, en application de l'Article 16 de la Directive 90/220/EEC: Nouveaux éléments en matière d'évaluation du risque pour l'environnement*" sets out the reasons for France's safeguard measures on MS1/RF1 oilseed rape and Topas oilseed rape (Exhibits EC-161/At. 2 and EC-162/At. 5).

[1742] The Panel notes that this decision adopted by France on 26 July 2001 to suspend the placing on the market of MS1/RF1 for a period of two years, was not submitted to the Panel.

[1743] The safeguard measure was renewed on the basis of Article 23 of Directive 2001/18 (Exhibits EC-161/At. 3 and EC-161/At. 5).

[1744] It is not clear to the Panel whether this opinion of the BEC was submitted as evidence by the European Communities. We note that the documents contained in Exhibits EC-161/At. 7 and EC-161/At. 8, which seem to be translations of the document contained in EC-161/At. 6, are not dated.

[1745] Exhibit EC-161/At. 9.

insects in its transport, as well as the effects of persistence of oilseed rape plants resulting from seed dispersal during transportation and pollenisation of neighbouring oilseed rape plants. The opinion further indicates that modalities for management are necessary in order to limit the direct and indirect effects of re-growth of oilseed rape in the case of herbicide tolerance, and that large scale experiments are necessary in order to validate such modalities.

7.2712 In its July 2003 opinion, the BEC pointed to the existence of new elements of information, including, *inter alia*, with respect to the issues of pollen dispersal, characterization of inter-specific hybrids and re-growth. The BEC considered that these new elements of information required further analysis in order to determine whether they put into question the conclusions of the February 2001 opinion, on which the decision to maintain the safeguard measure on MS1/RF1oilseed rape (EC-161) was based.[1746] To this end, the BEC recommended the organization of a scientific workshop to take stock of ongoing research and to eventually identify modalities for the management of genetically modified oilseed rape. [1747]

7.2713 We note that France further elaborated on its concerns with respect to MS1/RF1 oilseed rape (EC-161) in a Note addressed to the Commission in July 2003 regarding the extension of the safeguard measure. In this Note, France recalls that the decision to apply a safeguard measure on MS1/RF1 oilseed rape (EC-161) is based on the potential risk of contamination of conventional oilseed rape by genetically modified oilseed rape.[1748]

7.2714 A further informal Note was provided by France to the Commission after the establishment of the Panel.[1749] The Note recalls the concerns underlying, *inter alia*, the safeguard measure on MS1/RF1 oilseed rape (EC-161) , including those relating to the environmental consequences of gene transfer to other plants and the economic consequences of contamination (co-existence issue). The Note indicates that the BEC was to hold a scientific workshop in November 2003 and that the safeguard measure on MS1/RF1 oilseed rape (EC-161) might be withdrawn if after the workshop the BEC provided favourable scientific advice on the outstanding concerns. Looking ahead, the Note concludes that the maintenance of the safeguard measure at issue was justified at the time by the precautionary principle, pending a clearer and more complete scientific picture. The Note goes on to state, however, that the safeguard measure would in any event not be withdrawn before the entry into force of the new EC regulations on labelling and traceability as well as on GM food and feed.

7.2715 Finally, we note that the BEC delivered an opinion in February 2004 based on the conclusions of a scientific workshop held in November 2003.[1750] The opinion concludes that the cultivation of MS1/RF1 oilseed rape (EC-161) does not present any direct risk for the environment, but that modalities are nonetheless required to manage indirect ecological risks, which are related to practices associated with the cultivation of MS1/RF1 oilseed rape (EC-161).

7.2716 Based on the foregoing, we consider that at the time of review by the Panel, France applied its safeguard measure to address concerns about:

(1) transfer of the herbicide-tolerance gene to adventitious flora;

[1746] Exhibit EC-161/At. 9. *See also* Exhibit EC-161/At. 5.

[1747] *Ibid.*

[1748] Exhibit EC-161/At. 3.

[1749] Exhibit EC-161/At. 4. While the document is not dated, we note that it makes reference to the proceedings before this Panel, thus suggesting that the document was circulated after the establishment of the Panel.

[1750] Exhibit EC-161/At. 10.

(2) adverse effects on the environment, including from persistence and management practices associated with the cultivation of MS1/RF1 oilseed rape (EC-161); and
(3) contamination of conventional oilseed rape by genetically modified oilseed rape.

7.2717 The European Communities asserts that France's safeguard measure on MS1/RF1 oilseed rape (EC-161) is also applied in view of concerns about labelling, but provides no substantiation or explanation of this assertion. The labelling concern asserted by the European Communities was not articulated by France in any of the documents discussed by us above which date from before the date of establishment of this Panel. However, as we have pointed out, after the establishment of the Panel, France in an informal Note to the Commission made reference to the new EC regulation on labelling and traceability as well as to the new EC regulation on GM food and feed. These regulations contain new labelling requirements. Nevertheless, for the reasons which follow, we are not persuaded that it can be inferred from this post-2003 reference to labelling that France in August 2003 applied its safeguard measure on MS1/RF1 oilseed rape (EC-161) to address concerns about labelling.

7.2718 To begin with, we recall that according to the Note the relevant safeguard measure is justified by the precautionary principle, pending a clearer and more complete scientific picture. Insufficient labelling is not claimed as a separate justification. Indeed, the Note indicates that in July 2003 France extended its safeguard measure for one year on the basis of scientific advice received from the BEC in July 2003. Moreover, the reference to labelling is made in a forward-looking context, *i.e.*, in the context of a discussion of the "way ahead".[1751] It is clear from the Note that France at the time was waiting for further advice from the BEC (in the wake of the November 2003 scientific workshop to be held by the BEC) which it said could lead to the withdrawal of the safeguard measure if the outstanding concerns were satisfactorily addressed by the BEC. The Note states, however, that even if the BEC were to offer favourable scientific advice, France would not withdraw its safeguard measure prior to the entry into force of the new EC regulations. We consider that it may be appropriate to infer from this statement that in case of favourable advice from the BEC following the November 2003 workshop, concerns about labelling would be the reason for maintaining the safeguard measure.[1752] But we do not think that it may be properly inferred from this forward-looking statement that concerns about labelling were a reason for applying the relevant safeguard measure in August 2003, when France was still waiting for the results of the November 2003 scientific workshop and subsequent scientific advice from the BEC. In the light of this, as indicated, we are not persuaded that France at the time of review by the Panel was applying its safeguard measure to address concerns about labelling as asserted by the European Communities.

7.2719 Having determined the purposes for which France applied its safeguard measure at the time of review by the Panel, we now go on to assess whether these purposes fall within one of the categories of purposes which according to Annex A(1) characterize an SPS measure. To that end, we will consider one by one each of the above-noted purposes of France's safeguard measure.

Transfer of the herbicide-tolerance gene to adventitious flora

7.2720 We turn first to France's stated objective for prohibiting the placing on the market of MS1/RF1 oilseed rape (EC-161) due to concerns over the transfer of the herbicide-tolerance gene contained in MS1/RF1 oilseed rape (EC-161) to adventitious flora. We understand this to be essentially a concern about the potential environmental impacts associated with gene transfer from

[1751] The Note uses the French word "perspectives".
[1752] We note in this context that the Note in question is an informal note which bears no official letterhead nor a date or signature which would allow us to confirm that the views expressed in the Note are attributable to, and expressed on behalf of, France.

MS1/RF1 oilseed rape (EC-161) to adventitious flora, and in particular about the environmental impacts of the possible development of herbicide resistant weeds.

7.2721 We recall our finding in Section VII.C that cross-breeds between conventional and GM plants could be regarded as "pests" for the purposes of Annex A(1), to the extent they have undesired introduced traits (such as herbicide resistance) and harm animal or plant life or health or result in other damage. We have determined on that basis that measures applied to protect animal or plant life or health from risks arising directly (*e.g.*, through changes in selective advantage) from the entry, establishment or spread of cross-breeds with undesired traits resulting from the transfer of genetic material from a GM plant fall within the scope of Annex A(1)(a), while measures applied to prevent "other damage" to the environment from the entry, establishment or spread of cross-breeds fall within the scope of Annex A(1)(d).

7.2722 In addition, we recall that one possible concern arising from cross-breeds that have acquired herbicide resistance is that they may lead to the need for an increased use of the same herbicides, or different, more toxic herbicides, to control the resistant weeds. We determined that risks to animal or plant life or health, or other damage to the environment, resulting from a change in pesticide use may be viewed as arising indirectly from the entry, establishment or spread of cross-breeds *qua* relevant pest. We deduced from this that measures applied to avoid such indirect adverse effects on the environment fall within the scope of Annex A(1)(a) and (d).

7.2723 Consistent with our reasoning above, we consider that France's safeguard measure on MS1/RF1 oilseed rape (EC-161), to the extent it is applied to avoid risks to the environment associated with the transfer of the herbicide-tolerance gene contained in MS1/RF1 oilseed rape (EC-161) to adventitious flora, and in particular the development of resistance in weeds, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

> *Adverse effects on the environment, including from persistence and management practices associated with the cultivation of MS1/RF1 oilseed rape*

7.2724 We turn now to the next objective stated by France for prohibiting the placing on the market of MS1/RF1 oilseed rape (EC-161), namely, France's concerns over potential adverse effects on the environment, including the environmental effects of persistence resulting from seed dispersal during transportation and of management techniques associated with the cultivation of MS1/RF1 oilseed rape (EC-161).

7.2725 In Section VII.C we have found that to the extent a measure is applied to avoid adverse effects on plant life or health that might arise if GM plants crowd out or eliminate other plants due to a potential competitive advantage, invasiveness or persistence, such a measure would be covered by Annex A(1)(a), as it would be applied "to protect [...] plant life or health […] from risks arising from the entry, establishment or spread" of GM plants *qua* "pests".

7.2726 In Section VII.C we also found that to the extent that GM plants may result in changes in plant populations, this may increase or decrease the food available for particular animal populations and thus enhance, or detract from, the fitness and health of these animal populations, which in turn may have a deleterious effect on the life or health of plants, *e.g.*, by affecting their ability to reproduce. We state that, by causing harm to the health of animals or other plants in this way, the GM plants would act as "pests" within the meaning of Annex A(1), and that to the extent a measure is applied to avoid this kind of adverse effect, it can be considered a measure covered by Annex A(1)(a).

7.2727 Moreover, we stated that to the extent a measure is applied to avoid adverse effects on the life or health of animals or plants which arise from particular management (weed control) practices associated with GMOs, such a measure falls within the scope of Annex A(1)(a), in that it can be viewed as a measure applied to protect the life or health of animals or plants from risks arising indirectly from the entry, establishment or spread of weeds *qua* "pests".

7.2728 Finally, we found that to the extent a measure seeks to avoid adverse effects of GMOs on the environment other than adverse effects on animal or plant life or health, such a measure can be considered to be covered by Annex A(1)(d), inasmuch as it can be viewed as a measure which is applied to prevent or limit "other damage" from the entry, establishment or spread of "pests". As noted earlier, the GMOs themselves might qualify as the relevant pest, or other plants or animals might become pests as a result of the release of GMOs into the environment. Furthermore, we said that to the extent that a measure is applied to avoid adverse environmental effects arising from management (weed control) practices associated with GMOs other than damage to the life or health of animals or plants, that measure can be considered as a measure applied to prevent or limit "other damage" resulting indirectly from the entry, establishment or spread of weeds *qua* "pests" and would thus also be covered by Annex A(1)(d).

7.2729 Consistent with our reasoning above, we consider that France's safeguard measure on MS1/RF1 oilseed rape (EC-161), to the extent it is applied to avoid adverse effects on the environment, including from management practices associated with the cultivation of MS1/RF1 oilseed rape (EC-161), falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

Contamination of conventional oilseed rape by genetically modified oilseed rape

7.2730 We finally address France's concern with regard to the risk of contamination of conventional oilseed rape by genetically modified oilseed rape, *i.e.*, MS1/RF1 oilseed rape (EC-161).

7.2731 We have already addressed France's concern about the possible transfer of the introduced herbicide-tolerance gene from MS1/RF1 oilseed rape to adventitious flora, which includes gene transfer from MS1/RF1 oilseed rape to different species (resulting in inter-specific hybrids), but also includes gene transfer to wild or cultivated conventional oilseed rape. Thus, for the reasons which we have outlined above, we consider that to the extent France's safeguard measure on MS1/RF1 oilseed rape is applied to avoid adverse environmental effects arising from the contamination of conventional oilseed rape by MS1/RF1 oilseed rape due to gene transfer from MS1/RF1 oilseed rape to conventional oilseed rape, it falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

7.2732 In our understanding, France's concern about contamination of conventional oilseed rape is also a concern that farmers cultivating conventional oilseed rape might experience a loss of economic value of their crop due to the existence of unwanted genetically modified oilseed rape plants in their fields. The loss would result from the circumstance that the farmers might no longer be able to market their crops as non-GM crops. Even if France's concern about contamination were understood in this way, however, France's safeguard measure would, in our view, fall within the scope of Annex A(1) of the *SPS Agreement*.

7.2733 We recall in this regard that in Section VII.C we found that the term "other damage" as it appears in Annex A(1)(d) includes economic damage which arises from the entry, establishment or spread of pests and which is not a consequence of damage to the life or health of animals or plants. We also found that plants growing where they are undesired can be considered as "pests". Such plants include cross-breeds between GM oilseed rape and conventional oilseed rape which grow in a

conventional oilseed rape field as a result of pollen dispersal. Such plants further include GM oilseed rape plants growing in a conventional oilseed rape field as a result of unintentional dispersal of GM seed. Thus, we consider that to the extent France's safeguard measure on MS1/RF1 oilseed rape (EC-161) is applied to prevent economic damage resulting from the contamination of conventional oilseed rape due to the entry, establishment or spread of MS1/RF1 oilseed rape (via dispersal of GM seed), or of cross-breeds between MS1/RF1 oilseed rape and conventional oilseed rape (via dispersal of GM pollen), in cultivated conventional oilseed rape fields, it falls within the scope of Annex A(1)(d) of the *SPS Agreement.*

7.2734 In view of the above findings, we consider that France's safeguard measure on MS1/RF1 oilseed rape (EC-161), to the extent it is applied to avoid adverse effects arising from the possible contamination of conventional oilseed rape by MS1/RF1 oilseed rape (EC-161), falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

Conclusion with regard to the purpose of the safeguard measure

7.2735 In the light of the above considerations, we conclude that the safeguard measure applied by France with respect to MS1/RF1 oilseed rape (EC-161) qualifies as an SPS measure within the meaning of Annex A(1) as far as its purpose is concerned.

Form and nature of the measure

7.2736 We now turn to the issue of form and nature of France's safeguard measure on MS1/RF1 oilseed rape (EC-161). We start by recalling the Parties' arguments on this matter.

7.2737 The **United States** argues that the measure is in the form of a "decree" from the French Minister of Agriculture and Fishing, which is among the types of measures explicitly mentioned in Annex A(1) of the *SPS Agreement*.

7.2738 **Canada** argues that the French measure is in the form of a "decree", one of the types of measures expressly enumerated in Annex A(1) of the *SPS Agreement*.

7.2739 The **Panel** recalls that the second paragraph of Annex A(1) addresses the form and nature of measures which may qualify as SPS measures. In respect of the form of SPS measures, we have indicated earlier in this report that the reference in the second paragraph to "laws, decrees [and] regulations" should not be taken to prescribe a particular legal form and that SPS measures may in principle take many different legal forms.[1753] Furthermore, in respect of the nature of SPS measures, we have indicated earlier that the reference in the same paragraph to "requirements" is broad and unqualified. Hence, both an authorization to market a particular product and a ban on the marketing of a particular product may be considered "requirements". The second example would constitute a negative requirement.

7.2740 We note that the French safeguard measure on MS1/RF1 oilseed rape (EC-161) was implemented through a decree to prohibit commercialisation of MS1/RF1 oilseed rape (EC-161). Annex A(1) specifically refers to "decrees". We therefore consider that, for the purposes of Annex A(1), the French decree is an SPS measure in respect of the form of the measure.

7.2741 In respect of the nature of the French measure, we note that the decree prohibits the marketing of MS1/RF1 oilseed rape (EC-161). As indicated above, we are of the view that a prohibition on the

[1753] *See supra*, para. 7.1334.

marketing of a particular product (within a particular territory) may be considered a "requirement" for the purposes of Annex A(1).

7.2742 We therefore conclude that the safeguard measure taken by France with respect to MS1/RF1 oilseed rape qualifies as an SPS measure within the meaning of Annex A(1) as far as its form and nature are concerned.

Conclusion

7.2743 We have now considered France's safeguard measure on MS1/RF1 oilseed rape (EC-161) in terms of its purpose, its form and its nature. In relation to each of these issues, we have found that France's measure satisfies the definition of the term "SPS measure" set out in Annex A(1). In the light of this, we come to the conclusion that the safeguard measure applied by France with respect to MS1/RF1 oilseed rape (EC-161) constitutes an "SPS measure" within the meaning of Annex A(1).

7.2744 At this juncture, we could go on and address the question of whether, in view of its multiple purposes, the French safeguard measure could be considered to embody more than one SPS measure. However, neither the United States nor Canada or the European Communities have argued that to the extent any of the safeguard measures at issue falls to be assessed under the *SPS Agreement*, it should be deemed to constitute more than one SPS measure. In their submissions to the Panel, the Parties treated the relevant safeguard measures as constituting one SPS measure each. In the light of this, like the Parties, we will treat the French safeguard measure as constituting one single SPS measure. We will revisit this issue, however, if our disposition of the relevant claims under the *SPS Agreement* (and, where appropriate, any implementing action to be taken in view of our disposition of particular claims) were to depend on, and be affected by, whether we treat the French safeguard measure as constituting a single SPS measure or as embodying more than one SPS measure.

Effect on international trade

7.2745 We now turn to the issue of whether France's safeguard measure on MS1/RF1 oilseed rape (EC-161) is a measure that affects international trade, and that is therefore subject to the provisions of the *SPS Agreement*. We recall that according to Article 1.1 of the *SPS Agreement*, the *SPS Agreement* applies to all SPS measures which "may, directly or indirectly, affect international trade." Accordingly, for France's safeguard measure on MS1/RF1 oilseed rape (EC-161) to be subject to the *SPS Agreement*, it must be a measure which may, directly or indirectly, affect international trade. We recall the Parties' arguments on this matter.

7.2746 The **United States** argues that the measure adopted by France prohibits the "placing on the market" of MS1/RF1 oilseed rape (EC-161), thereby effectively blocking the importation of the product.

7.2747 **Canada** argues that the measure suspends commercialization of MS1/RF1 oilseed rape (EC-161), as well as prohibiting its importation on the French territory. Since the measure effectively blocks market access for the targeted biotech product, it clearly affects international trade.

7.2748 The **Panel** notes that the arguments of the parties regarding the effects on trade of France's safeguard measure on MS1/RF1 oilseed rape (EC-161) are essentially the same as their arguments with respect to Austria's safeguard measure on T25 maize. We recall our reasoning and conclusions with respect to Austria's measure on T25 maize in paragraphs 7.2603-7.2609 above. Therefore, in view of the fact that France's safeguard measure prohibits imports of MS1/RF1 oilseed rape (EC-161), we have no difficulty concluding that the safeguard measure applied by France is an SPS measure

which may affect international trade within the meaning of Article 1.1 of the *SPS Agreement* and, as such, is subject to the provisions of the *SPS Agreement*.

Overall conclusions

7.2749 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(vi) France – Topas oilseed rape

7.2750 We now turn to the safeguard measure applied by France on Topas oilseed rape. We recall that the application for placing on the market, growing and obtaining seeds of this oilseed rape was initially submitted to the United Kingdom.[1754] The product was authorized by the European Commission in April 1998.[1755] In November 1998, France adopted a Decree suspending the placing on the market of Topas oilseed rape for a period of two years.[1756] This Decision, which was taken on the basis of Article 16 of Directive 90/220, was notified to the Commission in May 1999. The period of application of the French safeguard measure on Topas oilseed rape was extended twice, namely in July 2001[1757] and July 2003.[1758]

Is the French safeguard measure on Topas oilseed rape an SPS measure?

7.2751 We start with the issue of whether the French safeguard measure on Topas oilseed rape is an SPS measure. In order to make this determination, we need to consider two distinct elements, namely: (1) the purpose of the measure; and (2) the form and nature of the measure.

[1754] C/UK/95/M5/1.

[1755] Commission Decision 98/291, April 1998.

[1756] France, Ministry of Agriculture and Fishing, Decree of 16 November 1998 involving suspension of the commercialization of genetically modified colza by virtue of Article 16 of Directive 90/220 of 23 April 1990, pursuant to Decision 98/291 of 22 April 1998, Official Journal, 18 November 1998, at 17379 (Exhibit CDA-64).

[1757] France, Ministry of Agriculture and Fishing, Decree of 26 July 2001 regarding suspension of the sale of genetically modified colza by virtue of Article 16 of Directive 90/220/European Communities of 23 April 1990, pursuant to Decision 96/158/European Communities of 6 February 1996, Official Journal, 30 August 2001 at 13903 (Exhibit CDA-70).

[1758] France, Ministry of Agriculture, Food, Fisheries and Rural Affairs, Order of 25 July 2003 suspending the marketing of genetically modified rapeseed pursuant to Article 23 of Directive 2001/18/European Communities of 12 March 2001, Official Journal, 14 August 2003 at 14061 (Exhibit CDA-71).

Purpose of the safeguard measure

7.2752 We first consider the issue of the purpose of the safeguard measure. Before turning to the arguments of the Parties on this issue, we recall that we must determine whether the purpose of the safeguard measure falls within one of the categories of purposes set out in Annex A(1) of the *SPS Agreement*.

7.2753 The **United States** notes that according to the SCP, France justified the ban based on its "concern over the environmental impact of genetic escape" and the "spread of herbicide tolerance" to other plants. This justification indicates that the French measures are sanitary and phytosanitary measures as they are applied "to protect [...] plant life or health" from the "spread of pests" and "prevent or limit other damage" from the "spread of pests".

7.2754 **Canada** notes that the French safeguard measure against Topas oilseed rape is predicated on concerns that its release into the environment may have detrimental effects on the surrounding plant life or health. More specifically, France indicated that it was concerned about genetic escape from the biotech varieties, leading to the transfer of herbicide resistance through hybridization with wild oilseed rape varieties. In essence, the concerns of France were related to potential risks arising from the release into the environment of the biotech oilseed rape varieties because of their alleged potential to function as a pest in relation to the surrounding environment, and in particular, related wild species of oilseed rape.

7.2755 The **European Communities** argues that the main reasons for which the measure was adopted and maintained include, *inter alia*, persistence and invasiveness in agricultural and natural habitats; development of resistance; out-crossing; undesirable effects on management practices; biodiversity; monitoring; labelling; co-existence; and human and animal health.

7.2756 The **Panel** observes that the French decisions to suspend the placing on the market of Topas oilseed rape identify exactly the same purposes for this safeguard measure at the time of review by the Panel as those invoked by France with respect to its safeguard measure on MS1/RF1 oilseed rape.[1759] Thus, based on the relevant information provided by the Parties, we consider that at the time of review by the Panel, France applied its safeguard measure on Topas oilseed rape to address concerns about:

(1) transfer of the herbicide-tolerance gene to adventitious flora;
(2) adverse effects on the environment, including from persistence; and
(3) contamination of conventional oilseed rape by genetically modified oilseed rape.

7.2757 The European Communities asserts that France's safeguard measure on Topas oilseed rape is also applied in view of concerns about labelling, but provides no substantiation or explanation of this assertion. The labelling concern asserted by the European Communities was not articulated by France in any of the relevant documents which date from before the date of establishment of this Panel. However, after the establishment of the Panel, France in an informal Note to the Commission made reference to the new EC regulation on labelling and traceability as well as to the new EC regulation on GM food and feed.[1760] We have already examined this document in the context of our analysis of the French safeguard measure on MS1/RF1 oilseed rape. Since the document also concerns the French safeguard measure on Topas oilseed rape, our earlier analysis is applicable to the safeguard

[1759] We note, however, that unlike MS1/RF1 oilseed rape, Topas oilseed rape was not approved for cultivation. It was approved for import, storage and processing.

[1760] Exhibit EC-161/At. 4.

measure on Topas oilseed rape as well. Thus, for the reasons we have outlined earlier in paragraph 7.2718, we are not persuaded that it can be inferred from the post-2003 reference to labelling in the French Note that France in August 2003 applied its safeguard measure on Topas oilseed rape to address concerns about labelling.

7.2758 Having determined the purposes for which France applied its safeguard measure at the time of review by the Panel, we now go on to assess whether these purposes fall within one of the categories of purposes which according to Annex A(1) characterize an SPS measure. To that end, we will consider one by one each of the above-noted purposes of France's safeguard measure.

Transfer of the herbicide-tolerance gene to adventitious flora

7.2759 Considering first France's stated objective for prohibiting the placing on the market of Topas oilseed rape due to concerns over the transfer of the herbicide-tolerance gene contained in Topas oilseed rape to adventitious flora, we recall our analysis of this concern in the context of our discussion of France's safeguard measure on MS1/RF1 oilseed rape.

7.2760 Consistent with our reasoning there, we consider that France's safeguard measure on Topas oilseed rape, to the extent it is applied to avoid risks associated with the transfer of the herbicide-tolerance gene contained in Topas oilseed rape to adventitious flora, and in particular the development of resistance in weeds due to cultivation of Topas oilseed rape, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

Adverse effects on the environment, including from persistence

7.2761 We turn now to the next objective stated by France for prohibiting the placing on the market of Topas oilseed rape, namely, France's concerns over potential adverse effects on the environment, including the environmental effects of persistence resulting from seed dispersal during transportation.[1761] We recall our analysis of this concern in the context of our discussion of France's safeguard measure on MS1/RF1 oilseed rape.

7.2762 Consistent with our reasoning there, we consider that France's safeguard measure on Topas oilseed rape, to the extent it is applied to avoid adverse effects on the environment, including from persistence, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

Contamination of conventional oilseed rape by genetically modified oilseed rape

7.2763 We address finally France's concern with regard to the risk of contamination of conventional oilseed rape by genetically modified oilseed rape. We recall in this regard our analysis of this concern in the context of our discussion of France's safeguard measure on MS1/RF1 oilseed rape.

7.2764 Consistent with our reasoning there, we consider that France's safeguard measure on Topas oilseed rape, to the extent it is applied to avoid adverse environmental or economic effects arising from the possible contamination of conventional oilseed rape by Topas oilseed rape, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

[1761] Since Topas oilseed rape was not approved for cultivation, our analysis in the context of MS1/RF1 oilseed rape relating to the adverse environmental effects resulting from management practices associated with the cultivation of MS1/RF1 oilseed rape is not applicable here.

Conclusion with regard to the purpose of the safeguard measure

7.2765 In the light of the above considerations, we therefore conclude that the safeguard measure applied by France with respect to Topas oilseed rape qualifies as an SPS measure within the meaning of Annex A(1) as far as its purpose is concerned.

Form and nature of the measure

7.2766 We now turn to the issue of the form and nature of France's safeguard measure on Topas oilseed rape. We note that the Parties have made the same arguments with respect to France's safeguard measure on Topas oilseed rape as for France's safeguard measure on MS1/RF1 oilseed rape (EC-161).

7.2767 Consistent with our analysis with respect to France's safeguard measure on MS1/RF1 oilseed rape (EC-161), we conclude that France's safeguard measure on Topas oilseed rape qualifies as an SPS measure within the meaning of Annex A(1) as far as its form and nature are concerned.

Conclusion

7.2768 We have now considered France's safeguard measure on Topas oilseed rape in terms of its purpose, its form and its nature. In relation to each of these issues, we have found that France's measure satisfies the definition of the term "SPS measure" set out in Annex A(1). In the light of this, we come to the conclusion that the safeguard measure applied by France with respect to Topas oilseed rape constitutes an "SPS measure" within the meaning of Annex A(1).

7.2769 At this juncture, we could go on and address the question of whether, in view of its multiple purposes, the French safeguard measure could be considered to embody more than one SPS measure. However, neither the United States nor Canada or the European Communities have argued that to the extent any of the safeguard measures at issue falls to be assessed under the *SPS Agreement*, it should be deemed to constitute more than one SPS measure. In their submissions to the Panel, the Parties treated the relevant safeguard measures as constituting one SPS measure each. In the light of this, like the Parties, we will treat the French safeguard measure as constituting one single SPS measure. We will revisit this issue, however, if our disposition of the relevant claims under the *SPS Agreement* (and, where appropriate, any implementing action to be taken in view of our disposition of particular claims) were to depend on, and be affected by, whether we treat the French safeguard measure as constituting a single SPS measure or as embodying more than one SPS measure.

Effect on international trade

7.2770 We now turn to the issue of whether France's safeguard measure on Topas oilseed rape is a measure that affects international trade, and that is therefore subject to the provisions of the *SPS Agreement*. We recall that according to Article 1.1 of the *SPS Agreement*, the *SPS Agreement* applies to all SPS measures which "may, directly or indirectly, affect international trade." Accordingly, for France's safeguard measure on Topas oilseed rape to be subject to the *SPS Agreement*, it must be a measure which may, directly or indirectly, affect international trade. We recall the Parties' arguments on this matter.

7.2771 The **United States** argues that the measure adopted by France prohibits the "placing on the market" of Topas oilseed rape, thereby effectively blocking the importation of the product.

7.2772 **Canada** argues that the measure suspends commercialization of Topas oilseed rape, and prohibits its importation on the French territory. Since the measure effectively blocks market access for the targeted biotech product, it clearly affects international trade.

7.2773 The **Panel** notes that the arguments of the parties regarding the effects on trade of France's safeguard measure on Topas oilseed rape are essentially the same as their arguments with respect to Austria's safeguard measure on T25 maize. We recall our reasoning and conclusions with respect to Austria's measure on T25 maize in paragraphs 7.2603-7.2609 above. Therefore, in view of the fact that France's safeguard measure prohibits imports of Topas oilseed rape, we have no difficulty concluding that the safeguard measure applied by France is an SPS measure which may affect international trade within the meaning of Article 1.1 of the *SPS Agreement* and, as such, is subject to the provisions of the *SPS Agreement*.

Overall conclusions

7.2774 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that the French safeguard measure on Topas oilseed rape is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that the French safeguard measure on Topas oilseed rape is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(vii) Germany – Bt-176 maize

7.2775 We now turn to the safeguard measure applied by Germany on Bt-176 maize. We recall that the application for placing on the market of this product was initially submitted to France.[1762] The product was authorized by the European Commission in 1996.[1763] Germany informed the Commission of its decision to restrict the authorization for the placing on the market of Bt-176 maize in a letter dated 2 March 2000.[1764] Germany amended its original decision on Bt-176 maize by a further decision adopted on 31 March 2000.[1765] This amended decision suspends the placing on the market of Bt-176 maize and its progeny in Germany, unless cultivation is intended for research and

[1762] C/F/94/11-03.
[1763] Commission Decision 97/98 (Exhibits US-97; ARG-37).
[1764] The letter is from the Robert Koch Institute (Exhibit EC-158/At. 19_trans).
[1765] Exhibits US-65; ARG-13.

testing purposes in certain specified areas.[1766] This decision was notified to the Commission in April 2000.[1767]

Is the German safeguard measure on Bt-176 maize an SPS measure?

7.2776 We start with the issue of whether Germany's safeguard measure on Bt-176 maize is an SPS measure. In order to make this determination, we need to consider two distinct elements, namely: (1) the purpose of the measure; and (2) the form and nature of the measure.

Purpose of the safeguard measure

7.2777 We first consider the issue of the purpose of the safeguard measure. Before turning to the arguments of the Parties on this issue, we recall that we must determine whether the purpose of the safeguard measure falls within one of the categories of purposes set out in Annex A(1) of the *SPS Agreement*.

7.2778 The **United States** notes that the concerns expressed by Germany with regard to Bt-176 maize include the effect of Bt toxin on non-target organisms, the development of insect resistance to Bt toxin, and the transfer of antibiotic resistant genes to humans and animals. On the basis of these justifications, the United States argues that the German safeguard measure is an SPS measure, as it is applied to "protect animal life or health" from "disease-causing organisms"; or "protect human life or health" from "toxins" or "disease-causing organisms in foods"; or "to prevent or limit [...] damage" from the "spread of pests".

7.2779 **Argentina** argued that the purpose of the safeguard measures may be inferred from the Community legislation under which the bans were adopted, and that the relevant provisions of EC Directive 90/220 and Regulation 258/97 clearly indicate that the purpose of the EC legislation is the "protection of human health and the environment". Since the EC member States have taken their measures explicitly on the basis of this legislation, it can be inferred that the measures were imposed for the purpose of protecting human health or the environment. The safeguard measures are, therefore, SPS measures as defined in the *SPS Agreement*.

7.2780 The **European Communities** argues that the main reasons for which the measure was adopted and maintained include, *inter alia*, horizontal gene transfer; antibiotic resistance; effects on non-target organisms; toxicity or allergenicity; persistence and invasiveness in agricultural and natural habitats; development of resistance; out-crossing; undesirable effects on management practices; biodiversity; monitoring; labelling; co-existence; and human and animal health.

7.2781 The **Panel** notes that Germany sets out its reasons for adopting the safeguard measure on Bt-176 maize in a letter to the Commission dated 4 April 2000.[1768] In this document, Germany refers to recent laboratory investigations and relevant studies with insect species which suggest that the ingestion of pollen from maize plants expressing Bt-toxin may produce harmful effects in non-target

[1766] The prohibition did not apply in the case of cultivation intended for research and testing purposes in the following areas: effects on target or non-target organisms, the development of resistance, counter measures to resistance development, horizontal or vertical gene transfer, ecological assessments or the enhancement of agronomic and plant protection knowledge for practical application.

[1767] The amended decision was notified to the Commission on 4 April 2000 (Exhibit EC-158/At. 21), and again on 28 April 2000 with the relevant scientific evidence considered by Germany in the context of the adoption of its safeguard measure (Exhibits EC-158/At. 23-29).

[1768] Exhibit EC-158/At. 21. The Panel notes that the concerns of Germany with respect to Bt-176 maize are also outlined in the letter of 31 March 2000 (Exhibit US-65).

insects through their absorption of the Bt-toxin.[1769] Germany notes that in the case of unrestricted cultivation, resistance to Bt toxin may develop in maize pests and non-target organisms, thereby impeding the applicability of Bt toxin as a pesticide. Other studies reported that Bt toxin enters the soil from the roots of genetically modified maize plants. Germany submits that these studies suggest that if cultivation is unrestricted, the presence of Bt toxin could have adverse effects on living organisms in the soil. Finally, Germany notes that the cultivation of a transgenic variety with antibiotic-resistant genes might increase the development of antibiotic resistance following the ingestion of the gene by humans and animals.

7.2782 Based on the foregoing, we consider that at the time of review by the Panel, Germany applied its safeguard measure on Bt-176 maize to address concerns about:

(1) effects on non-target organisms;
(2) the development of resistance to Bt toxin in insects;
(3) possible adverse effects of the Bt toxin in the soil; and
(4) the transfer of the *bla*-ampicillin resistance gene to bacteria of the intestine of humans and animals.

7.2783 The European Communities asserts that Germany's safeguard measure on Bt-176 maize is also applied in view of concerns about labelling and co-existence. These asserted concerns were not articulated by Germany in the documents discussed by us above. Furthermore, the European Communities has neither substantiated nor explained its assertion. In the light of this, we are not persuaded that Germany is applying its safeguard measure to address these additional concerns identified by the European Communities.

7.2784 Having determined the purposes for which Germany applied its safeguard measure at the time of review by the Panel, we now go on to assess whether these purposes fall within one of the categories of purposes which according to Annex A(1) characterize an SPS measure. To that end, we will consider one by one each of the above-noted purposes of Germany's safeguard measure.

Effects on non-target organisms

7.2785 We begin our analysis with the purpose of managing potential risks associated with effects on non-target organisms.

7.2786 We refer to our conclusions in Section VII.C that a GM crop that is eaten by animals can be considered to be a "food" for that animal. This would include, for example, pollen of the GM crop which is consumed by insects and GM plants consumed by non-target insects, deer, rabbits or other wild fauna. As we previously noted, a poisonous substance, such as the Bt toxin, which is produced by a GM crop could qualify as a "toxin" within the meaning of Annex A(1)(b).[1770] We determined on that basis that measures applied to protect the life or health of animals (not including target organisms) from risks arising from toxins produced in GM plants are covered by Annex A(1)(b).

7.2787 Moreover, we indicate in Section VII.C our view that if a GM plant produces a poisonous substance which could adversely affect the health of non-target organisms, even if the non-target organisms do not eat the GM plant, *e.g.* through exposure other than through ingestion of food, the GM plant could be considered a "pest" within the meaning of Annex A(1)(a). Thus, a measure

[1769] It is noted, however, that adverse effects are not expected in respect of the specified cultivation purposes if the quantity sown is limited to 12 tonnes per year in a cultivation area limited to 500 hectares.

[1770] We recall our view that the term "toxin" as it appears in Annex A(1)(b) includes allergens.

applied to protect from risks arising from such exposure to GM plants would, in our view, fall within the scope of Annex A(1)(a).

7.2788 In addition, in Section VII.C we conclude that to the extent that GM plants may result in changes in animal or plant populations, this may increase or decrease the food available for particular non-target animal populations and thus alter the fitness and health of these animal populations, which may in turn lead to further deleterious effects on the life or health of animals or other plants. We also recall our conclusion that by causing harm to the health of animals or other plants in this way, GM plants would act as "pests" within the meaning of Annex A(1), and that to the extent a measure is applied to avoid this kind of adverse effect, it can be considered a measure covered by Annex A(1)(a). Furthermore, we found that Annex A(1)(a) covers measures applied to protect animal or plant life or health from risks arising directly or indirectly from the entry, establishment or spread of cross-breeds with undesired traits (such as insecticidal traits) resulting from transfer of genetic material from a GM plant.

7.2789 Consistent with our reasoning above, we consider that Germany's safeguard measure on Bt-176 maize, to the extent it is applied to avoid potential risks to the health of non-target organisms from the consumption of Bt-176 maize, falls within the scope of Annex A(1)(b) of the *SPS Agreement*. Furthermore, to the extent that Germany's safeguard measure is applied to avoid other potential adverse effects on non-target organisms arising from Bt-176 maize, it falls within the scope of Annex A(1)(a) of the *SPS Agreement*.

Development of resistance to Bt toxin in insects

7.2790 Turning next to the concern regarding the development of resistance to Bt toxins in insects, we refer to our analysis of this type of concern in Section VII.C and in the context of our discussion of Austria's safeguard measure on Bt-176 maize above.

7.2791 We refer to our analysis in Section VII.C regarding the development of pesticide-resistance in target organisms. We found that resistant target organisms (insects) could be regarded as "pests" within the meaning of Annex A(1), inasmuch as they present a risk to animal, plant or human life or health or result in other damage. We further determined that risks to animal or plant life or health, or other damage to the environment, resulting from a change in pesticide use may be viewed as arising indirectly from the entry, establishment or spread of resistant target organisms *qua* relevant pest. We found that to the extent that a measure seeks to avoid such risks and damage, it can be considered to be covered by Annex A(1)(a) and (d) of the *SPS Agreement*.

7.2792 Consistent with our reasoning above, we consider that Germany's safeguard measure on Bt-176 maize, to the extent it is applied to protect from risks associated with the development of resistance to Bt toxin in insects due to the cultivation of Bt-176 maize, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

Possible adverse effects of the Bt toxin in the soil

7.2793 We turn next to Germany's concern related to the possible adverse effects of the Bt toxin in the soil. We understand Germany's concern to be about adverse effects on living organisms in the soil.

7.2794 In Section VII.C, we found that the phrase "animal and plant" in Annex A(1) covers also soil microfauna or –flora. In addition, we found that to the extent that GM plants might affect the life or health of non-target soil microfauna or –flora, they could be considered as "pests" in the sense of

Annex A(1). Thus, to the extent Germany's safeguard measure is applied to address concerns that Bt-176 maize might affect the life or health of non-target soil microfauna or –flora, it can, in our view, be considered to be a measure applied to protect the life or health of soil microfauna or –flora from risks arising from the entry, establishment or spread of a Bt-producing GM plant *qua* "pest" within the meaning of Annex A(1)(a) of the *SPS Agreement*.

7.2795 Consistent with our reasoning above, we consider that Germany's safeguard measure on Bt-176 maize, to the extent it is applied to avoid risks associated with adverse effects of the Bt toxin on living organisms in the soil, falls within the scope of Annex A(1)(a) of the *SPS Agreement*.

Transfer of the bla-ampicillin resistance gene to bacteria of the intestine of humans or animals

7.2796 We turn finally to Germany's stated concern regarding the potential transfer of the *bla*-ampicillin resistance gene to bacteria of the intestine of humans or animals due to consumption of Bt-176 maize. With respect to the transfer of antibiotic resistance marker genes to the intestine of humans or animals, we note that the Parties' arguments are the same as those made in relation to Austria's safeguard measures on T25 maize and Bt-176 maize. We refer to our discussion in Section VII.C regarding ARMG. More particularly, we recall that, in our view, the concern relates to the potential transfer to pathogens of ARMG present in certain GMOs, and the possible resulting decrease in effectiveness of medical treatments involving specific antibiotics which might pose a risk to the life or health of animals infected with the resistant pathogen.

7.2797 In Section VII.C we found that Annex A(1)(a) covers measures applied to protect animal life or health from risks arising from the entry, establishment or spread of disease-causing organisms which have or might become resistant to antibiotics due to the transfer of ARMG from a GM plant. Similarly, we found that Annex A(1)(a) covers measures applied to protect animal life or health from risks arising from the entry, establishment or spread of diseases due to the reduced effectiveness of antibiotics used to treat the pathogens which have become resistant to these antibiotics through gene transfer. Furthermore, we found that Annex A(1)(b) covers measures applied to protect human or animal life or health from risks arising indirectly, namely *via* the potential transfer to humans or animals of marker genes conferring resistance to antibiotics used in human or veterinary medicine, from additives in foods or feedstuffs. We recall in this respect that, in our view, ARMGs can be considered to be additives for the purposes of Annex A(1)(b).

7.2798 Consistent with our reasoning above, we consider that Germany's safeguard measure on Bt-176 maize, to the extent it is applied to avoid risks associated with the transfer of the *bla*-ampicillin resistance gene from Bt-176 maize to bacteria in the intestine of humans or animals, falls within the scope of Annex A(1)(a) and (b) of the *SPS Agreement*.

Conclusion with regard to the purpose of the safeguard measure

7.2799 In the light of the above considerations, we conclude that the safeguard measure applied by Germany with respect to Bt-176 maize qualifies as an SPS measure within the meaning of Annex A(1) as far as its purpose is concerned.

Form and nature of the measure

7.2800 We now turn to the issue of the form and nature of Germany's safeguard measure on Bt-176 maize. We start by recalling the arguments of the Parties on this matter.

7.2801 The **United States** argues that the measure was in the form of a "notice" from the government agency with responsibility for the regulation of biotech products. Through this "notice", the German Government "ordered" suspension of the approval for commercialization of Bt-176 maize on the German territory. The word "order" is defined as "an authoritative direction", which is similar to the definition of "regulation". A "regulation" is among the types of measures explicitly mentioned in Annex A(1).

7.2802 **Argentina** notes that the measure was implemented by means of an amendment notice suspending the entry of Bt-176 maize. The measure has the same binding nature as a law, regulation, order or requirement.

7.2803 The **Panel** recalls that the second paragraph of Annex A(1) addresses the form and nature of measures which may qualify as SPS measures. In respect of the form of SPS measures, we have indicated earlier in this report that the reference in the second paragraph to "laws, decrees [and] regulations" should not be taken to prescribe a particular legal form and that SPS measures may in principle take many different legal forms.[1771] Furthermore, in respect of the nature of SPS measures, we have indicated earlier that the reference in the same paragraph to "requirements" is broad and unqualified. Hence, both an authorization to market a particular product and a ban on the marketing of a particular product may be considered "requirements". The second example would constitute a negative requirement.

7.2804 We note that the German safeguard measure on Bt-176 maize was implemented through a decision by the Robert Koch Institute, the competent German authority, to prohibit commercialization of Bt-176 maize on the German territory. Annex A(1) does not specifically refer to "decisions". As we have pointed out, this fact alone does not necessarily mean that Germany's safeguard measure is not an SPS measure, since no specific legal form is prescribed. Germany's decision clearly is a measure attributable to the German Government. It is also not in dispute that the decision is legally binding. We therefore consider that, for the purposes of Annex A(1), the German decision may be assimilated to measures adopted in the form of "laws", "decrees" or "regulations".

7.2805 In respect of the nature of the German measure, we note that the decision prohibits the marketing of Bt-176 maize. As indicated above, we are of the view that a prohibition on the marketing of a particular product (within a particular territory) may be considered a "requirement" for the purposes of Annex A(1).

7.2806 We therefore conclude that the safeguard measure taken by Germany with respect to Bt-176 maize qualifies as an SPS measure within the meaning of Annex A(1) as far as its form and nature are concerned.

Conclusion

7.2807 We have now considered Germany's safeguard measure on Bt-176 maize in terms of its purpose, its form and its nature. In relation to each of these issues, we have found that Germany's measure satisfies the definition of the term "SPS measure" set out in Annex A(1). In the light of this, we come to the conclusion that the safeguard measure applied by Germany with respect to Bt-176 maize constitutes an "SPS measure" within the meaning of Annex A(1).

7.2808 At this juncture, we could go on and address the question of whether, in view of its multiple purposes, the German safeguard measure could be considered to embody more than one SPS measure.

[1771] *See supra*, footnote 1753.

However, neither the United States nor Argentina or the European Communities have argued that to the extent any of the safeguard measures at issue falls to be assessed under the *SPS Agreement*, it should be deemed to constitute more than one SPS measure. In their submissions to the Panel, the Parties treated the relevant safeguard measures as constituting one SPS measure each. In the light of this, like the Parties, we will treat the German safeguard measure as constituting one single SPS measure. We will revisit this issue, however, if our disposition of the relevant claims under the *SPS Agreement* (and, where appropriate, any implementing action to be taken in view of our disposition of particular claims) were to depend on, and be affected by, whether we treat the German safeguard measure as constituting a single SPS measure or as embodying more than one SPS measure.

Effect on international trade

7.2809 We now turn to the issue of whether Germany's safeguard measure on Bt-176 maize is a measure that affects international trade, and that is therefore subject to the provisions of the *SPS Agreement*. We recall that according to Article 1.1 of the *SPS Agreement*, the *SPS Agreement* applies to all SPS measures which "may, directly or indirectly, affect international trade." Accordingly, for Germany's safeguard measure on Bt-176 maize to be subject to the *SPS Agreement*, it must be a measure which may, directly or indirectly, affect international trade. We recall the Parties' arguments on this matter.

7.2810 The **United States** argues that the measure adopted by Germany suspends the approval for commercialization of Bt-176 maize, thereby effectively blocking the importation of the product. The measure as such therefore affects international trade.

7.2811 **Argentina** notes that since the safeguard measure prevents access of Bt-176 maize to Germany, resulting in the absence of imports of this product, the measure can be said to affect international trade.

7.2812 The **Panel** notes that the arguments of the parties regarding the effects on trade of Germany's safeguard measure on Bt-176 maize are essentially the same as their arguments with respect to Austria's safeguard measure on T25 maize. We recall our reasoning and conclusions with respect to Austria's measure on T25 maize in paragraphs 7.2603-7.2609 above. Therefore, in view of the fact that Germany's safeguard measure prohibits imports of Bt-176 maize, we have no difficulty concluding that the safeguard measure applied by Germany is an SPS measure which may affect international trade within the meaning of Article 1.1 of the *SPS Agreement* and, as such, is subject to the provisions of the *SPS Agreement*.

Overall conclusions

7.2813 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that the German safeguard measure on Bt-176 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that the German safeguard measure on Bt-176 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(viii) Greece – Topas oilseed rape

7.2814 We now turn to the safeguard measure applied by Greece with respect to Topas oilseed rape. We recall that the application for placing on the market of this product was initially submitted to the United Kingdom.[1772] The product was approved for import and processing by the European Commission in April 1998[1773], and Greece adopted its safeguard measure to prohibit imports of Topas oilseed rape pursuant to Article 16 of Directive 90/220 in September 1998.[1774]

Is the Greek safeguard measure on Topas oilseed rape an SPS measure?

7.2815 We start with the issue of whether the Greek safeguard measure on Topas oilseed rape is an SPS measure. In order to make this determination, we need to consider two distinct elements, namely: (1) the purpose of the measure; and (2) the form and nature of the measure.

Purpose of the safeguard measure

7.2816 We first consider the issue of the purpose of the safeguard measure. Before turning to the arguments of the Parties on this issue, we recall that we must determine whether the purpose of the safeguard measure falls within one of the categories of purposes set out in Annex A (1) of the *SPS Agreement*.

7.2817 The **United States** notes that according to the SCP, Greece justified its safeguard measure on the basis of its concern for "genetic escape" and the consequences it could have on agriculture, the natural environment of Greece and consumer health. Concerns regarding "genetic escape" relate to adverse effects from the transfer of the herbicide tolerant gene to other plants or to consuming organisms. According to the United States, the Greek measure is an SPS measure, as it is applied to protect "plant life or health" from the "spread of pests"; to protect "human life or health" from "contaminants" or "disease-causing organisms in food"; or "to prevent or limit other damage" from the "spread of pests".

7.2818 **Canada** notes that the Greek safeguard measure was predicated on concerns that release into the environment of Topas oilseed rape may have a detrimental effect on the surrounding plant life or health. More specifically, Greece indicated that it was concerned about genetic escape from the biotech varieties, leading to the transfer of herbicide resistance through hybridization with wild oilseed rape varieties. In essence, the concerns of Greece were related to potential risks arising from the release into the environment of the biotech oilseed rape varieties because of their alleged potential to function as a "pest" in relation to the surrounding environment, and in particular, related wild species of oilseed rape.

[1772] C/UK/95/M5/1.

[1773] Commission Decision 98/291 (Exhibits US-97; CDA-61).

[1774] Greece, Minister of Environment, Regional Planning and Public Works, Prohibition of seeds of the genetically-modified rape-plant line bearing reference number C/UK/95/M5/1, Government Gazette, 1008, 25 September 1998, at 11941 (Exhibits CDA-72; US-69).

7.2819 The **European Communities** argues that the main reasons for which the measure was adopted and maintained include, *inter alia*, persistence and invasiveness in agricultural and natural habitats; development of resistance; out-crossing; undesirable effects on management practices; biodiversity; monitoring; labelling; co-existence; and human and animal health.

7.2820 The **Panel** notes that the Ministerial decision adopted by the Greek authorities on 8 September 1998 prohibiting imports of Topas oilseed rape refers, without elaboration, to potential "risks for the natural environment of Greece".[1775] Greece provided the justification for its safeguard measure in a Note addressed to the Commission on 3 November 1998.[1776]

7.2821 In this document, Greece indicated that although the consent for Topas oilseed rape was not given for cultivation, the seeds could nonetheless escape into the environment during transport and grow into viable plants. Greece notes that since oilseed rape is capable of out-crossing and giving fertile hybrids with wild *Brassica* species, the release into the environment of oilseed rape could therefore generate hybrid plants bearing the glufosinate tolerance gene. The Greek climate would permit the spreading not only of volunteer oilseed rape plants, but also of their hybrids with wild related species in both the agricultural and the natural environment, with unpredictable consequences.[1777] Greece further notes that in Greece some of the wild plant varieties at issue are collected and consumed as food. Greece points out in this regard that if out-crossing were to confer on these wild plant varieties the herbicide resistance trait, the consequences of the consumption of these varieties would be unpredictable.

7.2822 Furthermore, in a letter form the Greek authorities to the Commission dated March 2004[1778] Greece highlights concerns about gene flow through pollen transfer to wild related species. This letter also notes that the maintenance of the safeguard measure at issue is justified by the precautionary principle, until new scientific information was available regarding risks to human health and the environment.

7.2823 Finally, we note that a memorandum was provided by Greece to the Commission in March 2004.[1779] It recalls the concerns underlying the safeguard measure on Topas oilseed rape, including those relating to the harm for wildlife and the environment and possible problems for consumers and farmers, specifically related to possible consumption of hybrids from outcrosses of Topas oilseed rape and wild plant species and the potential difficulties associated with managing herbicide tolerant weeds arising from these types of outcrosses. The memorandum concludes that the maintenance of the safeguard measure at issue is justified by the precautionary principle, pending complete scientific proof of the existence and seriousness of risks. The memorandum also states that the issue of co-existence is not relevant in the case of the oilseed rape since its import by Greece, if it were allowed, would be for the use of the product for oil extraction and not for cultivation.

7.2824 Based on the foregoing, we consider that at the time of review by the Panel, Greece applied its safeguard measure to address concerns about:

(1) adverse environmental effects of hybridisation and out-crossing;
(2) adverse environmental effects of volunteer Topas oilseed rape plants; and
(3) consumer health.

[1775] Exhibit EC-162/At. 4_trans.
[1776] *Ibid.*
[1777] *Ibid.*
[1778] Exhibit EC-162/At. 6.
[1779] Exhibit EC-162/At. 7.

7.2825 The European Communities asserts that Greece's safeguard measure on Topas oilseed rape is also applied in view of concerns about labelling and co-existence. These asserted concerns were not articulated by Greece in the documents discussed by us above. Furthermore, the European Communities has neither substantiated nor explained its assertion. In the light of this, we are not persuaded that Greece is applying its safeguard measure to address these additional concerns identified by the European Communities.

7.2826 Having determined the purposes for which Greece applied its safeguard measure at the time of review by the Panel, we now go on to assess whether these purposes fall within one of the categories of purposes which according to Annex A(1) characterize an SPS measure. To that end, we will consider one by one each of the above-noted purposes of Greece's safeguard measure.

Adverse environmental effects of hybridisation and out-crossing

7.2827 We begin with Greece's stated purpose of managing risks associated with the environmental impacts of hybridisation and out-crossing. We recall that the documentation reviewed by the Panel with respect to the Greek safeguard measure on Topas oilseed rape highlighted concerns regarding the potential loss of seeds during transportation, which could result in the establishment of viable biotech oilseed rape in the environment and potential hybridisation with other *Brassicae*. The Panel understands this concern to be related, *inter alia*, to potential out-crossing between Topas oilseed rape plants and unmodified plants, and the introduction of herbicide resistance in the out-crossed plants.

7.2828 We refer to our finding in Section VII.C that cross-breeds between conventional and GM plants could be regarded as "pests" for the purposes of Annex A(1), to the extent they have undesired introduced traits (such as herbicide resistance) and harm animal or plant life or health or result in other damage. We have determined on that basis that measures applied to protect animal or plant life or health from risks arising directly (*e.g.*, through changes in selective advantage) from the entry, establishment or spread of cross-breeds with undesired traits resulting from the transfer of genetic material from a GM plant fall within the scope of Annex A(1)(a), while measures applied to prevent "other damage" to the environment from the entry, establishment or spread of cross-breeds fall within the scope of Annex A(1)(d).

7.2829 In addition, we recall that one possible concern arising from cross-breeds that have acquired herbicide resistance is that they may lead to the need for an increased use of the same herbicides, or different, more toxic herbicides, to control the resistant cross-breeds. We determined that risks to animal or plant life or health, or other damage to the environment, resulting from a change in pesticide use may be viewed as arising indirectly from the entry, establishment or spread of cross-breeds *qua* relevant pest. We deduced from this that measures applied to avoid such indirect adverse effects on the environment fall within the scope of Annex A(1)(a) and (d).

7.2830 Consistent with our findings above, we consider that Greece's safeguard measure on Topas oilseed rape, to the extent it is applied to avoid risks to the environment associated with the transfer of the herbicide-tolerance gene contained in Topas oilseed rape to wild related species, and in particular the development of resistance in these wild hybrid plants, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

Adverse environmental effects of volunteer Topas oilseed rape plants

7.2831 We next turn to Greece's concerns about other adverse environmental effects, notably adverse environmental effects of volunteer Topas oilseed rape plants which are the result of accidental dispersal of Topas oilseed rape seeds during transportation.

7.2832 In Section VII.C we found that to the extent a measure is applied to avoid adverse effects on plant life or health, including adverse effects on genetic diversity, that might arise if volunteer GM plants crowd out or eliminate other plants due to a potential competitive advantage, invasiveness or persistence, such a measure would be covered by Annex A(1)(a), as it would be applied "to protect [...] plant life or health […] from risks arising from the entry, establishment or spread" of GM plants *qua* "pests".

7.2833 In Section VII.C we also found that to the extent that volunteer GM plants may result in changes in plant populations, this may increase or decrease the food available for particular animal populations and thus enhance, or detract from, the fitness and health of these animal populations, which in turn may have a deleterious effect on the life or health of plants, *e.g.*, by affecting their ability to reproduce. We stated that, by causing harm to the health of animals or other plants in this way, the GM plants would act as "pests" within the meaning of Annex A(1), and that to the extent a measure is applied to avoid this kind of adverse effect, it can be considered a measure covered by Annex A(1)(a).

7.2834 Finally, we found that to the extent a measure seeks to avoid adverse effects of GM plants on the environment other than adverse effects on animal or plant life or health, such a measure can be considered to be covered by Annex A(1)(d), inasmuch as it can be viewed as a measure which is applied to prevent or limit "other damage" from the entry, establishment or spread of "pests". As noted earlier, the GM plants themselves might qualify as the relevant pest, or other plants or animals might become pests as a result of the release of GMOs into the environment.

7.2835 Consistent with our findings above, we consider that Greece's safeguard measure on Topas oilseed rape, to the extent it is applied to avoid adverse effects on the environment arising from volunteer Topas oilseed rape plants, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

Consumer health

7.2836 Turning last to Greece's stated concern regarding the potential risks to consumer health associated with Topas oilseed rape, we recall that Greece expressed concern with respect to consumer health, since some wild varieties of oilseed rape are apparently consumed in Greece as food. Specifically, Greece noted that if out-crossing were to confer on these wild plant varieties the herbicide resistance trait, the consequences of the consumption of these varieties would be unpredictable. We understand this concern to be related to potential adverse health effects associated with the consumption of GM material or the consumption of proteins produced through the expression of modified genes, in hybrids of conventional oilseed rape and Topas oilseed rape.

7.2837 In Section VII.C we found that Annex A(1) covers food safety risks which might potentially arise from the consumption of GM foods, namely, risks to human life or health from the presence in food of additives, contaminants, toxins (including allergens) or disease-causing organisms. More particularly, we found that genes intentionally added for a technological purpose to GM plants that are eaten or being used as an input in processed foods can be considered "additives" in foods within the meaning of Annex A(1)(b). We also recall our finding that substances which are produced through

the unintended expression of modified plant genes may be considered "contaminants" within the meaning of Annex A(1)(b). Finally, we recall our finding that a poisonous substance which is produced during the metabolism or growth of a plant, including allergens, could qualify as a "toxin" within the meaning of Annex A(1)(b). Therefore, we consider that potential risks to human health associated with consumption of hybrids of GM and conventional cultivated or wild plants can be considered to be risks associated with "additives", "contaminants" or "toxins" in foods within the meaning of Annex A(1)(b). Measures applied to protect from such food safety risks can thus be considered to fall within the scope of Annex A(1)(b).

7.2838 Greece did not specify the nature of the potential adverse health effects associated with the consumption of cross-breeds between Topas oilseed rape and wild oilseed rape. Hence, we cannot determine whether Greece's concern relates to the presence in hybrids of additives, contaminants or toxins (including allergens). However, in the absence of any information suggesting otherwise, there are no grounds for believing that Greece's concern about consumer health does not relate to any of the aforementioned types of risks potentially associated with the consumption of GM foods.

7.2839 Thus, consistent with our findings above, we consider that Greece's safeguard measure on Topas oilseed rape, to the extent it is applied to avoid risks to consumer health associated with the consumption of cross-breeds between Topas oilseed rape and wild oilseed rape, or food products derived therefrom, falls within the scope of Annex A(1)(b) of the *SPS Agreement*.

Conclusion with regard to the purpose of the safeguard measure

7.2840 In the light of the above considerations, we therefore conclude that the safeguard measure applied by Greece with respect to Topas oilseed rape qualifies as an SPS measure within the meaning of Annex A(1) as far as its purpose is concerned.

Form and nature of the measure

7.2841 We now turn to the issue of the form and nature of Greece's safeguard measure on Topas oilseed rape. We start by recalling the arguments of the Parties on this matter.

7.2842 The **United States** argues that the measure is in the form of a ministerial decision, which is synonymous with the term "regulation", which is one of the types of measure explicitly mentioned in Annex A(1) of the *SPS Agreement*.

7.2843 **Canada** argues that the measure falls within the scope of "laws, decrees, regulations, requirements and procedures." As indicated by the use of the word "include", Annex A provides a non-exhaustive list of the forms that an SPS measure can take. The Greek measure is in the form of a "ministerial decision". Although this form of measure is not explicitly mentioned in Annex A, it can be equated to a regulation or other form of subordinate legislation, if legally binding and lawfully promulgated by the central government authorities.

7.2844 The **Panel** recalls that the second paragraph of Annex A(1) addresses the form and nature of measures which may qualify as SPS measures. In respect of the form of SPS measures, we have indicated earlier in this report that the reference in the second paragraph to "laws, decrees [and] regulations" should not be taken to prescribe a particular legal form and that SPS measures may in principle take many different legal forms. Furthermore, in respect of the nature of SPS measures, we have indicated earlier that the reference in the same paragraph to "requirements" is broad and unqualified. Hence, both an authorization to market a particular product and a ban on the marketing

of a particular product may be considered "requirements". The second example would constitute a negative requirement.

7.2845 We note that Greece's safeguard measure on Topas oilseed rape was implemented through a ministerial decision to prohibit commercialization of Topas oilseed rape on the Greek territory. Annex A(1) does not specifically refer to "ministerial decisions". As we have pointed out, this fact alone does not necessarily mean that Greece's safeguard measure is not an SPS measure, since no specific legal form is prescribed. Greece's decision clearly is a measure attributable to the Greek Government. It is also not in dispute that the decision is legally binding. We therefore consider that, for the purposes of Annex A(1), the Greek decision may be assimilated to measures adopted in the form of "laws", "decrees" or "regulations".

7.2846 In respect of the nature of the Greek measure, we note that the decision prohibits the marketing of Topas oilseed rape. As indicated above, we are of the view that a prohibition on the marketing of a particular product (within a particular territory) may be considered a "requirement" for the purposes of Annex A(1).

7.2847 We therefore conclude that the safeguard measure taken by Greece with respect to Topas oilseed rape qualifies as an SPS measure within the meaning of Annex A(1) as far as its form and nature are concerned.

Conclusion

7.2848 We have now considered Greece's safeguard measure on Topas oilseed rape in terms of its purpose, its form and its nature. In relation to each of these issues, we have found that Greece's measure satisfies the definition of the term "SPS measure" set out in Annex A(1). In the light of this, we come to the conclusion that the safeguard measure applied by Greece with respect to Topas oilseed rape constitutes an "SPS measure" within the meaning of Annex A(1).

7.2849 At this juncture, we could go on and address the question of whether, in view of its multiple purposes, the Greek safeguard measure could be considered to embody more than one SPS measure. However, neither the United States nor Canada or the European Communities have argued that to the extent any of the safeguard measures at issue falls to be assessed under the *SPS Agreement*, it should be deemed to constitute more than one SPS measure. In their submissions to the Panel, the Parties treated the relevant safeguard measures as constituting one SPS measure each. In the light of this, like the Parties, we will treat the Greek safeguard measure as constituting one single SPS measure. We will revisit this issue, however, if our disposition of the relevant claims under the *SPS Agreement* (and, where appropriate, any implementing action to be taken in view of our disposition of particular claims) were to depend on, and be affected by, whether we treat the Greek safeguard measure as constituting a single SPS measure or as embodying more than one SPS measure.

Effect on international trade

7.2850 We now turn to the issue of whether Greece's safeguard measure on Topas oilseed rape is a measure that affects international trade, and that is therefore subject to the provisions of the *SPS Agreement*. We recall that according to Article 1.1 of the *SPS Agreement*, the *SPS Agreement* applies to all SPS measures which "may, directly or indirectly, affect international trade." Accordingly, for Greece's safeguard measure on Topas oilseed rape to be subject to the *SPS Agreement*, it must be a measure which may, directly or indirectly, affect international trade. We recall the Parties' arguments on this matter.

7.2851 The **United States** argues that the measure adopted by Greece prohibits the "importation" of Topas oilseed rape. The measure as such therefore affects international trade.

7.2852 **Canada** argues that the measure prohibits the importation of Topas oilseed rape on the Greek territory. Since the measure effectively blocks market access for the targeted biotech product, it clearly affects international trade.

7.2853 The **Panel** notes that the arguments of the parties regarding the effects on trade of Greece's safeguard measure on Topas oilseed rape are essentially the same as their arguments with respect to Austria's safeguard measure on T25 maize. We recall our reasoning and conclusions with respect to Austria's measure on T25 maize above. Therefore, in view of the fact that Greece's safeguard measure prohibits imports of Topas oilseed rape, we have no difficulty concluding that the safeguard measure applied by Greece is an SPS measure which may affect international trade within the meaning of Article 1.1 of the *SPS Agreement* and, as such, is subject to the provisions of the *SPS Agreement*.

Overall conclusions

7.2854 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that the Greek safeguard measure on Topas oilseed rape is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that the Greek safeguard measure on Topas oilseed rape is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(ix) Italy – T25 maize, MON810 maize, MON809 maize, Bt-11 maize (EC-163)

7.2855 We now turn to the Italian safeguard measure applied on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163). We recall that the applications for placing on the market of these products were originally submitted to the United Kingdom.[1780] The products were authorized by the European Commission under the simplified authorization procedure set out in Article 3(4) of Regulation 258/97.[1781] By Decree of the President of the Council of Ministers dated 4 August 2000 (hereafter "the Decree"), Italy adopted a measure pursuant to Article 12 of Regulation 258/97 to suspend the commercialisation and use on its territory of T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163).[1782]

[1780] Exhibit EC-163.
[1781] Commission Decision 98/292 (Exhibits CDA-80; ARG-35).
[1782] Italy, President of the Council of Ministers, Precautionary suspension of the commercialisation and utilization of certain transgenic products [Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25

Is the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) an SPS measure?

7.2856 We start with the issue of whether the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is an SPS measure[1783]. In order to make this determination, we need to consider two distinct elements, namely: (1) the purpose of the measure; and (2) the form and nature of the measure.

Purpose of the safeguard measure

7.2857 We first consider the issue of the purpose of the safeguard measure. Before turning to the arguments of the Parties on this issue, we recall that we must determine whether the purpose of the safeguard measure falls within one of the categories of purposes set out in Annex A (1) of the *SPS Agreement*.

7.2858 The **United States** notes that according to the SCF, one of the documents provided by Italy suggested that the herbicide tolerant biotech products Bt-11 maize and T25 maize could have adverse effects on consuming animals. The United States also notes that with respect to the products protected by Bt toxin (Bt-11, MON810 maize, MON809 maize), Italy cited another report which raised the issue of "occupational allerg[ies] to Bt bacterium spores in farmers using Bt pesticides". Based on these justifications, the Italian measure is an SPS measure, given that it is applied "to protect [...] animal life or health" from "contaminants, toxins or disease-causing organisms" in "feedstuffs"; or "to protect human life or health" from "toxins" in "foods".

7.2859 **Canada** notes that the Italian measure was predicated on concerns about the finding of substantial equivalence of T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) to existing foodstuffs pursuant to Article 3(4) of Regulation 258/97. Canada argues that these concerns were triggered by laboratory tests which indicated that the products in question contained proteins derived from genetic modification at levels ranging from 0.04 to 30 parts per million.[1784]

7.2860 **Argentina** argued that the purpose of the safeguard measures may be inferred from the Community legislation under which the bans were adopted, and that the relevant provisions of EC Directive 90/220 and Regulation 258/97 clearly indicate that the purpose of the EC legislation is the "protection of human health and the environment". Since the EC member States have taken their measures explicitly on the basis of this legislation, it can be inferred that the measures were imposed for the purpose of protecting human health or the environment. The safeguard measures are, therefore, SPS measures as defined in the *SPS Agreement*.

7.2861 The **European Communities** argues that the main concerns with regard to T25 maize were, *inter alia*, horizontal gene transfer; antibiotic resistance; effects on non-target organisms; persistence and invasiveness in agricultural and natural habitats; development of resistance; out-crossing; undesirable effects on management practices; biodiversity; monitoring; labelling; co-existence; and human and animal health. With regard to MON810 maize, the concerns related to, *inter alia*, horizontal gene transfer; antibiotic resistance; effects on non-target organisms; toxicity or

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maize] in the national territory, according to Article 12 of Regulation (European Communities) No. 258/97, 4 August 2000, Official Gazette, 8 August 2000, 184 (Exhibit EC-157/At. 1).

[1783] In respect of the safeguard measure imposed by Italy, while the complaints by the United States and Canada refer to four products, *i.e.*, Bt-11 maize (EC-163), MON809 maize, MON810 maize and T25 maize, the complaint by Argentina refers to only three products, *i.e.*, Bt-11 maize (EC-163), MON810 maize and T25 maize.

[1784] Exhibit CDA-86.

allergenicity; development of resistance; biodiversity; monitoring; labelling; co-existence; and human and animal health. Finally, with regard to MON809 maize and Bt-11, the European Communities asserts that the concerns of Italy relate to, *inter alia*, toxicity and allergenicity; biodiversity; monitoring; labelling; co-existence; and human and animal health.

7.2862 The **Panel** notes that the Italian Decree sets out the reasons for Italy's decision to suspend the trade in and use of transgenic foodstuffs.[1785] In the Decree, Italy notes its concerns with respect to the simplified procedure under Regulation 258/97 pursuant to which the products at issue were authorized by the Commission. In particular, Italy points to the ambiguity of the term "substantial equivalence" in Article 3(4) of Regulation 258/97. In a letter addressed to the Commission before the adoption of the safeguard measure, the Italian authorities expressed their concern with the assessment carried out as part of the simplified procedure to evaluate whether a particular product is "substantially equivalent" to existing equivalent foods or food ingredients, in terms of its potential risks to human health or the environment.[1786] Similar concerns were also expressed in a subsequent letter addressed by the Italian Health Minister to the President of the European Commission and the Health and Consumer Protection Commissioner on 5 June 2000.[1787] The Decree further states that since it had been established that residues of modified components remain in the four products, the information available from the simplified procedure was also inadequate with regard to the risks arising from "environmental release" of the GMOs in question, or their products.

7.2863 The reasons set out in the Italian Decree are further based on opinions from the Italian *Consiglio Superiore di Sanità* (hereafter the "Superior Council of Health") and the *Istituto Superiore di Sanità* (hereafter the "Superior Institute of Health"). We note that the opinion of the Superior Council of Health of 16 December 1999 was not submitted to the Panel. However, according to the text of the Decree, the Superior Council of Health calls in its opinion for specific research to be undertaken on the consequences of genetic modifications before novel foodstuffs are placed on the market.[1788]

7.2864 The opinion of the Superior Institute of Health dated 28 July 2000, which is also mentioned in the Italian Decree, addresses the concept of "substantial equivalence" in the context of the product applications.[1789] In particular, the opinion identifies shortcomings in the original applications with respect to the data required to support the establishment of substantial equivalence of the product to its conventional counterpart.[1790] In this respect, the Superior Institute of Health notes that the maize products in question contain levels of protein deriving from the genetic modifications ranging from 0.04 to 30 parts per million and that, therefore, the foodstuff has been permanently affected by the modified elements. Italy observes in the Decree that even though the Superior Institute of Health concluded that there were no apparent risks to the health of humans or livestock from the consumption of derivatives of the biotech products, there were inadequacies in the risk assessment procedures.[1791]

[1785] *See supra*, footnote 1782.

[1786] The Decree refers to a letter from the Italian Health Minister to the European Health and Consumer Protection Commissioner dated 23 December 1999, which is referenced internally as document No. 100/338.7/13126. On the basis of this reference number, the Panel notes that this letter is one of the translated documents submitted by the European Communities in Exhibit EC-157/At. 2_trans.

[1787] Exhibit EC-157/At. 2_trans.

[1788] *See supra*, footnote 1782.

[1789] We note that this opinion from the Superior Institute of Health is one of the translated documents provided by the European Communities in Exhibit EC-158/At. 2_trans.

[1790] *Ibid.*

[1791] *See supra*, footnote 1782.

7.2865 The opinion of the Superior Institute of Health also raises the issue that the herbicide glyphosate is metabolised by the herbicide-tolerant biotech plant to a non-toxic metabolite, but that this metabolite can revert to the parent compound in the gut of test animals. The opinion of the Superior Institute mentions in this context a recently published observation on occupational allergy to Bt bacterium spores in farmers using Bt pesticides.[1792] Furthermore, the Superior Institute of Health addresses in its opinion the issue of antibiotic resistance transfer, but concludes that "[t]he effect on antibiotic resistance of a possible resistant gene transfer from the GMOs to the components of the intestinal flora is minimal compared to the prevalence of antibiotic-resistant genes normally present in the intestinal flora of humans and animals."[1793] Finally, the Institute opinion also indicates that observations regarding the risk of possible "environmental release" of the GMOs in question, or of their products, are unnecessary.

7.2866 Based on the foregoing, we consider that at the time of review by the Panel, Italy applied its safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) to address concerns about:

(1) adverse effects on consumer health due to the possibility that the herbicide glyphosate could revert from its non-toxic metabolite back to its original chemical composition in the gut of humans[1794]; and

(2) adverse effects on the environment arising from "environmental release" of the GM plants in question, or of the products derived therefrom.

7.2867 The European Communities asserts that Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is also applied in view of concerns about labelling. However, this concern asserted by the European Communities was not articulated by Italy in the documents discussed by us above. Furthermore, the European Communities has neither substantiated nor explained its assertion. In the light of this, we are not persuaded that Italy is applying its safeguard measure to address the additional concern identified by the European Communities.

7.2868 Having determined the purposes for which Italy applied its safeguard measure at the time of review by the Panel, we now go on to assess whether these purposes fall within one of the categories of purposes which according to Annex A(1) characterize an SPS measure.

Consumer health

7.2869 We consider first Italy's concerns regarding risks to human health arising from the consumption of food or food ingredients from the relevant GM plants, due to the possibility that the herbicide glyphosate could revert from its non-toxic metabolite back to its original chemical composition in the human gut.

7.2870 With respect to this concern, we recall our analysis in Section VII.C regarding contaminants, specifically our conclusion that the term "contaminants" in Annex A(1)(b) could encompass herbicide residues present in foods, and that these residues may have adverse effects on human life or health, such as allergenic effects. We determined on that basis that measures applied to protect human life or

[1792] *Ibid.*
[1793] *Ibid.*
[1794] This concern was raised generally in Exhibit EC-157/At. 1, and more specifically in Exhibit EC-157/At. 2.

health from risks arising from pesticide residues, and hence contaminants, in GM plants used as or in foods can be considered to fall within the scope of Annex A(1)(b).

7.2871 Consistent with our reasoning above, we consider that Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163), to the extent it is applied to avoid potential risks to human health arising from residues in food of the herbicide glyphosate, which is associated with the cultivation of the aforementioned biotech products and thus linked to these products, falls within the scope of Annex A(1)(b) of the *SPS Agreement*.

Environmental release

7.2872 We now consider the second concern identified by Italy, that the information available from the simplified procedure under which the relevant GMOs were approved was inadequate with regard to risks arising from "environmental release" of the GMOs in question or their products. Although no further explanation of this concern is provided in Italy's Decree, and although the Italian Superior Institute of Health indicated that any observations regarding the risk to the environment of possible "environmental release" were unnecessary, it appears to us that Italy was concerned about potential adverse effects on the environment which might arise from "environmental release" of the GMOs in question or their products.

7.2873 In Section VII.C we found that measures applied to protect animal or plant life or health from risks arising directly or indirectly from the entry, establishment or spread of (i) GM plants *qua* "pests", (ii) cross-breeds with undesired traits resulting from transfer of genetic material from a GM plant or (iii) other animals or plants which become pests as a result of the release of GMOs into the environment, are measures within the scope of Annex A(1)(a). We have also determined in Section VII.C that measures applied to avoid adverse effects of GMOs on the environment other than adverse effects on animal or plant life or health, including on geochemical processes, can be considered as measures applied to prevent "other damage" to the environment resulting from the entry, establishment or spread of a pest and, as such, are covered by Annex A(1)(d).

7.2874 Consistent with our reasoning above, we consider that Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163), to the extent it is applied to address potential risks to the environment arising from the "environmental release" of these GMOs, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

Conclusion with regard to the purpose of the safeguard measure

7.2875 In the light of the above considerations, we conclude that the safeguard measure applied by Italy with respect to T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) qualifies as an SPS measure within the meaning of Annex A(1) as far as its purpose is concerned.

Form and nature of the measure

7.2876 We now turn to the issue of the form and nature of Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163). We start by recalling the arguments of the Parties on this matter.

7.2877 The **United States** argues that the Italian measure is in the form of a "decree", which is one of the types of measures expressly enumerated in Annex A(1) of the *SPS Agreement.*

7.2878 **Canada** argues that the Italian measure is in the form of a "decree", one of the types of measures expressly enumerated in Annex A(1) of the *SPS Agreement*.

7.2879 **Argentina** notes that the measure was taken in the form of a decree, one of the forms explicitly mentioned in Annex A(1).

7.2880 The **Panel** recalls that the second paragraph of Annex A(1) addresses the form and nature of measures which may qualify as SPS measures. In respect of the form of SPS measures, we have indicated earlier in this report that the reference in the second paragraph to "laws, decrees [and] regulations" should not be taken to prescribe a particular legal form and that SPS measures may in principle take many different legal forms. Furthermore, in respect of the nature of SPS measures, we have indicated earlier that the reference in the same paragraph to "requirements" is broad and unqualified. Hence, both an authorization to market a particular product and a ban on the marketing of a particular product may be considered "requirements". The second example would constitute a negative requirement.

7.2881 We note that Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) was implemented through a decree to prohibit commercialization of the products concerned on the Italian territory. We note that Annex A(1) specifically refers to "decrees". We therefore consider that, for the purposes of Annex A(1), the Italian decree is an SPS measure in respect of the form of the measure.

7.2882 In respect of the nature of the Italian measure, we note that the decree prohibits the marketing of T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163). As indicated above, we are of the view that a prohibition on the marketing of a particular product (within a particular territory) may be considered a "requirement" for the purposes of Annex A(1).

7.2883 We therefore conclude that the safeguard measure taken by Italy with respect to T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) qualifies as an SPS measure within the meaning of Annex A(1) as far as its form and nature are concerned.

Conclusion

7.2884 We have now considered Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) in terms of its purpose, its form and its nature. In relation to each of these issues, we have found that Italy's measure satisfies the definition of the term "SPS measure" set out in Annex A(1). In the light of this, we come to the conclusion that the safeguard measure applied by Italy with respect to T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) constitutes an "SPS measure" within the meaning of Annex A(1).

7.2885 At this juncture, we could go on and address the question of whether, in view of its multiple purposes, the Italian safeguard measure could be considered to embody more than one SPS measure. However, neither the Complaining Parties nor the European Communities have argued that to the extent any of the safeguard measures at issue falls to be assessed under the *SPS Agreement*, it should be deemed to constitute more than one SPS measure. In their submissions to the Panel, the Parties treated the relevant safeguard measures as constituting one SPS measure each. In the light of this, like the Parties, we will treat the Italian safeguard measure as constituting one single SPS measure. We will revisit this issue, however, if our disposition of the relevant claims under the *SPS Agreement* (and, where appropriate, any implementing action to be taken in view of our disposition of particular claims) were to depend on, and be affected by, whether we treat the Italian safeguard measure as constituting a single SPS measure or as embodying more than one SPS measure.

Effect on international trade

7.2886 We now turn to the issue of whether Italy's safeguard measure with respect to T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is a measure that affects international trade, and that is therefore subject to the provisions of the *SPS Agreement*. We recall that according to Article 1.1 of the *SPS Agreement*, the *SPS Agreement* applies to all SPS measures which "may, directly or indirectly, affect international trade." Accordingly, for Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) to be subject to the *SPS Agreement*, it must be a measure which may, directly or indirectly, affect international trade. We recall the Parties' arguments on this matter.

7.2887 The **United States** argues that the measure adopted by Italy bans the "commercialization and use" of T25 maize, MON810 maize, MON809 maize and Bt-11 maize, thereby effectively blocking the importation of these products on the Italian territory. The measure as such therefore affects international trade, and meets the second requirement under Article 1.1 of the *SPS Agreement*.

7.2888 **Canada** notes that the measure suspends the commercialization of the maize biotech varieties T25 maize, MON810 maize, MON809 maize and Bt-11. Since the measure effectively blocks market access for the targeted biotech products, it clearly affects international trade.

7.2889 **Argentina** notes that since the safeguard measure prevents access of T25 maize, MON810 maize, MON809 maize and Bt-11 maize to Italy, resulting in the absence of imports of these products, the measure can be said to affect international trade.

7.2890 The **Panel** notes that the arguments of the parties regarding the effects on trade of Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) are the same as their arguments with respect to Austria's safeguard measure on T25 maize. We recall our reasoning and conclusions with respect to Austria's measure on T25 maize in paragraphs 7.2603-7.2609above. Therefore, in view of the fact that Italy's safeguard measure prohibits imports of T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163), we have no difficulty concluding that the safeguard measure applied by Italy is an SPS measure which may affect international trade within the meaning of Article 1.1 of the *SPS Agreement* and, as such, is subject to the provisions of the *SPS Agreement*.

Overall conclusions

7.2891 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize

(EC-163) is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that the Italian safeguard measure on T25 maize, MON810 maize and Bt-11 maize (EC-163) is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(x) Luxembourg – Bt-176 maize

7.2892 We now turn to the safeguard measure applied by Luxembourg on Bt-176 maize. We recall that the application for placing on the market of this product was initially submitted to France.[1795] The product was authorized by the European Commission in 1996[1796], and Luxembourg adopted its safeguard measure to prohibit the sale of Bt-176 maize on its territory pursuant to Article 16 of Directive 90/220 by a Ministerial Order issued in February 1997.[1797]

Is the Luxembourg safeguard measure on Bt-176 maize an SPS measure?

7.2893 We start with the issue of whether Luxembourg's safeguard measure on Bt-176 maize is an SPS measure. In order to make this determination, we need to consider two distinct elements, namely: (1) the purpose of the measure; and (2) the form and nature of the measure.

Purpose of the safeguard measure

7.2894 We first consider the issue of the purpose of the safeguard measure. Before turning to the arguments of the Parties on this issue, we recall that we must determine whether the purpose of the safeguard measure falls within one of the categories of purposes set out in Annex A(1) of the *SPS Agreement*.

7.2895 The **United States** notes that in the preamble of its decision to adopt a safeguard measure concerning Bt-176 maize, Luxembourg refers to potential risks for human health related to the antibiotic resistant gene. The United States argues that the safeguard measure is an SPS measure, as it is applied "to protect human life or health" from "toxins or disease-causing organisms in foods".

7.2896 **Argentina** argues that the purpose of the safeguard measures may be inferred from the Community legislation under which the bans were adopted, and that the relevant provisions of EC Directive 90/220 and Regulation 258/97 clearly indicate that the purpose of the EC legislation is the "protection of human health and the environment". Since the EC member States have taken their measures explicitly on the basis of this legislation, it can be inferred that the measures were imposed for the purpose of protecting human health or the environment. The safeguard measures are, therefore, SPS measures as defined in the *SPS Agreement*.

[1795] C/F/94/11-03.
[1796] Commission Decision 97/98 (Exhibits US-97, ARG-37).
[1797] Luxembourg, Journal Officiel du Grand Duché de Luxembourg, A – No.10, 28 February 1997, p. 618 (Exhibit US-63).

7.2897 The **European Communities** argues that the main reasons for which the measure was adopted and maintained include, *inter alia*, horizontal gene transfer; antibiotic resistance; effects on non-target organisms; toxicity or allergenicity; persistence and invasiveness in agricultural and natural habitats; development of resistance; out-crossing; undesirable effects on management practices; biodiversity; monitoring; labelling; co-existence; and human and animal health.

7.2898 The **Panel** notes that Luxembourg explained the reasons for its safeguard measure in a document submitted to the Commission at the time of notification of its measure (hereafter the "Reasons document").[1798] The document identifies two main concerns for the adoption of the safeguard measure, namely the transfer of the antibiotic (ampicillin)-resistance gene to the bacteria of the intestinal tract of animals, and the development of insect resistance to Bt toxin. With respect to the transfer of the ampicillin-resistance gene, Luxembourg justifies its measure by arguing that although the risk is low, some of the mechanisms operating in such a transfer are still being studied. With respect to the development of insect resistance to Bt toxin, Luxembourg notes that given the risks involved, the commercialization of Bt-176 maize should be made conditional upon the adoption of relevant monitoring programmes.

7.2899 Based on the foregoing, we consider that at the time of review by the Panel, Luxembourg applied its safeguard measure on Bt-176 maize to address concerns about:

(1) the transfer of the *bla*-ampicillin resistance gene to bacteria of the intestine of animals; and

(2) the development of resistance to Bt toxin in insects.

7.2900 The European Communities asserts that Luxembourg's safeguard measure on Bt-176 maize is also applied in view of concerns about labelling, co-existence, out-crossing, and toxicity and allergenicity. The asserted concerns were not articulated by Luxembourg in the Reasons document discussed above. Furthermore, the European Communities has neither substantiated nor explained its assertion. In the light of this, we are not persuaded that Luxembourg is applying its safeguard measure to address these additional concerns identified by the European Communities.

7.2901 Having determined the purposes for which Luxembourg applied its safeguard measure at the time of review by the Panel, we now go on to assess whether these purposes fall within one of the categories of purposes which according to Annex A(1) characterize an SPS measure. To that end, we will consider one by one each of the above-noted purposes of Luxembourg's safeguard measure.

Transfer of the bla-ampicillin resistance gene to bacteria of the intestine of animals

7.2902 We consider first Luxembourg's stated concern regarding the potential transfer of the *bla*-ampicillin resistance gene to bacteria of the intestine of animals due to consumption of Bt-176 maize. The concern identified by Luxembourg with regard to Bt-176 maize is similar to that identified by Austria with regard to its safeguard measures T25 maize and Bt-176 maize. Thus, as in Austria's case, we refer to our discussion in Section VII.C regarding ARMG, and in particular our view that the concern relates to the potential transfer to pathogens of ARMG present in certain GMOs, and the

[1798] The document is entitled "Interdiction provisoire d'importer le maïs génétiquement modifié ayant subi la modification combinée lui assurant les propriétés insecticides conférées par le gène Bt-endotoxine et une meilleure résistance à l'herbicide glufosinate-ammonium – Motivation de la décision luxembourgeoise", communicated to the Commission with the "Arrêté ministériel" on 17 March 1997 (Exhibit EC-158/At. 9).

possible resulting decrease in effectiveness of medical treatments involving specific antibiotics which might pose a risk to the life or health of animals infected with the resistant pathogen.

7.2903 In Section VII.C we found that Annex A(1)(a) covers measures applied to protect animal life or health from risks arising from the entry, establishment or spread of disease-causing organisms which have or might become resistant to antibiotics due to the transfer of ARMG from a GM plant. Similarly, we found that Annex A(1)(a) covers measures applied to protect animal life or health from risks arising from the entry, establishment or spread of diseases due to the reduced effectiveness of antibiotics used to treat the pathogens which have become resistant to these antibiotics through gene transfer. Furthermore, we found that Annex A(1)(b) covers measures applied to protect animal life or health from risks arising indirectly, namely *via* the potential transfer to animals of marker genes conferring resistance to antibiotics used in veterinary medicine, from additives in feedstuffs. We recall in this respect that, in our view, ARMGs can be considered to be additives for the purposes of Annex A(1)(b).

7.2904 Consistent with our reasoning above, we consider that Luxembourg's safeguard measure on Bt-176 maize, to the extent it is applied to avoid risks associated with the transfer of the *bla*-ampicillin resistance gene to bacteria of the intestine of animals, falls within the scope of Annex A(1)(a) and (b) of the *SPS Agreement*.

Development of resistance to Bt toxin in insects

7.2905 Turning now to Luxembourg's stated concern regarding potential risks associated with the development of resistance to Bt toxin in insects, we understand the concern identified by Luxembourg to be that resistance in insects to Bt toxin may develop due to frequent exposure to this pesticide (the Bt toxin) and that the development of high levels of resistance in insect populations might require the application of a pesticide where none was used before, the increased application of a pesticide, or the application of more harmful pesticides to control the resistant populations.

7.2906 We refer to our analysis in Section VII.C regarding the development of pesticide-resistance in insects. We found that resistant target organisms (insects) could be regarded as "pests" within the meaning of Annex A(1), inasmuch as they present a risk to animal, plant or human life or health or result in other damage. We further determine that risks to animal or plant life or health, or other damage to the environment, resulting from a change in pesticide use may be viewed as arising indirectly from the entry, establishment or spread of resistant target organisms *qua* relevant pest. We find that to the extent that a measure seeks to avoid such risks and damage, it can be considered to be covered by Annex A(1)(a) and (d) of the *SPS Agreement*.

7.2907 In view of the above findings, we consider that Luxembourg's safeguard measure on Bt-176 maize, to the extent it is applied to protect from potential risks associated with the development of resistance to Bt toxin in insects due to the cultivation of Bt-176 maize, falls within the scope of Annex A(1)(a) and (d) of the *SPS Agreement*.

Conclusion with regard to the purpose of the safeguard measure

7.2908 In the light of the above considerations, we conclude that the safeguard measure applied by Luxembourg with respect to Bt-176 maize qualifies as an SPS measure within the meaning of Annex A(1) as far as its purpose is concerned.

Form and nature of the measure

7.2909 We now turn to the issue of the form and nature of Luxembourg's safeguard measure on Bt-176 maize. We start by recalling the arguments of the Parties on this matter.

7.2910 The **United States** argues that the measure was enacted by ministerial "decree", a form of measure explicitly mentioned in Annex A(1) of the *SPS Agreement*.

7.2911 **Argentina** notes that the measure was adopted in the form of an "arrêté ministériel", which is defined as a "written decision by an administrative authority". The term "décret" is defined as "a decision by the governmental authority by which the effects are similar to those of laws". According to Argentina, an "arrêté ministériel" is similar in nature to a decree, which is one of the measures listed in Annex A.

7.2912 The **Panel** recalls that the second paragraph of Annex A(1) addresses the form and nature of measures which may qualify as SPS measures. In respect of the form of SPS measures, we have indicated earlier in this report that the reference in the second paragraph to "laws, decrees [and] regulations" should not be taken to prescribe a particular legal form and that SPS measures may in principle take many different legal forms. Furthermore, in respect of the nature of SPS measures, we have indicated earlier that the reference in the same paragraph to "requirements" is broad and unqualified. Hence, both an authorization to market a particular product and a ban on the marketing of a particular product may be considered "requirements". The second example would constitute a negative requirement.

7.2913 We note that Luxembourg's safeguard measure on Bt-176 maize was implemented through an "arrêté ministériel", or a Ministerial Order, to prohibit the commercialization of Bt-176 maize on Luxembourg's territory. Annex A(1) does not specifically refer to "Ministerial Orders". As we have pointed out, this fact alone does not necessarily mean that Luxembourg's safeguard measure is not an SPS measure, since no specific legal form is prescribed. Luxembourg's decision clearly is a measure attributable to Luxembourg's Government. It is also not in dispute that the decision is legally binding. We therefore consider that, for the purposes of Annex A(1), Luxembourg's decision may be assimilated to measures adopted in the form of "laws", "decrees" or "regulations".

7.2914 In respect of the nature of Luxembourg's measure, we note that the decision prohibits the marketing of Bt-176 maize. As indicated above, we are of the view that a prohibition of the marketing of a particular product (within a particular territory) may be considered a "requirement" for the purposes of Annex A(1).

7.2915 We therefore conclude that the safeguard measure taken by Luxembourg with respect to Bt-176 maize qualifies as an SPS measure within the meaning of Annex A(1) as far as its form and nature are concerned.

Conclusion

7.2916 We have now considered Luxembourg's safeguard measure in terms of its purpose, its form and its nature. In relation to each of these issues, we have found that Luxembourg's measure satisfies the definition of the term "SPS measure" set out in Annex A(1). In the light of this, we come to the overall conclusion that the safeguard measure taken by Luxembourg with respect to Bt-176 maize constitutes an "SPS measure" within the meaning of Annex A(1).

7.2917 At this juncture, we could go on and address the question of whether, in view of its multiple purposes, Luxembourg's safeguard measure could be considered to embody more than one SPS measure. However, neither the United States nor Argentina or the European Communities have argued that to the extent any of the safeguard measures at issue falls to be assessed under the *SPS Agreement*, it should be deemed to constitute more than one SPS measure. In their submissions to the Panel, the Parties treated the relevant safeguard measures as constituting one SPS measure each. In the light of this, like the Parties, we will treat Luxembourg's safeguard measure as constituting one single SPS measure. We will revisit this issue, however, if our disposition of the relevant claims under the *SPS Agreement* (and, where appropriate, any implementing action to be taken in view of our disposition of particular claims) were to depend on, and be affected by, whether we treat Luxembourg's safeguard measure as constituting a single SPS measure or as embodying more than one SPS measure.

Effect on international trade

7.2918 We now turn to the issue of whether Luxembourg's safeguard measure on Bt-176 maize is a measure that affects international trade, and that is therefore subject to the provisions of the *SPS Agreement*. We recall that according to Article 1.1 of the *SPS Agreement*, the *SPS Agreement* applies to all SPS measures which "may, directly or indirectly, affect international trade." Accordingly, for Luxembourg's safeguard measure on Bt-176 maize to be subject to the *SPS Agreement*, it must be a measure which may, directly or indirectly, affect international trade. We recall the Parties' arguments on this matter.

7.2919 The **United States** argues that the measure adopted by Luxembourg prohibits the "use and sale" of Bt-176 maize, thereby effectively blocking the importation of the product. The measure as such therefore affects international trade.

7.2920 **Argentina** notes that since the safeguard measure prevents access of Bt-176 maize to Luxembourg's territory, resulting in the absence of imports of this product, the measure can be said to affect international trade.

7.2921 The **Panel** notes that the arguments of the parties regarding the effects on trade of Luxembourg's safeguard measure on Bt-176 maize are the same as their arguments with respect to Austria's safeguard measure on T25 maize. We recall our reasoning and conclusions with respect to Austria's measure on T25 maize in paragraphs 7.2603-7.2609 above. Therefore, in view of the fact that Luxembourg's safeguard measure prohibits imports of Bt-176 maize, we have no difficulty concluding that the safeguard measure applied by Luxembourg is an SPS measure which may affect international trade within the meaning of Article 1.1 of the *SPS Agreement* and, as such, is subject to the provisions of the *SPS Agreement*.

Overall conclusions

7.2922 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that Luxembourg's safeguard measure on Bt-176 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(ii) DS293 (Argentina)

> With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that Luxembourg's safeguard measure on Bt-176 maize is an SPS measure within the meaning of Annex A(1) and Article 1.1 of the *SPS Agreement*.

(b) Preliminary issue: The relationship between Article 5.1 and Article 5.7 of the *SPS Agreement*

7.2923 We have determined above that the *SPS Agreement* is applicable to all safeguard measures which are being challenged. If we were to follow the Complaining Parties' approach, we would now proceed to examine the consistency of the relevant safeguard measures with Article 5.1 of the *SPS Agreement*, which requires that these safeguard measures be based on a risk assessment, as appropriate to the circumstances. The European Communities objects to this manner of proceeding, arguing that the safeguard measures at issue, to the extent they fall within the scope of the *SPS Agreement*, fall to be assessed under Article 5.7 of the *SPS Agreement*, to the exclusion of Article 5.1. Article 5.7 stipulates that in cases where relevant scientific evidence is insufficient, SPS measures may be provisionally adopted on the basis of available pertinent information.

7.2924 The European Communities presents two arguments in support of its contention that the safeguard measures must not be assessed under Article 5.1. *First*, the European Communities argues that the safeguard measures are provisional measures, and that, for this reason, the applicable provision is Article 5.7, and not Article 5.1. *Secondly*, the European Communities argues, more broadly, that the relationship between Article 5.1 and Article 5.7 is one of exclusion, and that Article 5.7 is not an exception to Article 5.1. We will address these arguments below and will then determine whether to assess the safeguard measures under Article 5.1, as requested by the Complaining Parties.

(i) "Provisionally adopted" SPS measures

7.2925 It is useful to begin our consideration of the EC argument concerning "provisionally adopted" SPS measures by setting out the text of relevant provisions.

7.2926 Article 2.2 provides:

> "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5."

7.2927 Article 5.1 provides:

> "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations."

7.2928 Article 5.7 provides:

> "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available

> pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

7.2929 In relation to Article 5.7, the Appellate Body has found that there are four requirements which a Member must meet in order to adopt and maintain a provisional SPS measure as contemplated in Article 5.7. These requirements are:[1799]

(a) the measure is imposed in respect of a situation where "relevant scientific evidence is insufficient";

(b) the measure is adopted "on the basis of available pertinent information";

(c) the Member which adopted the measure "seek[s] to obtain the additional information necessary for a more objective assessment of risk"; and

(d) the Member which adopted the measure "review[s] the … measure accordingly within a reasonable period of time".

7.2930 The **European Communities** argues that Article 5.7 contains specific rules regarding provisional measures, and that it is therefore by reference to these rules, not the rules in Article 5.1, that the safeguard measures must be assessed. Regarding Article 5.7, the European Communities submits that it applies only to provisional measures. In the European Communities' view, if, objectively, an SPS measure is "provisionally adopted", it falls within the scope of Article 5.7. The European Communities considers that the Appellate Body in *Japan – Apples* confirmed this when it stated that "[w]hen a panel reviews a measure claimed by a Member to be provisional, that panel must assess whether 'relevant scientific evidence is insufficient'".[1800] In the European Communities' view, this statement indicates that the provisionality is the "demarcation line" between Article 5.1 and Article 5.7.

7.2931 The European Communities considers that Article 5.1 also supports its view. According to the European Communities, Article 5.1 concerns risk assessments to be carried out for SPS measures other than provisional SPS measures. The European Communities contends that for provisional SPS measures the first sentence of Article 5.7 requires an "assessment", but not a "risk assessment" as that term is defined in the *SPS Agreement*. The European Communities points out in this connection that the second sentence of Article 5.7 refers to a "more objective assessment", which in the European Communities' view means an assessment that is more objective than that to be carried out on the basis of the first sentence of Article 5.7. Thus, the European Communities maintains that the first sentence of Article 5.7 implies the need for an "assessment", but one which is different from the risk assessment envisaged in Article 5.1.

7.2932 The European Communities further submits that its view that provisional measures are not subject to Article 5.1 does not imply that provisional measures are not subject to a full set of controls under the *SPS Agreement*. Rather, in the European Communities' view, there are two "parallel universes" in the *SPS Agreement*, one for definitive measures and another for provisional measures. According to the European Communities, provisional measures must comply with the requirements of

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[1799] Appellate Body Reports, *Japan – Agricultural Products II*, para. 89; *Japan – Apples*, para. 176.
[1800] Appellate Body Report, *Japan – Apples*, para. 179.

Article 5.7, as well as with those of Articles 2.1[1801], 2.3[1802] and 2.4[1803] of the *SPS Agreement*. The European Communities considers that these provisions contain rules and obligations that are analogous to those set out in Articles 2.2 and 5.1 to 5.6 for definitive measures.

7.2933 Having regard to the present dispute, the European Communities asserts that all of the safeguard measures at issue are provisional measures within the meaning of Article 5.7. The European Communities notes in this regard that the text of the applicable EC legislation provides that member States may "provisionally restrict" (Article 16 of Directive 90/220) or "temporarily restrict" (Article 12 of Regulation 258/97) the use of a biotech product which has received EC-wide marketing approval. The European Communities further argues that the European Court of Justice has confirmed that measures adopted based on the aforementioned legislation are temporary measures.[1804] Finally, the European Communities submits that the provisional nature of the safeguard measures is also reflected in the text of these measures as well as the national laws on which these measures are based.

7.2934 The **United States** argues that in order to be covered by Article 5.7, a measure must meet each of the criteria set out in that paragraph. The mere label of a measure as "provisional" is not sufficient to bring it within the scope of Article 5.7. Regarding the safeguard measures at issue, the United States also notes that none of these measures satisfies the four criteria set out in Article 5.7. Specifically, the evidence is sufficient to perform a risk assessment, because the EC itself has conducted positive risk assessments for each product subject to a member State measure. Secondly, the EC's own scientific committees have confirmed that the member State measures are not based on "available pertinent information." Third, there is no information in the record that the Member States have sought to perform risk assessments that would support their bans. Fourth, the EC argument that "measures are constantly subject to review"[1805] does not meet the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption.

7.2935 **Canada** argues that neither in the text of the *SPS Agreement* nor in relevant jurisprudence is there a basis for the European Communities' bifurcation of the SPS regime on the basis of whether measures are "definitive" or "provisional". Neither in *Japan – Agricultural Products II* nor in *Japan – Apples* did the panels or the Appellate Body characterize provisionality as an *a priori* condition to be met for Article 5.7 to apply. In Canada's view, this strongly suggests that, for Article 5.7 to apply, it is not relevant whether the measure in question is expressed in provisional terms. What matters,

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[1801] Article 2.1 provides:

Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.

[1802] Article 2.3 provides:

Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.

[1803] Article 2.4 provides:

Sanitary or phytosanitary measures which conform to the relevant provisions of this Agreement shall be presumed to be in accordance with the obligations of the Members under the provisions of GATT 1994 which relate to the use of sanitary or phytosanitary measures, in particular the provisions of Article XX(b).

[1804] The European Communities refers to Case C-236/01, *Monsanto Agricoltura Italia SpA and Others v. Presidenza del Consiglio dei Ministri and Others*, judgement of 9 September 2003, para. 109.

[1805] EC replies to Panel questions, para. 324.

according to Canada, is whether there is evidence to demonstrate that each of the conditions set out in Article 5.7 has been fulfilled. Canada submits in this regard that the first condition, which concerns the sufficiency of relevant scientific evidence, is qualitatively different from the other conditions. Canada considers that the first condition represents a logical threshold – a textual bridge – between Article 2.2 and Article 5.7.

7.2936 Regarding the present dispute, Canada notes that it is true that the EC legislation indicates that safeguard measures are meant to be temporary. Canada submits, however, that when one considers the five safeguard measures challenged by Canada, the provisional quality of safeguard measures is not obvious, as none of the five measures in question has been in place less than 45 months, and some have been in place for more than five years.

7.2937 **Argentina** argues that Article 5.7 is not applicable to any measure which is labelled or deemed "provisional". Rather, Article 5.7 establishes a specific requirement that a Member must meet if it wishes provisionally to adopt an SPS measure: relevant scientific evidence must be insufficient. Argentina considers, therefore, that for a measure to be covered by Article 5.7, what matters is not whether that measure is designed to be provisional or definitive, but whether there is sufficient relevant scientific evidence. Only in such cases may a Member provisionally adopt an SPS measure on the basis of available pertinent information.

7.2938 The **European Communities** responds that the sufficiency or insufficiency of scientific evidence cannot be the "demarcation line" between Article 5.1 and Article 5.7 in view of the statement by the Appellate Body in *Japan – Agricultural Products II* that insufficiency of relevant scientific evidence is one of four requirements set out in Article 5.7 and that "[t]hese four requirements are clearly cumulative in nature and are equally important for the purposes of determining consistency with this provision".[1806] According to the European Communities, this statement confirms that none of the four requirements has a special role to play in the demarcation of the respective scopes of Articles 5.1 and 5.7, and that these requirements are relevant to the question of consistency with Article 5.7, not to the question of the "demarcation line" to be drawn between Articles 5.1 and 5.7.

7.2939 The **Panel** recalls the European Communities' argument that, for the purposes of the Panel's analysis of the safeguard measures, the relevant provision is Article 5.7 rather than Article 5.1. We first turn to examine this argument in the light of Article 5.7 itself. The first sentence of Article 5.7 provides in relevant part that "[i]n cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information". The first sentence follows a classic "if – then" logic: if a certain condition is met (*in casu*, insufficiency of relevant scientific evidence), a particular right is conferred (*in casu*, the right provisionally to adopt an SPS measure based on available pertinent information). Thus, it is clear that Article 5.7 is applicable whenever the relevant condition is met, that is to say, in every case where relevant scientific evidence is insufficient.[1807] The provisional adoption of an SPS measure is not a condition for the applicability of Article 5.7. Rather, the provisional adoption of an SPS measure is permitted by the first sentence of Article 5.7.

[1806] Appellate Body Report, *Japan – Agricultural Products II*, para. 89

[1807] When we refer to the "applicability of Article 5.7", we address the issue of whether or not the right conferred by the first sentence of Article 5.7 is, in principle, available to a Member. In a specific case, a Member must, of course, satisfy the various requirements set forth in Article 5.7 if it wishes to benefit from the right conferred by Article 5.7.

7.2940 If the provisional adoption of an SPS measure had been intended as a condition for the applicability of Article 5.7, the first sentence of Article 5.7 would, in our view, have opened with a different phrase, such as "In cases where a Member provisionally adopts an SPS measure […]". Also, we note that in *Japan – Apples* the Appellate Body stated that "the application of Article 5.7 is triggered not by the existence of scientific uncertainty, but by the insufficiency of scientific evidence".[1808] The Appellate Body made no mention of any additional "triggering factors".

7.2941 The European Communities draws our attention to the statement by the Appellate Body in *Japan – Apples* that "[w]hen a panel reviews a measure claimed by a Member to be provisional, that panel must assess whether 'relevant scientific evidence is insufficient'".[1809] According to the European Communities, this statement indicates that the provisional nature of a measure is what determines whether a measure falls within the scope of Article 5.7. We do not agree. The European Communities' interpretation is at odds with the aforementioned statement by the Appellate Body in *Japan – Apples* that "the application of Article 5.7 is triggered [...] by the insufficiency of scientific evidence". Reading the two statements by the Appellate Body harmoniously, we think that the statement identified by the European Communities must be understood as referring to a situation where a measure is claimed to be a provisional measure within the meaning of Article 5.7. In fact, the Appellate Body in *Japan – Apples* pointed out that "Japan claimed, in the alternative, that its measure is a provisional measure consistent with Article 5.7".[1810] In any event, we note that the Appellate Body in *Japan – Apples* did not begin its Article 5.7 analysis by examining whether the measure at issue was provisional, as claimed by Japan.

7.2942 The European Communities identifies another statement by the Appellate Body which it considers supports its position. In *Japan – Agricultural Products II*, the Appellate Body stated that "[the] four requirements [contained in Article 5.7] are clearly cumulative in nature and are equally important for the purposes of determining consistency with this provision".[1811] The European Communities submits that this statement confirms that the requirement that relevant scientific evidence be insufficient cannot be accorded a special role in the demarcation of the respective scopes of Articles 5.1 and 5.7. Here again, we consider that the European Communities' argument is at odds with the subsequent statement by the Appellate Body in *Japan – Apples* that "the application of Article 5.7 is triggered [...] by the insufficiency of scientific evidence". Moreover, we note that in *Japan – Agricultural Products II* the Appellate Body was addressing the issue of *consistency* with Article 5.7, not *applicability* of Article 5.7. It is correct to say that for the specific purposes of determining *consistency* with Article 5.7, all four requirements are "equally important", for if any one of these requirements is not met, a Member is not acting consistently with the provisions of Article 5.7.[1812]

7.2943 The European Communities considers that its view regarding Article 5.7 is consistent with the provisions of Article 5.1. In the European Communities' view, Article 5.1 prescribes risk assessment only for SPS measures other than provisionally adopted SPS measures. Article 5.1 requires Members to "ensure that their [SPS] measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health". We note, however, that Article 5.1 does not qualify the term "SPS measures". Thus, the text of Article 5.1 provides no basis for the EC argument that Article 5.1 prescribes risk assessment only for SPS measures other than provisionally adopted SPS measures.

[1808] Appellate Body Report, *Japan – Apples*, para. 184.
[1809] Appellate Body Report, *Japan – Apples*, para. 179.
[1810] *Ibid.*, para. 170.
[1811] Appellate Body Report, *Japan – Agricultural Products II*, para. 89
[1812] We also address this issue below at paras. 7.3216-7.3220.

7.2944 Notwithstanding the lack of textual basis in Article 5.1, the European Communities argues that provisionally adopted SPS measures should not be considered to be subject to Article 5.1 because the first sentence of Article 5.7 also requires Members to carry out an "assessment". According to the European Communities, the "assessment" required by the first sentence of Article 5.7 is different from a "risk assessment" as that term is defined in the *SPS Agreement*.[1813] Even assuming the European Communities' argument regarding the required "assessment" were correct[1814], it is apparent from the text of Article 5.7 that such an "assessment" would only be necessary for SPS measures which were provisionally adopted in respect of situations where "relevant scientific evidence [was] insufficient". Article 5.7 is not applicable to SPS measures which were provisionally adopted in respect of situations where relevant scientific evidence was *not* insufficient. Therefore, even accepting the EC argument, Article 5.7 would not assist the European Communities in establishing that Article 5.1 does not apply to any provisionally adopted SPS measures, as first it would need to be established that these measures were adopted in respect of situations where relevant scientific evidence was insufficient.

7.2945 In response to a question from the Panel, the European Communities stated that the provisions of Article 2.2 confirm that provisionality is the "demarcation line" between Articles 5.1 and 5.7. The European Communities points out that Article 2.2 refers to SPS measures which are "maintained" while Article 5.7 refers to SPS measures which have been "provisionally adopted". The European Communities concludes from this that definitive measures fall to be assessed under Articles 2.2 and 5.1 while provisional measures fall to be assessed under Article 5.7. In our view, the verb "maintain" in Article 2.2 does not support the conclusion that only definitive measures are subject to Article 2.2. It is not apparent to us why a provisional measure could not likewise be "maintained" within the meaning of Article 2.2. The fact that Article 5.7, which is part of the context of Article 2.2, refers to SPS measures which have been "provisionally adopted", and that Article 2.2 does not explicitly refer to such measures, does not imply that any measure which has been "provisionally adopted" is excluded, *a priori*, from the scope of application of Article 2.2. Indeed, by its terms, Article 2.2 is applicable to "any" SPS measures.

7.2946 The European Communities advances another argument based on Article 2.2. The European Communities argues that the sufficiency or insufficiency of scientific evidence cannot have been intended as a "demarcation line" between Articles 2.2 and 5.1, on the one hand, and Article 5.7, on the other hand, because the word "sufficient" has different meanings in the context of Article 2.2 and Article 5.7. We see no force in this argument. Our view that Article 5.7 is applicable in every case where relevant scientific evidence is insufficient is based on the clause "[i]n cases where relevant scientific evidence is insufficient" in Article 5.7. The Appellate Body in *Japan – Apples* has clarified the meaning of the word "insufficient" as it appears in Article 5.7.[1815]

7.2947 The European Communities also puts forward the argument that Articles 2.1, 2.3 and 2.4 of the *SPS Agreement* serve to demonstrate that there are two "parallel universes" in the *SPS Agreement*, one for definitive measures and another for provisional measures. While we have no difficulty accepting that the "basic rights and obligations" set out in these provisions are in principle applicable to provisional SPS measures, we see nothing in the text of these provisions which would suggest that they are applicable exclusively to provisional SPS measures. In our view, the provisions in question are applicable also to definitive SPS measures. We note in this regard that Article 2 is captioned "Basic Rights and Obligations". In the light of this, we do not think that these provisions serve to

[1813] To recall, the second sentence of Article 5.7 refers to "a *more objective* assessment of risk" (emphasis added).

[1814] We further address this issue below at para. 7.2992.

[1815] Appellate Body Report, *Japan – Apples*, para. 179.

demonstrate that the *SPS Agreement* sets out separate and special regimes – "parallel universes", in the European Communities' parlance – for provisional SPS measures and for definitive SPS measures.

7.2948 For all these reasons, we are unable to accept the European Communities' argument that since the safeguard measures at issue are provisionally adopted SPS measures, they fall to be assessed under Article 5.7, to the exclusion of Article 5.1. The safeguard measures may or may not have been provisionally adopted. If they were provisionally adopted, this fact alone would not exclude the applicability of Article 5.1.

(ii) Article 5.7 of the SPS Agreement – right or exception from the "general obligation" under Article 5.1?

7.2949 We now examine the second argument put forward by the European Communities in support of its view that the safeguard measures must not be assessed under Article 5.1. To recall, the second argument is that the relationship between Article 5.1 and Article 5.7 is one of exclusion, not exception. In developing its argument, the European Communities made reference to Articles 3.1 and 3.3 of the *SPS Agreement*. The text of these provisions is set out below.

7.2950 Article 3.1 provides:

> "To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3."

7.2951 Article 3.3 provides:

> "Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5."[1816]

7.2952 The **European Communities** argues that the relationship between Articles 3.1 and 3.3 of the *SPS Agreement* is one of exclusion, not exception.[1817] The European Communities notes that Article 2.2 contains wording substantially identical to that of Article 3.1. According to the European Communities, it necessarily follows that the relationship between Article 2.2 and Article 5.7 is also one of exclusion. In other words, Article 2.2 excludes from its scope of application the kinds of situations covered by Article 5.7. The European Communities further notes that in *EC – Hormones* the Appellate Body stressed that Article 2.2 and Article 5.1 must be constantly read together.[1818] The European Communities deduces from this that the relationship between Article 5.1 and Article 5.7 must, equally, be one of exclusion. Thus, in the European Communities' view, Article 5.7 is an autonomous right, and not an exception to Articles 2.2 and 5.1.

[1816] (*original footnote*) For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.

[1817] The European Communities refers to Appellate Body Report, *EC – Hormones*, para. 104.

[1818] The European Communities refers to Appellate Body Report, *EC – Hormones*, para. 180.

7.2953 In support of its view that Article 5.7 is not an exception to Article 2.2, the European Communities further argues that the text of Article 5.7 is incorporated by reference into the text of Article 2.2. The European Communities considers that Article 5.7 is therefore part of Article 2, which is entitled "Basic Rights and Obligations". In the European Communities' view, Article 5.7 thus sets out basic rights and obligations of equivalent status to the basic rights and obligations set out in Article 2.

7.2954 The European Communities notes that none of the Complaining Parties has presented a claim of violation under Article 5.7. The European Communities submits that in view of this circumstance, and given the fact that, in its view, the safeguard measures are provisional measures falling within the scope of application of Article 5.7, it is irrelevant whether the safeguard measures meet the four requirements of Article 5.7. By bringing a claim of inconsistency with Article 5.1, the European Communities maintains, the Complaining Parties have simply invoked the wrong provision. The European Communities considers that there is therefore no basis for the Panel to conclude that the safeguard measures are inconsistent with Article 5.1.

7.2955 Moreover, the European Communities considers that if the Panel nonetheless were to determine that the safeguard measures did not meet one of the requirements of Article 5.7, *e.g.*, because there was sufficient scientific evidence, the Panel would need to conclude that the provisional measure in question is inconsistent with Article 5.7, and not that Article 2.2 or Article 5.1 becomes the relevant applicable provision. The European Communities contends that this has been confirmed by the Appellate Body in *Japan – Agricultural Products II* when it stated that "[w]henever one of [the] requirements [of Article 5.7] is not met, the measure at issue is inconsistent with Article 5.7".[1819]

7.2956 The **United States** argues that Article 5.7 does not provide a basis for a claim of an alleged breach of a WTO obligation, but acts as a defence to shield measures that would otherwise violate Articles 2.2 and 5.1. The United States submits that Article 5.7 provides an exception to Article 2.2 as well as Article 5.1, as these two articles "should constantly be read together".[1820] The United States points out that in *Japan – Agricultural Products II* and *Japan – Apples* the responding party invoked Article 5.7 to defend the challenged measure. The complaining party did not assert Article 5.7 as an independent claim of violation in either dispute, nor did the panels in these disputes suggest that the complaining party should have invoked Article 5.7.

7.2957 With regard to the issue of burden of proof, the United States is not arguing in this dispute that the responding party has the burden of proof to show that Article 5.7 applies to a particular SPS measure. The United States considers that in the present dispute it has established that the member State safeguard measures are inconsistent with Articles 2.2 and 5.1. In the United States' view, this necessarily means that Article 5.7 does not apply. Moreover, by showing that each of the products subject to a member State safeguard measure was subject to positive risk assessments by the European Communities' own scientists, the United States has met any burden of proof to show that scientific evidence was not "insufficient" and that Article 5.7 does not apply.

7.2958 **Canada** argues that equating the relationship between Articles 2.2 and 5.1, and Article 5.7, with the relationship between Articles 3.1 and 3.3 is inappropriate because the purposes, and therefore the relationships between these articles, respectively, are quite different. Articles 3.1 and 3.3 represent "separate but equal" tracks to follow in adopting an SPS measure. A Member can adopt a measure that is based on a relevant international standard, where such a standard exists. Alternatively, a Member can adopt a measure in accordance with the provisions of Article 3.3, where

[1819] Appellate Body Report, *Japan – Agricultural Products II*, para. 89 (emphasis omitted).
[1820] The United States refers to Appellate Body Report, *EC – Hormones*, para. 180.

it seeks a level of protection that is higher than the level of protection implied by the international standard. Article 3.3 is not merely a qualified exemption from the basic obligation in Article 3.1. It is the expression of the autonomous right of Members to establish their own appropriate levels of protection.

7.2959 Canada argues that in contrast, Articles 2.2 and 5.7 are not "separate but equal" tracks for Members to follow. Canada submits that Article 5.7 does not exist as an option that can be freely chosen by the Member concerned in place of Articles 2.2 and 5.1. Canada points out that unlike Article 3.3, Article 5.7 is a temporary solution. Ultimately, Article 5.7 must give way to the basic obligation in Article 2.2. Canada further argues that the application of Article 5.7 logically only arises where it has been determined that a measure is maintained without sufficient scientific evidence, which, unless justified under Article 5.7, would amount to a violation of Article 2.2. For these reasons, Canada considers that Article 5.7 operates as an exception to Articles 2.2 and 5.1. Therefore, Canada maintains, it is only if a challenged measure is found by a panel to be inconsistent with Article 2.2 and/or Article 5.1 that Article 5.7 comes into play, provided the importing Member invokes the provision as a source of justification for maintaining the challenged measure. Canada considers that it would be the Member invoking Article 5.7 that would have the initial burden of demonstrating a prima facie case.

7.2960 **Argentina** argues that Article 5.7 operates as a defence for measures which would otherwise be inconsistent with Articles 2.2 and 5.1. Argentina considers that when a Member meets the conditions set out in Article 5.7, it is entitled to adopt and maintain a measure under Article 5.7, and to depart from the general conditions set out in Article 2.2. In Argentina's view, a failure to meet the first condition of Article 5.7 – namely, that relevant scientific evidence must be insufficient – does not lead to an infringement of Article 5.7. Rather, it would prevent the relevant Member from departing from the general conditions set out in Article 2.2. According to Argentina, it is up to the responding party to invoke a defence under Article 5.7 and to meet the burden of establishing that defence.

7.2961 The **Panel** finds it appropriate to begin its examination of the relationship between Article 5.1 and Article 5.7 by examining the relationship between Article 2.2 and Article 5.7. It should be noted in this regard that Article 5.1 and Article 2.2 should "constantly be read together"[1821], and that Article 2.2 is an important part of the context of Article 5.1.

Relationship between Article 2.2 and Article 5.7

7.2962 The European Communities argues that Article 5.7 is not an exception to Article 2.2 in the sense that it could be invoked as an affirmative defence to a claim of violation under Article 2.2. Rather, the European Communities maintains, Article 5.7 establishes an autonomous right of the importing Member. The European Communities further submits that in cases where Article 5.7 is applicable, it is for the complaining party to establish that the importing Member has acted inconsistently with Article 5.7.

7.2963 In *EC – Tariff Preferences*, the Appellate Body was called on to determine whether the Enabling Clause constituted a right or an exception to Article I:1 of the GATT 1994. In that context, the Appellate Body made the following statement:

> "We recall that the Appellate Body has addressed the allocation of the burden of proof in similar situations. In cases where one provision permits, in certain circumstances, behaviour that would otherwise be inconsistent with an obligation in

[1821] Appellate Body Report, *EC – Hormones*, para. 180.

> another provision, and one of the two provisions refers to the other provision, the Appellate Body has found that the complaining party bears the burden of establishing that a challenged measure is inconsistent with the provision permitting particular behaviour *only* where one of the provisions suggests that the obligation is not applicable to the said measure. Otherwise, the permissive provision has been characterized as an exception, or defence, and the onus of invoking it and proving the consistency of the measure with its requirements has been placed on the responding party. However, this distinction may not always be evident or readily applicable."[1822]

7.2964 As an illustration of a case of two WTO provisions where the "permissive provision" was characterized by the Appellate Body as a right rather than an exception, the Appellate Body cited a paragraph in its report in *EC – Hormones*.[1823] The paragraph in question addresses the relationship between Article 3.1 and Article 3.3 of the *SPS Agreement*. The paragraph states in relevant part that:

> "Article 3.1 of the *SPS Agreement* simply excludes from its scope of application the kinds of situations covered by Article 3.3 of that Agreement, that is, where a Member has projected for itself a higher level of sanitary protection than would be achieved by a measure based on an international standard. Article 3.3 recognizes the autonomous right of a Member to establish such higher level of protection, provided that that Member complies with certain requirements in promulgating SPS measures to achieve that level. The general rule in a dispute settlement proceeding requiring a complaining party to establish a *prima facie* case of inconsistency with a provision of the *SPS Agreement* before the burden of showing consistency with that provision is taken on by the defending party, is *not* avoided by simply describing that same provision as an 'exception'."[1824]

7.2965 Later in the same report, the Appellate Body found that:

> "[T]his right of a Member to establish its own level of sanitary protection under Article 3.3 of the *SPS Agreement* is an autonomous right and *not* an 'exception' from a 'general obligation' under Article 3.1."[1825]

7.2966 Returning to the general test enunciated by the Appellate Body in *EC – Tariff Preferences*, we note that, indeed, the relationship between Article 3.1 and Article 3.3 may be described as one where "one provision [namely, Article 3.3] permits, in certain circumstances, behaviour that would otherwise be inconsistent with an obligation in another provision [namely, the obligation in Article 3.1 to base SPS measures on international standards], [where] one of the two provisions [namely, Article 3.1] refers to the other provision, [and] where one of the provisions [namely, Article 3.1] suggests that the obligation [in Article 3.1 to base SPS measures on international standards] is not applicable" to measures falling within the scope of Article 3.3. With regard to this last element, we note that Article 3.1 contains the clause "except as otherwise provided for in this Agreement, and in particular in paragraph 3".

7.2967 The European Communities submits that we should conceive of the relationship between Article 2.2 and Article 5.7 in the same way that the Appellate Body conceived of the relationship between Article 3.1 and Article 3.3. The European Communities notes in this regard that there are

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[1822] Appellate Body Report, *EC – Tariff Preferences*, para. 88 (footnotes omitted).
[1823] *Ibid.*, footnote 189.
[1824] Appellate Body Report, *EC – Hormones*, para. 104.
[1825] *Ibid.*, para. 172.

significant textual similarities between Article 3.1 and Article 2.2. Indeed, whereas Article 3.1 contains the clause "except as otherwise provided for in this Agreement, and in particular in paragraph 3", Article 2.2 contains the closely similar clause "except as provided for in paragraph 7 of Article 5". It is clear from the Appellate Body's statement in *EC – Tariff Preferences* that in the context of Article 3.1, the relevant clause played an important part in the Appellate Body's determination of whether Article 3.3 constituted a right or an exception. As a result, we agree with the European Communities that we may in principle attach similar weight to the corresponding clause in Article 2.2, provided there is also a correspondence of the other elements highlighted by the Appellate Body in its statement in *EC – Tariff Preferences*.

7.2968 Evaluating the relationship between Article 2.2 and Article 5.7 in the light of the general test provided by the Appellate Body in *EC – Tariff Preferences*, we consider that the relationship in question is one where "one provision [namely, Article 5.7] permits, in certain circumstances, behaviour [namely, the provisional adoption of SPS measures in cases where scientific evidence is insufficient on the basis of available pertinent information] that would otherwise be inconsistent with an obligation in another provision [namely, the obligation in Article 2.2 not to maintain SPS measure without sufficient scientific evidence], [where] one of the two provisions [namely, Article 2.2] refers to the other provision, [and] where one of the provisions [namely, Article 2.2, and in particular the clause "except as provided for in paragraph 7 of Article 5"] suggests that the obligation [in Article 2.2 not to maintain SPS measure without sufficient scientific evidence] is not applicable" to measures falling within the scope of Article 5.7.

7.2969 Thus, we find the general test provided by the Appellate Body in *EC – Tariff Preferences* to be applicable, and application of that test leads us to the conclusion that Article 5.7 should be characterized as a right and not an exception from a general obligation under Article 2.2.[1826] In other words, we consider that in the same way that "Article 3.1 of the *SPS Agreement* [...] excludes from its scope of application the kinds of situations covered by Article 3.3 of that Agreement"[1827], Article 2.2 excludes from its scope of application the kinds of situations covered by Article 5.7. As we will explain further below, characterizing Article 5.7 as a right rather than as an exception has implications for the allocation of the burden of proof.

7.2970 We have said that Article 2.2 excludes from its scope of application the kinds of situations covered by Article 5.7. We recall in this connection that Article 2.2 contains three distinct obligations. It is therefore important to note that the Appellate Body did not say that Article 5.7 operates as a qualified exemption from the first and second obligations in Article 2.2, *i.e.*, the obligation to ensure that SPS measures are applied only to the extent necessary to protect human, animal or plant life or health, and the obligation to ensure that they are based on scientific principles. In the present case, it is not necessary, however, to examine the legal issue of whether the phrase "except as provided for in paragraph 7 of Article 5" relates only to the third obligation contained in Article 2.2 – the obligation not to maintain SPS measures without sufficient scientific evidence – or whether it relates to all three obligations laid down in Article 2.2.

[1826] Regarding our use of the term "right", we note that the Appellate Body's test in *EC – Tariff Preferences* does not provide a term to characterize the permissive provision in the kind of relationship we found to exist between Article 2.2 and Article 5.7. However, as we have noted, the Appellate Body referred to the relationship between Articles 3.1 and 3.3 as an illustration of the relevant kind of relationship. We have also pointed out that in *EC – Hormones*, the Appellate Body referred to the permissive provision, Article 3.3, as an "autonomous right", noting also that Article 3.3 does not constitute an exception from a general obligation under Article 3.1.

[1827] Appellate Body Report, *EC – Hormones*, para. 104.

7.2971 We note that Article 5.7 makes clear that SPS measures adopted and maintained pursuant to Article 5.7 are meant to be temporary in nature.[1828] In our view, the fact that Article 2.2 only temporarily excludes from its scope of application the kinds of situations covered by Article 5.7 does not detract from our characterization of Article 5.7 as a right. Where a right is conferred, it does not cease to be a right merely because it has been conferred on a temporary basis. Moreover, there is nothing unusual about the temporary inapplicability of a WTO provision. One need look no further than Article 14 of the *SPS Agreement*, which provides for specific transitional periods for least developed country Members and other developing country Members. During the applicable transitional periods, these Members are entitled to the non-application of some or all other provisions of the *SPS Agreement.*

7.2972 The view that Article 5.7 is not an exception in the nature of an affirmative defence is also consistent with the statement by the Appellate Body in *Japan – Agricultural Products II* that "Article 5.7 operates as a *qualified* exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence".[1829] Had the Appellate Body been of the view that Article 5.7 operates as an exception under which an importing Member could justify an inconsistency with an applicable obligation, it would, in our view, have been more natural and appropriate to use the term "exception" rather than the term "exemption", as the term "exemption" connotes freedom from, and hence inapplicability of, an obligation.[1830]

7.2973 We stress that Article 5.7 does not establish an absolute or unqualified right. In *Japan – Agricultural Products II*, the Appellate Body made clear that there are four cumulative requirements in Article 5.7 which must be met in order for a Member to adopt and maintain a provisional SPS measure consistently with Article 5.7.[1831] We think that these requirements are the reason why the Appellate Body emphasised that "Article 5.7 operates as a *qualified* exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence".[1832]

7.2974 In concrete terms, characterizing Article 5.7 as a qualified right rather than an exception means that if a challenged SPS measure was adopted and is maintained consistently with the four cumulative requirements of Article 5.7, the situation is "as provided for in paragraph 7 of Article 5" (Article 2.2), and the obligation in Article 2.2 not to maintain SPS measures without sufficient scientific evidence is not applicable to the challenged measure. Conversely, if a challenged SPS measure is not consistent with one of the four requirements of Article 5.7, the situation is not "as provided for in paragraph 7 of Article 5" (Article 2.2), and the relevant obligation in Article 2.2 is applicable to the challenged measure, provided there are no other elements which render Article 2.2 inapplicable.

7.2975 The European Communities draws our attention to the statement by the Appellate Body in *Japan – Agricultural Products II* that "[w]henever one of [the] requirements [of Article 5.7] is not

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[1828] The first sentence of Article 5.7 refers to SPS measures being "provisionally adopted" on the basis of available pertinent information, and the Appellate Body has noted that the requirements set out in the second sentence of Article 5.7 highlight the provisional nature of measures adopted pursuant to Article 5.7. Appellate Body Report, *Japan – Apples*, footnote 318.

[1829] Appellate Body Report, *Japan – Agricultural Products II*, para. 80 (emphasis in original).

[1830] The adjective "exempt" means "free from an obligation or liability imposed on others". *The Concise Oxford Dictionary*, 10th ed, J. Pearsall (ed.) (Clarendon Press, 1999), p. 498.

[1831] Appellate Body Report, *Japan – Agricultural Products II*, para. 89. *See also* Appellate Body Report, *Japan – Apples*, para. 176. We identify the four cumulative requirements contained in Article 5.7 above at para. 2.

[1832] Appellate Body Report, *Japan – Agricultural Products II*, para. 80 (emphasis in original).

met, the measure at issue is inconsistent with Article 5.7".[1833] The European Communities argues that in view of this statement, if a challenged SPS measure is not consistent with one of the four requirements of Article 5.7, the Panel should find that the challenged measure violates Article 5.7, and not that the relevant obligation in Article 2.2 is applicable to the measure in question. We do not consider that the aforementioned statement by the Appellate Body supports the European Communities' argument. To say, as the Appellate Body did, that a measure is "inconsistent" with Article 5.7 when the relevant requirements are not satisfied is not tantamount to saying that Article 2.2 is inapplicable to that measure. Indeed, as we have pointed out, the Appellate Body in *Japan – Agricultural Products II* also stated that Article 5.7 operates as a qualified exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence. Moreover, the ordinary meaning of the clause "except as provided for in paragraph 7 of Article 5" in Article 2.2 indicates that Article 2.2 would be applicable in a situation where a measure meets some, but not all, of the requirements of Article 5.7.

7.2976 Characterizing Article 5.7 as a qualified right and not an exception also has implications for the allocation of the burden of proof concerning the issue of the consistency of an SPS measure with Article 5.7. According to the Appellate Body's statement in *EC – Tariff Preferences*, in cases where the permissive provision constitutes a right rather than an exception, "the complaining party bears the burden of establishing that a challenged measure is inconsistent with the provision permitting particular behaviour".[1834] And in *EC – Sardines*, the Appellate Body observed that "[i]n *EC – Hormones*, we found that a 'general rule-exception' relationship between Articles 3.1 and 3.3 of the *SPS Agreement* does not exist, with the consequence that the complainant had to establish a case of inconsistency with *both* Articles 3.1 and 3.3".[1835] We deduce from these two statements that in cases where a complaining party alleges that an SPS measure is inconsistent with the obligation in Article 2.2 not to maintain SPS measures without sufficient scientific evidence, it is incumbent on the complaining party, and not the responding party, to demonstrate that the challenged SPS measure is inconsistent with at least one of the four requirements set forth in Article 5.7. If such non-compliance is demonstrated, then, and only then, does the relevant obligation in Article 2.2 apply to the challenged SPS measure.

7.2977 Our view of the nature of the relationship between Article 2.2 and Article 5.7 and of the proper allocation of the burden of proof under these provisions is consistent with that of the panel in *Japan – Agricultural Products II*. In that case, the United States as the complaining party claimed that the challenged measure was inconsistent, *inter alia*, with the obligation in Article 2.2 not to maintain SPS measures without sufficient scientific evidence. After reaching the provisional conclusion that the challenged measure was inconsistent with Article 2.2, the panel noted that Japan, the responding party, was invoking Article 5.7 in support of its measure. Recalling the text of Article 2.2, and notably the clause "except as provided for in paragraph 7 of Article 5", the panel then stated that in view of Japan's invocation of Article 5.7 it needed to examine whether the challenged measure was a measure meeting the requirements in Article 5.7. The panel noted that "[i]f the [challenged measure] meets these requirements, we cannot find that it violates Article 2.2".[1836] The panel then went on to analyse the measure in the light of the requirements of Article 5.7, finding that "the United States [as the complaining party] has established a presumption that Japan did not comply with the requirements in the second sentence of Article 5.7. We also consider that Japan has not been

[1833] Appellate Body Report, *Japan – Agricultural Products II*, para. 89 (emphasis omitted).
[1834] Appellate Body Report, *EC – Tariff Preferences*, para. 88.
[1835] Appellate Body Report, *EC – Sardines*, para. 275 (emphasis in original).
[1836] Panel Report, *Japan – Agricultural Products II*, para. 8.48.

able to rebut this presumption".[1837] In the light of this finding, the panel then reached the overall and final conclusion that the challenged measure was inconsistent with Article 2.2.[1838]

7.2978 We note that in a later case, *Japan – Apples*, the panel confronted a very similar situation. In that case, the United States as the complaining party also claimed that the challenged measure was inconsistent with the obligation in Article 2.2 not to maintain SPS measures without sufficient scientific evidence. Japan as the responding party contested this claim, but argued, in the alternative, that its measure was consistent with the requirements of Article 5.7. The panel recalled the approach followed by the panel in *Japan – Agricultural Products II*, stating that it agreed with that approach and that it would therefore make no final findings with respect to the consistency of the measure at issue with Article 2.2 until it had completed its analysis under Article 5.7.[1839] However, contrary to the approach of the panel in *Japan – Agricultural Products II*, the panel in *Japan – Apples* determined that "the burden [was] on Japan, as the party invoking Article 5.7, to make a prima facie case in support of its position".[1840] The panel did not elaborate further on why it had decided to place this burden of proof on Japan. Following the approach it had outlined, the panel then determined, on a provisional basis, that the challenged measure was inconsistent with Article 2.2. The panel next examined Japan's alternative argument under Article 5.7, finding that Japan had failed to establish that its measure was justified under Article 5.7. In view of this finding, the panel confirmed its provisional conclusion under Article 2.2, finding that the challenged measure was inconsistent with Article 2.2.[1841]

7.2979 In relation to the approach followed by the panel in *Japan – Apples*, it is important to point out that the Appellate Body in that same case noted that "[t]he Panel's assignment of the burden of proof to Japan to make a *prima facie* case of consistency with Article 5.7 is not challenged on appeal".[1842] We take this statement as a reservation expressed by the Appellate Body in respect of the panel's assignment of the burden of proof to Japan. In any event, as we have stated above, and for the reasons stated above, we consider that it is incumbent on the complaining party to establish a prima facie case of inconsistency with both Articles 2.2 and 5.7.

7.2980 Before proceeding to analyse the relationship between Article 5.1 and Article 5.7, we wish to address two arguments presented by Canada. First of all, Canada invokes basic logic in support of its position that Article 5.7 should be considered as an exception. In Canada's view, it is logically necessary to determine first whether a measure is maintained without sufficient evidence within the meaning of Article 2.2. Canada submits that only if a measure is maintained without sufficient evidence, the question arises whether maintaining that measure is nonetheless justifiable under Article 5.7. Canada's argument is based on the premise that Article 2.2 is applicable in the kinds of situations covered by Article 5.7. However, such a premise does not comport well with the text of Article 2.2. Indeed, the clause "except as provided for in paragraph 7 of Article 5" in Article 2.2 suggests the opposite of what Canada is assuming, namely, that the relevant obligation in Article 2.2 is *not* applicable in situations covered by Article 5.7. If, as we believe, Article 2.2 was not intended to apply in the situations covered by Article 5.7, it made entire sense for the drafters to include the aforementioned exclusionary clause in the text of Article 2.2. Conversely, if, as Canada argues, Article 5.7 was intended to constitute an affirmative defence to a claim of violation under Article 2.2, it was unnecessary to include the aforementioned exclusionary clause in the text of Article 2.2. The

[1837] *Ibid.*, para. 8.58.
[1838] *Ibid.*, para. 8.61.
[1839] Panel Report, *Japan – Apples*, para. 8.201.
[1840] *Ibid.*, para. 8.212.
[1841] *Ibid.*, paras. 8.199, 8.222 and 8.224.
[1842] Appellate Body Report, *Japan – Apples*, footnote 316.

"logical" way of giving expression to such an intention would have been for Article 2.2 not to include the aforementioned exclusionary clause, and for Article 5.7 to state that "notwithstanding the provisions of Article 2.2, in cases where relevant scientific evidence is insufficient, Members may provisionally adopt SPS measures on the basis of available pertinent information".[1843] Thus, while our view accounts for, and gives meaning and effect to, all of the terms used in Article 2.2, Canada's view renders the exclusionary clause effectively redundant. We recall in this regard that in interpreting Article 2.2, we must give meaning and effect to all of its terms – "*ut res magis valeat quam pereat*" – and must not adopt an interpretation which would result in rendering some of its terms effectively redundant.[1844]

7.2981 In any event, the logic argued for by Canada could also be said to apply to the relationship between Article 3.1 and Article 3.3. Thus, by the same token, it could be said that it is only once it has been determined that an SPS measure is not based on an existing international standard that it becomes relevant to ask whether a Member may nevertheless depart from that standard to achieve a higher level of protection. Yet the Appellate Body found that Article 3.3 is not an exception to a "general obligation" in Article 3.1.

7.2982 The second argument put forward by Canada which we wish to comment on is Canada's argument that, for the purposes of interpreting the relationship between Articles 2.2 and 5.7, any reliance on the Appellate Body's interpretation in *EC – Hormones* of the relationship between Article 3.1 and Article 3.3 would be misplaced and inappropriate. According to Canada, Article 3.1 and Article 3.3 give Members the free choice of basing their SPS measures either on an international standard or on a stricter national standard. In contrast, Canada maintains, Members do not have the option of either maintaining SPS measures with sufficient scientific evidence, as contemplated in Article 2.2, or of maintaining SPS measures on the basis of available pertinent information, as contemplated in Article 5.7. As an initial matter, we note that Articles 3.1 and 3.3 are part of the context of Articles 2.2 and 5.7. Moreover, we consider that there is an undeniable structural and textual similarity between Articles 3.1 and 3.3 and Articles 2.2 and 5.7. Both pairs of articles are linked to each other through a textual cross-reference, and Article 3.1 contains an "except as provided for" clause which is textually almost identical to the corresponding clause in Article 2.2. It is primarily this structural and textual similarity of Articles 3.1 and 3.3, coupled with the fact that these provisions, and their mutual relationship, have already been interpreted by the Appellate Body, which renders them relevant to, and hence has factored in, our examination of the relationship between Article 2.2 and Article 5.7.

7.2983 Thus, our view of the relationship between Articles 2.2 and 5.7 is not reliant on the premise that the relationship between Articles 3.1 and 3.3, on the one hand, and Articles 2.2 and 5.7, on the other hand, is the same in all respects. Indeed, we agree with Canada that there are important substantive differences. A Member can, subject to compliance with applicable requirements, choose whether to base an SPS measure on a relevant international standard in line with Article 3.1 or, alternatively, to avail itself of the qualified right not to do so provided in Article 3.3. In contrast, in cases where the relevant scientific evidence is insufficient, *e.g.*, because none is available, a Member who wishes nonetheless to take a precautionary SPS measure could not meet the requirement in Article 2.2 to ensure that this measure "is not maintained without sufficient scientific evidence". This further strengthens our conviction that Article 5.7 should be viewed as a qualified exemption from the relevant obligation in Article 2.2, confirming the right of Members to take measures which are "necessary for the protection of human, animal or plant life or health" in situations where the available scientific evidence is "insufficient". Therefore, while recognizing the existence of substantive

[1843] *See*, for a similar argument, Appellate Body Report, *US – Upland Cotton*, para. 609.
[1844] *See also* Appellate Body Report, *US – Gasoline*, p. 23.

differences between Articles 3.1 and 3.3, on the one hand, and Articles 2.2 and 5.7, on the other hand, we do not consider that these differences support Canada's view that Article 5.7 constitutes an exception to Article 2.2 in the nature of an affirmative defence.

Relationship between Article 5.1 and Article 5.7

7.2984 We now turn to examine the relationship between Article 5.1 and Article 5.7. We recall at the outset that Article 5.1 requires Members to base their SPS measures on a risk assessment, whereas pursuant to Article 5.7, in cases where relevant scientific evidence is insufficient, Members may provisionally adopt SPS measures on the basis of available pertinent information. The European Communities submits that we should view the relationship between Article 5.1 and Article 5.7 in the same way that we view the relationship between Article 2.2 and Article 5.7. Or as the European Communities also put it, Article 5.7 is not an exception from a general obligation under Article 5.1, but an autonomous right.

7.2985 We recall that in accordance with the guidance provided by the Appellate Body in *EC – Tariff Preferences*, we could characterize Article 5.7 as a right in relation to Article 5.1 if the relationship between Article 5.1 and Article 5.7 is one "where one provision permits, in certain circumstances, behaviour that would otherwise be inconsistent with an obligation in another provision, [where] one of the two provisions refers to the other provision, [and] where one of the provisions suggests that the obligation is not applicable to the said measure".[1845] We will therefore examine below whether the relationship between Article 5.1 and Article 5.7 meets these various elements of the general test articulated by the Appellate Body.

7.2986 We consider first whether Article 5.7 permits, in certain circumstances, what would otherwise be inconsistent with Article 5.1. We note in this regard the statement by the panel in *Australia – Salmon* that "Article 5.7 allows for an exception to the obligation to base sanitary measures on a risk assessment, namely 'in cases where relevant scientific evidence is insufficient'".[1846] This statement clearly suggests that Article 5.7 permits what Article 5.1 prohibits. This statement also suggests that Article 5.7 constitutes an exception, although it is less than clear that the panel conceived of Article 5.7 as an exception in the nature of an affirmative defence. As the panel did not explain why it described Article 5.7 as an exception, we are bound to recall the above-quoted statement by the Appellate Body in *EC – Hormones* that characterizing a treaty provision as an "exception" does not, by itself, place the burden of proof on the responding party.[1847]

7.2987 Looking at the first sentence of Article 5.7, we note that, by its terms, it does not require that Members provisionally adopting SPS measures perform a risk assessment as defined in Annex A(4) to the *SPS Agreement*, and that they base their measure on the completed risk assessment as contemplated in Article 5.1. The first sentence of Article 5.7 requires that in cases where relevant scientific evidence is insufficient, SPS measures be adopted "on the basis of available pertinent information".

7.2988 We note that the second sentence of Article 5.7 obligates Members maintaining SPS measures under Article 5.7 to seek to obtain the additional information necessary for "a more objective assessment of risk", and to review their measures "accordingly". We understand the phrase "a more objective assessment of risk", taken as a whole, to refer to a risk assessment which satisfies the definition provided in Annex A(4) – or at least which is closer to satisfying the definition in

[1845] Appellate Body Report, *EC – Tariff Preferences*, para. 88.
[1846] Panel Report, *Australia – Salmon*, para. 8.57.
[1847] Appellate Body Report, *EC – Hormones*, para. 104.

Annex A(4) than consideration of "available pertinent information". This also appears to be the Appellate Body's view, for it stated in *Japan – Agricultural Products II* that:

> "Article 5.7 states that the additional information is to be sought in order to allow the Member to conduct 'a more objective assessment of risk'. Therefore, the information sought must be germane to conducting *such a risk assessment*, i.e., the evaluation of the likelihood of entry, establishment or spread of, *in casu*, a pest, according to the SPS measures which might be applied."[1848]

7.2989 It is clear from this statement that by "such a risk assessment" the Appellate Body meant "a more objective assessment of risk". We consider that the use of "more" objective invokes a movement in a certain direction, that is, towards the eventual "objective" assessment of risk as defined in Annex A(4), *i.e.*, an evaluation of the likelihood of entry, establishment or spread of a pest, according to the SPS measures which might be applied.

7.2990 According to the Appellate Body, "'relevant scientific evidence' will be 'insufficient' within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*".[1849] Thus, if a Member may provisionally adopt an SPS measure on the basis of available pertinent information in situations where the scientific evidence is insufficient for an adequate risk assessment, as required by Article 5.1 and as defined in Annex A(4), it makes sense to require, as the second sentence of Article 5.7 does, that that Member seek to obtain "the additional information necessary" for such a risk assessment. Once a Member has obtained the additional information necessary for a risk assessment which meets the definition of Annex A(4), it will be in a position to comply with its obligation in Article 5.1 to base its SPS measure on a risk assessment which satisfies the definition of Annex A(4).

7.2991 Based on the foregoing considerations, we think the second sentence of Article 5.7 does not support the view that SPS measures which have been provisionally adopted pursuant to Article 5.7 can be maintained only if they are based on a risk assessment as required under Article 5.1 and as defined in Annex A(4). However, there is one element of the second sentence of Article 5.7 which we need to examine further.

7.2992 The second sentence of Article 5.7 refers to "a *more objective* assessment of risk" (emphasis added). The element "more objective" suggests that SPS measures provisionally adopted pursuant to the first sentence of Article 5.7 must also be based on a risk assessment, namely, a risk assessment which takes into account available pertinent information. It follows that if the first sentence of Article 5.7 required a risk assessment, it would necessarily be different in nature from the kind of risk assessment envisaged in Annex A(4). In other words, any risk assessment which might be required by the first sentence of Article 5.7 would not need to meet the definition of a risk assessment contained in Annex A(4). The above-mentioned interpretation by the Appellate Body of the phrase "[i]n cases where relevant scientific evidence is insufficient" also supports this view. For if the right conferred by the first sentence of Article 5.7 only arises in cases where the scientific evidence is insufficient for an adequate risk assessment as required by Article 5.1 and as defined in Annex A(4), then the kind of risk assessment which the first sentence might require by definition could not meet the standard set out in Annex A(4).

[1848] Appellate Body Report, *Japan – Agricultural Products II*, para. 92 (emphasis added).
[1849] Appellate Body Report, *Japan – Apples*, para. 179.

7.2993 In the light of the above, we consider that subject to compliance with the requirements set out in Article 5.7, SPS measures may be provisionally adopted and maintained under Article 5.7 even if these measures are not based on a risk assessment as defined in Annex A(4). Accordingly, we conclude that Article 5.7 permits Members to do, in certain circumstances, what they would not be permitted to do under Article 5.1.

7.2994 The next issue for consideration is whether either Article 5.1 or Article 5.7 refers to the other provision. The first thing to be noted with regard to this issue is that neither Article 5.1 nor Article 5.7 contains an explicit cross-reference to the other provision. Our previous discussion of the relationship between Article 5.1 and Article 5.7 shows, however, that Article 5.7 contains implicit references to Article 5.1. *First*, the second sentence of Article 5.7 refers to "a more objective risk assessment", a phrase which we have construed to refer to a risk assessment within the meaning given to that term in Annex A(4). We have also noted that only Article 5.1 requires a risk assessment as defined in Annex A(4). *Secondly*, we have noted earlier that according to the Appellate Body, relevant scientific evidence is "insufficient" within the meaning of the first sentence of Article 5.7 if it does not allow the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A(4). Thus, through its interpretation of the phrase "[i]n cases where relevant scientific evidence is insufficient", the Appellate Body has made explicit a reference to Article 5.1 which in its view is implicit in Article 5.7. Indeed, the Appellate Body justified its interpretation on the basis that there is "a link or relationship between the first requirement under Article 5.7 and the obligation to perform a risk assessment under Article 5.1".[1850] In view of these elements, we conclude that Article 5.7 should be considered to refer to Article 5.1.

7.2995 The last element we need to address in accordance with the general test set out in *EC – Tariff Preferences* is whether either Article 5.1 or Article 5.7 suggests that the obligation in Article 5.1 to base SPS measures on a risk assessment is not applicable to measures falling within the scope of Article 5.7. We begin by noting that unlike Article 2.2, Article 5.1 does not explicitly say that its provisions apply "except as provided for in paragraph 7 of Article 5". However, Article 5.7 opens with the phrase "[i]n cases where relevant scientific evidence is insufficient". As mentioned by us before, the Appellate Body opined that "'relevant scientific evidence' will be 'insufficient' within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*".[1851] Accordingly, if the right conferred by the first sentence of Article 5.7 only arises in cases where the scientific evidence is insufficient for an adequate risk assessment as defined in Annex A(4), and if, as the Appellate Body suggests, Article 5.1 requires such a risk assessment, then the logical conclusion to be drawn is that the obligation in Article 5.1 to base SPS measures on a risk assessment was not intended to be applicable to measures falling within the scope of Article 5.7. Indeed, "[i]n cases where relevant scientific evidence is insufficient", it is impossible, under the Appellate Body's interpretation of that phrase, for Members to meet the obligation to base their SPS measures on a risk assessment as defined in Annex A(4). We find it unreasonable to assume that Members would accept, even in principle, an obligation with which they cannot comply. In our view, the phrase "[i]n cases where relevant scientific evidence is insufficient" should, therefore, be taken to suggest that the obligation in Article 5.1 is not applicable to measures falling within the scope of Article 5.7.

7.2996 In addition, we think the clause "except as provided for in paragraph 7 of Article 5" in Article 2.2 also suggests that the obligation in Article 5.1 is not applicable to measures falling within the scope of Article 5.7. We recall in this regard that in *EC – Hormones* the Appellate Body agreed

[1850] *Ibid.*
[1851] *Ibid.*

with a statement by the panel in that case that Article 5.1 may be viewed as a specific application of the basic obligations contained in Article 2.2.[1852] If Article 5.1 is properly viewed as a specific application of the obligations provided for in Article 2.2, it follows that Article 5.1 cannot be applicable in situations where Article 2.2 is not applicable. We have explained above that the clause "except as provided for in paragraph 7 of Article 5" exempts the kinds of situations covered by Article 5.7 from the obligation in Article 2.2 to ensure that SPS measures are not maintained without sufficient scientific evidence. Since Article 5.1 is not applicable in situations where Article 2.2 is not applicable, the clause "except as provided for in paragraph 7 of Article 5" in Article 2.2 necessarily implies that Article 5.1 cannot be applicable in situations covered by Article 5.7.

7.2997 From our analysis above, it is clear that the general test stated by the Appellate Body in *EC – Tariff Preferences* can be applied also to the relationship between Article 5.1 and Article 5.7. Our application of that test has shown that this relationship meets all the elements which according to the Appellate Body support characterizing Article 5.7 as a right *vis-à-vis* Article 5.1. Furthermore, we think it would be incongruous to reach the conclusion that Article 5.7 is a right *vis-à-vis* Article 2.2, but an exception *vis-à-vis* Article 5.1. For these reasons, we conclude that Article 5.7 should be characterized as a right also in relation to Article 5.1, rather than as an exception from a "general obligation" under Article 5.1. In our view, Article 5.7 operates as a qualified exemption from the obligation under Article 5.1 to base SPS measures on a risk assessment.

7.2998 We have already stated the main implications of characterizing Article 5.7 as a qualified right rather than as an exception in our discussion of the relationship between Article 2.2 and Article 5.7. Nonetheless, for clarity, it is useful to do so again given that we are concerned here with the relationship between Article 5.1 and Article 5.7. Thus, in terms of applicability of Article 5.1, characterizing Article 5.7 as a right means that if a challenged SPS measure was adopted and is maintained consistently with the four cumulative requirements of Article 5.7, the obligation in Article 5.1 to base SPS measures on a risk assessment is not applicable to the challenged measure. Conversely, if a challenged SPS measure is not consistent with one of the four requirements of Article 5.7, the aforementioned obligation in Article 5.1 is applicable to that measure, provided there are no other elements which render Article 5.1 inapplicable.

7.2999 We note in this context that in relation to the safeguard measures at issue in this dispute, the European Communities has advanced the argument that in the event the Panel deemed Article 5.1 applicable, the phrase "as appropriate to the circumstances" in Article 5.1 would send the Panel right back to Article 5.7, because, in the European Communities' view, the safeguard measures in question are provisional measures, and the circumstances are that the scientific evidence is insufficient. The European Communities has not explained how the phrase "as appropriate to the circumstances" would "send the Panel back" to Article 5.7. We note that the European Communities' argument is premised on the applicability of Article 5.1. In view of the assumptions posited by the European Communities – provisional adoption of the safeguard measures in a situation where relevant scientific evidence is insufficient – Article 5.1 would be applicable only if the safeguard measures are not maintained consistently with the second sentence of Article 5.7. We fail to see how in such a case, that is, in a

[1852] Appellate Body Report, *EC – Hormones*, para. 180. *See also* Appellate Body Report, *Japan – Agricultural Products II*, para. 82. It appears that the Appellate Body views Article 5.1 as a specific application of the second and third obligation in Article 2.2, *i.e.*, the obligation to base SPS measures on scientific principles and the obligation not to maintain SPS measures without sufficient scientific evidence. In *Australia – Salmon*, the Appellate Body agreed with the panel in that case that in the event an SPS measure is not based on a risk assessment as required in Article 5.1, this measure can be presumed, more generally, not to be based on scientific principles or to be maintained without sufficient scientific evidence within the meaning of Article 2.2. Appellate Body Report, *Australia – Salmon*, para. 138.

case where the right conferred by Article 5.7 could not be validly asserted, the phrase "as appropriate to the circumstances" in Article 5.1 could "send the Panel back" to Article 5.7.

7.3000 We now turn to the implications of characterizing Article 5.7 as a qualified right rather than as an exception for the allocation of the burden of proof concerning the issue of the consistency of an SPS measure with Article 5.7. In our view, the implication is that in cases where a complaining party alleges that an SPS measure is inconsistent with Article 5.1, it is incumbent on the complaining party, and not the responding party, to demonstrate that the challenged measure is inconsistent with at least one of the four requirements set forth in Article 5.7. If such non-compliance is demonstrated, then, and only then, is Article 5.1 applicable to the challenged SPS measure. Accordingly, we think that when a complaining party presents a claim of violation under Article 5.1, the burden is on the complaining party to establish a prima facie case of inconsistency with both Articles 5.1 and 5.7.

7.3001 We recognize that previous panels have found inconsistencies with Article 5.1 without specifically examining whether the complaining party had established a prima facie case of inconsistency with both Articles 5.1 and 5.7.[1853] In our view, this reflects the fact that in these cases the responding party did not invoke the provisions of Article 5.7 in response to a claim of violation under Article 5.1. In other words, in previous cases, the responding parties did not contest that the relevant measure fell to be assessed under Article 5.1 as opposed to Article 5.7. Since we are confronted in this case with a different situation, it would be improper for us to place the burden of establishing a prima facie case of inconsistency with Article 5.7 on the responding party on the grounds that panels in the past did not explicitly require of the complaining party that it establish a prima facie case of inconsistency with both Articles 5.1 and 5.7. The fact that responding parties in the past did not contest the applicability of Article 5.1 does not, and should not, preclude the responding party in the present case from doing so and thus asserting the right conferred on it by Article 5.7.

7.3002 Additionally, we note that if we had determined that Article 5.7 is an exception from a "general obligation" under Article 5.1, the burden would be on the responding party to demonstrate that the challenged measure is consistent with all of the requirements set forth in Article 5.7. In contrast, in the context of a claim under Article 2.2, it is, according to our view, incumbent on the complaining party to establish a prima facie case of inconsistency with Article 5.7. If we were to accept such a situation, a complaining party could unilaterally determine whether to assume the burden of establishing a prima facie case of inconsistency with Article 5.7. If it wished to avoid that burden, all it would need to do is to present a claim of violation under Article 5.1 rather than under Article 2.2. This, we think, is a further reason for conceiving of the relationship between Article 5.1 and Article 5.7 in the same way as of the relationship between Article 2.2 and Article 5.7.

(iii) Conclusion

7.3003 We have now completed our analysis of the two arguments presented by the European Communities in support of its contention that the safeguard measures must not be assessed under Article 5.1. Regarding the first argument, we have found that even if the European Communities were correct in asserting that the safeguard measures at issue in this dispute are provisional measures, this fact alone would not render Article 5.1 inapplicable.

7.3004 Regarding the second argument, we have determined that Article 5.7 does not provide for an exception from Article 5.1, but establishes a qualified right. We have said that, on this view of the

[1853] *But see*, Panel Report, *Australia – Salmon*, para. 8.57, where the panel intimated, in the context of an inquiry under Article 5.1, that the challenged measure was not consistent with Article 5.7.

relationship between Article 5.1 and Article 5.7, if an SPS measure challenged under Article 5.1 was adopted and is maintained consistently with the cumulative requirements of Article 5.7, the obligation in Article 5.1 to base SPS measures on a risk assessment is not applicable to the challenged measure. In such a case, the complaining party would not have invoked the "wrong" provision, in the sense that it should have brought a challenge under Article 5.7 instead of Article 5.1. The complaining party would have invoked the "correct" provision, but the complaining party's claim under Article 5.1 could not succeed as long as the responding party complies with the requirements of Article 5.7.

7.3005 In the present case, the Complaining Parties are challenging the safeguard measures under Article 5.1. It is clear from the previous paragraph that, in such circumstances, it is both necessary and appropriate to examine the consistency of the safeguard measures with Article 5.7 within the context, and as part, of an examination of the consistency of the same measures with Article 5.1. Therefore, unlike the European Communities, we consider that we may, and indeed must, assess the safeguard measures under Article 5.1.[1854] Accordingly, in the next section, we will address the issue of the consistency of the individual safeguard measures with Article 5.1.

7.3006 Concerning the structure of our Article 5.1 analysis, one possibility would be to examine first whether the Complaining Parties have met their burden of establishing a prima facie case of inconsistency with Article 5.7 in respect of the relevant safeguard measures. However, in the specific circumstances of this case, the critical legal issue in our view is whether the relevant safeguard measures meet the requirements set out in the text of Article 5.1, not whether they are consistent with Article 5.7. Therefore, consistent with the order of analysis followed by the panels in *Japan – Agricultural Products II* and *Japan – Apples* when examining the consistency of measures with Articles 2.2 and 5.7, we prefer to begin our Article 5.1 analysis by examining whether the relevant safeguard measures meet the requirements set out in the text of Article 5.1, notably the requirement to base SPS measures on a risk assessment.

7.3007 Under this approach, should we find that a relevant safeguard measure meets the requirements set out in the text of Article 5.1, there would be no need to examine the Complaining Parties' claims under Article 5.1 further, as their claims would then fail even if we were satisfied that the safeguard measure is not consistent with Article 5.7 and that Article 5.1 therefore applies to the safeguard measure. Should we find, however, that the safeguard measure does not meet the requirements set out in the text of Article 5.1, we would need to go on to examine whether this measure is consistent with the requirements of Article 5.7. If the safeguard measure were consistent with the requirements of Article 5.7, Article 5.1 would not be applicable and we would consequently need to conclude that the European Communities has not acted inconsistently with its obligations under Article 5.1. Conversely, if the safeguard measure were inconsistent with the requirements of Article 5.7, Article 5.1 would be applicable and, in view of the assumed fact that the safeguard measure does not meet the requirements set out in the text of Article 5.1, we would need to conclude that the European Communities has acted inconsistently with its obligations under Article 5.1.

(c) Consistency with Article 5.1 of the *SPS Agreement* (initial assessment)

7.3008 As indicated, in this section, we will make an initial assessment of the consistency of the relevant safeguard measures with Article 5.1 of the *SPS Agreement*. Specifically, we will examine whether the safeguard measures meet the requirements set out in the text of Article 5.1. We begin this task by addressing a number of general arguments put forward by the Parties.

[1854] For clarity, we should mention that our assessment of the safeguard measures under Article 5.1 might lead us to conclude that Article 5.1 is not applicable.

(i) General

7.3009 To recall, Article 5.1 of the *SPS Agreement* provides:

> "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations."

7.3010 Annex A(4) of the *SPS Agreement* provides the following definition of the term "risk assessment":

> "*Risk assessment* – The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs."

7.3011 We have already determined that the relevant safeguard measures are "SPS measures". As such, they are subject to the provisions of Article 5.1. Thus, the safeguard measures must be based on an appropriate risk assessment.

7.3012 The **United States** claims that the safeguard measures are not based on a risk assessment and are, therefore, inconsistent with Article 5.1. Although the member States have offered reasons for their measures, they did not put forth a risk assessment as defined in Annex A(4) of the *SPS Agreement*. The member States have expressed concerns about the potential adverse effects of the relevant products, or biotech products in general, but there is no evidence that these objections were based on any risk assessments. The only risk assessments put forth for the banned products are those conducted by the member States to which the product applications were originally submitted, and by the European Communities' own scientific committees. These risk assessments were favourable to the products, and did not raise any concerns with respect to human health or the environment. Given that the information provided by the member States in support of their measures was rejected by the EC scientific committees, which reaffirmed their initial favourable risk assessment, it cannot be argued that the safeguard measures bear a "rational relationship" to these risk assessments. The United States contends that by failing to put forth their own risk assessments, or to provide sufficient information to overturn the European Communities' earlier positive assessments, the member States have violated Article 5.1.

7.3013 **Canada** similarly argues that the safeguard measures are not based on a risk assessment, and therefore violate Article 5.1. Although the member States have presented reasons when notifying their safeguard measures to the Commission, they did not file any supporting scientific evidence or analysis that meets the definition of a risk assessment set out in the *SPS Agreement*. Canada notes that while the notifications to the Commission pointed to the shortcomings in the risk assessments done as part of the approval process, or put forward general concerns with respect to risks to human health or the environment arising from the banned varieties of biotech products, they did not present a comprehensive analysis of the available scientific evidence. Furthermore, the risk assessments undertaken by the member States where the products were originally filed and by the EC scientific committees both supported the approval of the product applications. The EC scientific committees also rejected in each case the reasons presented by the member States to justify the safeguard measures. Therefore, it cannot be argued that the risk assessments available sufficiently support or

reasonably warrant the safeguard measures, nor that there is a rational relationship between these risk assessments and the member States measures.

7.3014 **Argentina** also argues that the member States measures are inconsistent with Article 5.1 and Annex A(4) of the *SPS Agreement*. It notes that the member States have failed to perform a risk assessment within the meaning of the *SPS Agreement*. The safeguard measures, it argues, have been adopted and maintained without reference to any type of scientific evidence, and in spite of the scientific committee opinions which "disqualified" the member State measures as lacking any scientific basis.

7.3015 The **European Communities** argues that Article 5.1 does not expressly require a "risk assessment". It requires only that Members take into account risk assessment techniques developed by the relevant international organizations.[1855] According to the European Communities, these risk assessment techniques generally recognize that in certain circumstances, namely in the case of the adoption of provisional measures, only an assessment, and not a "risk assessment" within the meaning of the *SPS Agreement*, is necessary. The European Communities argues, in the alternative, that the member States' safeguard measures are based on risk assessments within the meaning of the *SPS Agreement*, as can be inferred from the history of each safeguard measure as well as the sequence of events which led the member States to adopt and maintain those measures.[1856] In its response to a question from the Panel, the European Communities notes that "[a] risk assessment was carried out at the time when the original […] consent was given" for the product, and that such risk assessment "can serve, at least temporarily, as a basis both for the original Community consent, and for the Member States provisional [safeguard] measures".[1857]

7.3016 The European Communities further contends that the requirement that an SPS measure be "based on" a risk assessment does not necessarily mean that this measure must "conform to" the risk assessment. The same risk assessment may "sufficiently warrant", or "reasonably support", more than one possible SPS measure, depending, *inter alia*, on the specific circumstances of the legislator. There may be both a mainstream scientific opinion on which responsible and representative governments may base themselves, and divergent scientific views on the basis of which equally responsible and representative governments may act. In other words, the same risk assessment can reasonably support divergent responses by equally responsible and representative governments. The European Communities also notes that in any event, the member States have made their own risk assessments, and that further risk assessments may be forthcoming.[1858]

7.3017 **Canada** disagrees with the EC argument that Article 5.1 does not expressly require a "risk assessment", but only that Members take into account risk assessment techniques developed by relevant international organizations. That Article 5.1 creates a clear obligation on Members to base their measures on a risk assessment is supported by the definition of the term "risk assessment" in Annex A(4), as well as relevant jurisprudence.[1859] Canada further notes that it fails to see how the risk assessments that formed the basis for the European Communities' approval of the products can serve as the basis for both the original Community consent and for the member States' safeguard measures.

[1855] EC reply to Panel question No. 107.
[1856] EC first written submission, para. 610.
[1857] EC reply to Panel question No. 107.
[1858] *Ibid.*
[1859] Canada argues that relevant jurisprudence supports the interpretation that Article 5.1 creates a clear obligation on the Members to base their measures on a risk assessment, and that it, together with Article 2.2, is "essential for the maintenance of the delicate and carefully negotiated balance in the *SPS Agreement* between the shared, but sometimes competing, interests of promoting international trade and of protecting the life and health of human beings" (Appellate Body Report, *EC – Hormones*, para. 177).

The publicly available scientific opinions do not equivocate in their conclusions, nor do they present diverging views on the potential risks associated with these products.

7.3018 Canada notes that while the Appellate Body has recognized in *EC – Hormones* that a risk assessment can reflect diverging views, and that responsible and representative governments may act in good faith on the basis of divergent opinions, it did not say that "the same risk assessment can reasonably support divergent responses by equally responsible and representative governments" in cases where the risk assessments do not contain divergent views. This must be all the more true when the contrast between the two risk management options, i.e. full approval or complete ban of the product, is as stark as in this case. Finally, with regard to the European Communities' suggestion that the member States have conducted their own risk assessment and that such assessments may be forthcoming, Canada notes that the European Communities has failed to present any evidence of such assessments having been undertaken.

7.3019 The **Panel** recalls that pursuant to Article 5.1, Members must "base" their SPS measures on a "risk assessment". To determine whether an SPS measure is consistent with Article 5.1, we must therefore address two distinct issues: (i) whether there is a "risk assessment" within the meaning of the *SPS Agreement*; and (ii) whether the measure is "based on" this risk assessment.

7.3020 In relation to the first issue, i.e., the issue of whether a risk assessment was carried out, we note the European Communities' argument that Article 5.1 does not expressly require a "risk assessment" within the meaning of the *SPS Agreement*, but only requires that Members take into account risk assessment techniques developed by relevant international organizations.

7.3021 To the extent the European Communities is arguing that there is no requirement to assess "risks", we disagree. By its own terms, Article 5.1 requires Members to base their SPS measures on an appropriate assessment "of the risks to human, animal or plant life or health".[1860] The immediate context of Article 5.1 confirms this view. Article 5 is captioned "*Assessment of Risk* and Determination of the Appropriate Level of Sanitary and Phytosanitary Protection" (emphasis added). Moreover, Articles 5.2 and 5.3 of the *SPS Agreement* specify relevant factors to be taken into account by Members "in the assessment of risks" and "in assessing the risk to animal or plant life or health". Finally, Article 5.7 of the *SPS Agreement* provides that in circumstances where relevant scientific evidence is insufficient and a Member has adopted a provisional SPS measure based on available pertinent information, it must seek to obtain the additional information necessary for a more objective assessment of "risk".

7.3022 As the European Communities points out, Article 5.1 provides that Members must base their SPS measures on an appropriate assessment of risks, "taking into account risk assessment techniques developed by relevant international organizations". In our view, the phrase "taking into account risk assessment techniques developed by relevant international organizations" does not address the issue of whether risks are to be assessed, but rather how risks are to be assessed. This is clear from the reference to "techniques" of risk assessment. Contrary to the European Communities, we therefore do not consider that the phrase in question supports the view that no assessment of risks is required. To the contrary, the phrase in question would, in our view, be unnecessary if there were no requirement to assess risks.

7.3023 The European Communities asserts that risk assessment techniques developed by the relevant international organizations generally recognize that in circumstances where provisional SPS measures

[1860] In *Japan – Apples*, the Appellate Body referred to an "obligation to conduct an assessment of 'risk'". Appellate Body Report, *Japan – Apples*, para. 202.

are adopted, an assessment is required, but not a "risk assessment" as that term is defined in the *SPS Agreement*. It is not clear to us what the European Communities means by "an assessment". If it means to say that some type of assessment of risks would be required, but not an assessment which meets the definition of the term "risk assessment" provided in Annex A(4), we see no basis for such an argument. It is well established in WTO jurisprudence that the Annex A(4) definition is applicable to Article 5.1.[1861] Moreover, since the definition of the term "risk assessment" in Annex A(4) does not itself provide for a particular risk assessment "technique", we have difficulty seeing how a particular risk assessment "technique" developed by an international organization could render inapplicable the general definition of the term "risk assessment" in Annex A(4). In any event, the European Communities has not identified the risk assessment techniques which it says support its assertion that a "risk assessment" within the meaning of Annex A(4) is not required in the case of provisional SPS measures. We therefore do not examine this argument further.

7.3024 We have said that, in our view, an assessment of risks is required. We recall in this respect that Article 5.1 of the *SPS Agreement* does not require a Member to conduct its own risk assessment. As noted by the Appellate Body in *EC - Hormones*, "Article 5.1 does not insist that a Member that adopts a sanitary measure shall have carried out its own risk assessment. It only requires that the SPS measure be 'based on an assessment, as appropriate to the circumstances [...]'. The SPS measure might well find its objective justification in a risk assessment carried out by another Member, or an international organization".[1862] Thus, an SPS measure may be based on a risk assessment conducted by another Member, or an international organization.

7.3025 In the present case, the relevant member State safeguard measures might therefore be supported by a risk assessment carried out by these member States in respect of the product subject to their safeguard measures, or by a risk assessment performed by another entity.

7.3026 Regarding the possibility of there being a risk assessment performed by an entity other than the member State adopting a particular safeguard measure, we note that assessments were carried out in respect of the relevant products before their approval. Before their approval, assessments were performed by the CA of the member State to which the product application was originally submitted – the "lead CA"[1863]- and by the relevant EC scientific committee. Furthermore, after the approval of the product, these assessments were reviewed by the relevant EC scientific committee on the basis of the information provided by the member State adopting the safeguard measure.

7.3027 It is common ground among the Parties that the assessments carried out by the lead CA and by the EC scientific committees constitute "risk assessments" within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*. It is apparent from the assessments provided to us that they evaluated the likelihood of potential adverse effects on human health and/or the environment, as well as the associated potential consequences, according to the proposed use of the specific biotech product under consideration.[1864] These assessments were of a qualitative and not quantitative nature, however the WTO jurisprudence has clearly established that the *SPS Agreement* does not require that risk assessments be of a quantitative nature in order to satisfy the definition in Annex A(4). We therefore

[1861] *See, e.g.*, Appellate Body Reports, *Japan – Apples*, para. 196; *Australia – Salmon*, para. 121.

[1862] Appellate Body Report, *EC - Hormones*, para. 190.

[1863] We note that for none of the nine safeguard measures at issue the member State adopting the safeguard measure acted as the lead member State during the relevant approval procedure.

[1864] We note that the assessments by the relevant EC scientific committees which reviewed these committees' earlier assessments in the light of information provided by the member States taking safeguard measures are generally in the nature of supplemental assessments. Thus, the review assessments need to be read in conjunction with the earlier (original) assessments.

agree with the Parties that risk assessments within the meaning of Annex A(4) and Article 5.1 have been conducted in respect of the products subject to the safeguard measures by the lead CA and by the relevant EC scientific committee. Below, we will examine for each safeguard measure whether, in addition, other risk assessments have been conducted in respect of these same products, and in particular whether the EC member States applying safeguard measures have carried out their own risk assessment.

7.3028 Once we have determined that one or more risk assessments exist in respect of a product subject to one of the relevant safeguard measures – and we have already found in the previous paragraph that such risk assessments exist – we must go on to analyse any claims that the relevant safeguard measure is "based on" one or more of these risk assessments. With respect to the issue of whether an SPS measure is "based on" a risk assessment, we note that this requirement has been interpreted as meaning that there must be a rational relationship between a risk assessment and the SPS measure taken, or in other words, that the results of the risk assessment must "sufficiently warrant" or "reasonably support" the SPS measure at issue.[1865]

7.3029 Consistent with the foregoing considerations, we will determine below, for each safeguard measure, whether there exists a "risk assessment" upon which the safeguard measure is "based". Before undertaking this task, however, we must address one further issue. The issue to be addressed is whether the maintenance of the relevant safeguard measures may be justified both by reference to risk assessments which were carried out before these measures were adopted and by reference to risk assessments which were carried out after these measures were adopted.

7.3030 Article 5.1 does not explicitly speak to this specific issue. We recall that Article 5.1 requires Members to ensure that their SPS measures "are based on" an assessment, "as appropriate to the circumstances", of risks to animal, plant or human life or health. Regarding the requirement that SPS measures be "based on" a risk assessment, it is clear to us that SPS measures must be "based on", or "sufficiently warranted" or "reasonably supported" by, a risk assessment throughout the period of time for which these measures are maintained.[1866] In our view, both a risk assessment carried out before the adoption of a particular safeguard measure and a risk assessment carried out after its adoption could "sufficiently warrant", or "reasonably support", the maintenance of that measure.

7.3031 Also relevant to our inquiry is the requirement that a risk assessment be "appropriate to the circumstances". The phrase "as appropriate to the circumstances" is unqualified as far as its temporal scope is concerned. Notably, Article 5.1 does not say "as appropriate to the circumstances existing at the time of adoption of such measures", or "as appropriate to the circumstances existing at the time of the assessment". We think it may be inferred from the absence of any temporal limitation that at any given time, SPS measures must be based on an assessment of risks which is appropriate to the circumstances existing at that time. Indeed, this is consistent with the fact that relevant circumstances may change over time.[1867] A change in relevant circumstances may have an impact on a completed

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[1865] Appellate Body Report, *EC - Hormones*, paras. 193-194.

[1866] This view is consistent with the following finding by the panel in *Australia – Salmon*:

> We note Australia's statement that its policy of allowing imports of salmon products heat-treated in accordance with the 1988 Conditions will be reviewed and that for these purposes an import risk analysis is scheduled. It is possible that this risk analysis provides a rational basis for the measure at issue. However, *as of today* and on the basis of the risk assessment before us, we do not detect such a basis. (Panel Report, *Australia – Salmon*, para. 8.100 (emphasis added).)

[1867] Article 2.2 also contains separate requirements supporting this view, stating that Members shall ensure that their measures are 1) "based on scientific principles" and 2) "not maintained without sufficient scientific evidence".

risk assessment, and in some cases the impact may be such as to affect the continued relevance of a completed risk assessment and the validity of its conclusions.[1868] If and when a change in relevant circumstances affects the continued relevance and validity of a completed risk assessment, that assessment would, in our view, no longer constitute an assessment "appropriate to the circumstances".[1869]

7.3032 We note that the Appellate Body observed that the phrase "as appropriate to the circumstances" provides Members with "a certain degree of flexibility in meeting the requirements of Article 5.1".[1870] However, this statement did not relate to a situation such as the one we are considering here where relevant circumstances change over time. We see nothing in the ordinary meaning of the phrase "as appropriate to the circumstances", or in the aforementioned observation by the Appellate Body, to contradict our view that a change in relevant circumstances could in some cases render a completed risk assessment no longer "appropriate to the circumstances".

7.3033 This approach is also supported by the context of Article 5.1. Article 5.6 provides that "when establishing or *maintaining* [SPS] measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection" (emphasis added). We have previously observed that one of the purposes of a risk assessment is to allow the importing Member to determine the measure to be applied, if any, for achieving its appropriate level of protection. Thus, if a Member could maintain under Article 5.1 a significantly trade-restrictive SPS measure on the basis of a risk assessment which is no longer appropriate to the circumstances (*e.g.*, due to new scientific evidence which affects the continued relevance and validity of the risk assessment in question), and a risk assessment appropriate to the circumstances would establish that essentially no risk in fact exists, then that Member would be "maintaining" an SPS measure which *ex hypothesi* is more trade-restrictive than required to achieve its appropriate level of protection, contrary to the requirements of Article 5.6. Irrespective of whether the trade-restrictive measure could be challenged under Article 5.6, we consider that it would be improper to interpret Article 5.1 so as to allow the Member to maintain its trade-restrictive measure, as such an interpretation would frustrate an important purpose of a risk assessment, which is "to serve as a basis for regulatory actions"[1871]. The determination of a measure which is not more trade-restrictive than required to achieve a Member's appropriate level of protection is a relevant "regulatory action".

7.3034 In the present case, the Complaining Parties are challenging the maintenance by the European Communities of the relevant safeguard measures. Thus, in accordance with our interpretation of Article 5.1 we must examine whether, on the date of establishment of this Panel, each safeguard measure was based on an assessment of risks which was appropriate to the circumstances existing at that time. Since what is being challenged is the maintenance of each safeguard measure, it is of no

[1868] In our view, the state of scientific knowledge is one example of a circumstance which is relevant to the assessment of risks and which is subject to change over time. Indeed, evolution of science may result in new and/or better scientific evidence becoming available, and such evidence may have an effect on the continued relevance and validity of the conclusions of an existing risk assessment.

[1869] It should be noted in this context that, in our view, a completed risk assessment which meets the definition of Annex A(4) and is consistent with the requirements of Articles 5.2 and 5.3 of the *SPS Agreement* would not cease to satisfy that definition or these requirements merely because there was a change in relevant circumstances and that change affected the continued relevance of that risk assessment. To provide a simple example: A risk assessment within the meaning of Annex A(4) which has not been updated over time continues to be a risk assessment within the meaning of Annex A(4). However, as we have said, such a risk assessment may no longer be "appropriate to the circumstances" in the sense of Article 5.1.

[1870] Appellate Body Report, *EC – Hormones*, para. 129.

[1871] Panel Report, *Japan – Apples*, para. 7.12.

particular importance whether a specific risk assessment which is claimed to serve as a basis for a safeguard measure was performed before or after the adoption of that safeguard measure. What matters is that the relevant risk assessment was appropriate to the circumstances existing at the time this Panel was established. In the light of this, in our analysis of whether there are risk assessments on which individual safeguard measures were based at the relevant time, we will consider assessments which were carried out before these measures were adopted as well as assessments which were carried out after these measures were adopted.

(ii) Austria – T25 maize

7.3035 The Panel commences its analysis of individual safeguard measures with Austria's measure on T25 maize. The first issue we will address is whether the documents Austria relies on to justify its safeguard measure meet the definition of a risk assessment.

"Risk assessment"

7.3036 We first recall that in the Reasons document, Austria presented various concerns in support of its safeguard measure on T25 maize, including, *inter alia*, the fact that the product had not been examined under realistic conditions as far as the use of herbicide is concerned, and that no monitoring programme was foreseen to assess the long-term effects of T25 maize.[1872] With respect to its concern regarding the assessment of long-term effects, Austria invoked the need to protect sensitive areas, referring to a study by Hoppichler entitled "Concepts of GMO-Free Environmentally Sensitive Areas", which was commissioned by the Austrian Federal Ministry of Women's Affairs and Consumer Protection (hereafter the "Hoppichler study ").[1873] This study appears to be the only scientific evidence which Austria relied on at the time of adoption of its safeguard measure.

7.3037 As also noted earlier, Austria invoked further concerns in the January 2004 document, namely, with respect to risks related to allergenicity and toxicity, the potential environmental impact of *Bt* toxin as well as antibiotic resistance marker genes.[1874] In relation to the January 2004 document, we recall that our task is to assess whether the Austrian safeguard measure was based on a risk assessment as of 29 August 2003, when this Panel was established. A risk assessment completed after August 2003 in our view would not assist the European Communities in rebutting the Complaining Parties' claim that Austria's safeguard measure was not based on a risk assessment in August 2003. However, we note that one of the studies mentioned by Austria in the January 2004 document was published in March 2003, and we therefore take it into account. The study in question is a joint study by the Federal Ministry of the Environment ("Umweltbundesamt GmbH") and IFF/IFZ – Inter-University Research Centre for Technology, Work and Culture, entitled "*Toxicology and Allergology of GM Products: Investigations into practice and recommendations on the standardization of risk assessment of genetically modified food*" (hereinafter the "March 2003 document").[1875]

7.3038 Having identified the documents which Austria relies on to justify its safeguard measure, we can now go on to determine whether any of these documents constitutes a "risk assessment" within the meaning of the *SPS Agreement*.

[1872] Exhibit EC-160/At. 3.
[1873] Exhibit EC-160/At. 5.
[1874] Exhibit EC-158/At. 30.
[1875] Exhibit EC-158/At. 41_trans.

7.3039 We recall that Austria justified its safeguard measures by reference to concerns relating to the spread of pollen to cultivated surrounding fields, long-term ecological effects, the potential development of antibiotic resistance and allergenicity and toxicity. We have determined that to the extent Austria's measure is applied to address concerns over the spread of pollen to cultivated surrounding fields, long-term ecological effects and the development of antibiotic resistance, it falls within the scope of Annex A(1)(a) and/or (d) of the *SPS Agreement*. The first clause of Annex A(4) to the *SPS Agreement* provides the following definition for the "risk assessment" to be carried out for measures which have purposes falling within the scope of Annex A(1)(a) or (d):

> "*Risk assessment* – The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences."

7.3040 Based on this definition, the Appellate Body in *Australia – Salmon* found that a risk assessment must:[1876]

> "1) *identify* the diseases [or pests] whose entry, establishment or spread a Member wants to prevent on its territory, as well as the potential biological and economic consequences associated with the entry, establishment or spread of these diseases;
>
> 2) evaluate the *likelihood* of entry, establishment or spread of these diseases [or pests], as well as the associated potential biological and economic consequences; and
>
> 3) evaluate the likelihood of entry, establishment or spread of these diseases [or pests] *according to the SPS measures which might be applied*."

7.3041 We begin our analysis of Austria's Reasons document. In this document, Austria alleges that T25 maize was not examined under realistic conditions of the use of the herbicide and of correspondent agricultural practices; that there was no monitoring programme to assess the long-term effects of biotech plants and herbicides, and in particular with respect to the protection of environmentally sensitive areas; that there were no special measures to monitor the possible spread of pollen to fields in the surroundings cultivated with conventional maize (co-existence); and that regional ecological aspects were not differentiated as far as resistance development is concerned. We note that the Reasons document highlights concerns related to the lack of a monitoring programme for possible long term environmental impacts associated with herbicide use on GM plants and the spread of pollen from GM cultivated fields to fields in surrounding areas. Regarding the concern over the spread of pollen, the Reasons document includes references to possibilities of associated risks, but it does not provide an evaluation of the likelihood of such risks occurring. For example, the document states that the spread of pollen is "mostly regarded as safe."[1877] On the other hand, the Reasons document does not make explicit claims regarding the risks associated with the long-term environmental impacts of herbicide use in conjunction with GM crops in ecologically sensitive areas, but rather refers to the Hoppichler study for discussion of these risks.

[1876] Appellate Body Report, *Australia-Salmon*, para. 121 (bracketed text added).
[1877] Exhibit EC-160/At. 3.

7.3042 The Hoppichler study focuses on the protection of environmentally-sensitive areas. Based on the evidence submitted to us[1878], we understand that Austria is seeking to prevent the cultivation and other uses of GMOs on its territory due to possible long-term ecological risks associated with GMOs, particularly in fragile areas. In addition, the study argues that "multiple releases and the marketing of GMOs are irreversible processes, and [...] products of organic agriculture will also contain GMOs even if they are produced strictly on the basis of organic guidelines."[1879]

7.3043 In considering the Hoppichler study, we recall that the Commission requested the SCP to analyse the information provided by Austria, including the aforementioned study, in order to determine whether this information may "constitute relevant scientific evidence, which would cause the SCP to consider that this product constitutes a risk to human health and the environment."[1880] In response, the SCP prepared an opinion which notes that the Hoppichler study "does not contain any new scientific information which is relevant to the original scientific risk assessment that [the SCP] published in 1998. Rather the document contains arguments for the establishment of GMO-free environmentally-sensitive areas and summarises surveyed opinions of people who may be confronted professionally with any environmental effects of the release of GMOs." We understand this statement to indicate that the SCP did not view this study as a risk assessment.

7.3044 We also note that the Hoppichler study does not indicate relative probability of the potential risks it identifies, but rather makes reference to possibilities of risks or simply to the inability to determine probabilities. For example, the document states that "there are possibilities of direct risks which can be assessed within some limits according to the status of science and technology".[1881] In addition, the study cites two analyses regarding environmental risk assessment of releasing GMOs. A quote from the first analysis indicates that "the ecological impact of transgenic grasses *may be* pervasive" (emphasis added).[1882] The second analysis is said to demonstrate that "the contamination of natural gene pools through synthetic genes is incalculable in principle in predictive risk assessment".[1883] This statement highlights the lack of estimated risk associated with gene flow from GMOs.

7.3045 Regarding these references to possibilities of risks, we recall that the Appellate Body in *Australia – Salmon* stated that:

> "[I]t is not sufficient that a risk assessment conclude that there is a *possibility* of entry, establishment or spread of diseases and associated biological and economic consequences. A proper risk assessment of this type must evaluate the 'likelihood' i.e., the 'probability', of entry, establishment or spread of diseases and associated biological and economic consequences."[1884]

7.3046 Given the lack of evaluation of likelihood in the Hoppichler study, we consider that the study does not meet the definition of a risk assessment as provided in Annex A(4), and therefore does not constitute a risk assessment within the meaning of Annex A(4) and Article 5.1.

[1878] We note that the European Communities provided a summary of the Hoppichler study in English (Exhibit EC-160/At. 5).
[1879] Exhibit EC-160/At. 5, p. 8.
[1880] Exhibits US-56; CDA-77; ARG-45 and -46.
[1881] Exhibit EC-160/At. 5, p. 4.
[1882] Exhibit EC-160/At. 5, p. 4.
[1883] Exhibit EC-160/At. 5, p. 4.
[1884] Appellate Body Report, *Australia – Salmon*, paras. 123-124.

7.3047 We now turn to determine whether any of the relevant documents relied on by Austria contains a risk assessment with regard to Austria's concerns over the development of antibiotic resistance and allergencity and toxicity. We recall in this respect our earlier finding that to the extent Austria's measure is applied to address such concerns, it falls within the scope of Annex A(1)(b) the *SPS Agreement*. The second clause of Annex A(4) to the *SPS Agreement* provides the following definition for the "risk assessment" to be carried out for measures which have purposes falling within the scope of Annex A(1)(b):

> "*Risk assessment*: [...] the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs."

7.3048 We note that, unlike for the definition of risk assessment contained in the first clause of Annex A(4), WTO jurisprudence provides little guidance on the meaning of key concepts contained in the definition provided in the second clause. The Appellate Body merely observed in this respect that the first clause is substantially different from the second clause, and that the second clause requires "only" the evaluation of the "potential" for adverse effects on human or animal health arising from the presence of certain substances in foods, whereas the first clause requires an evaluation of the "likelihood" of entry, establishment or spread of a pest or disease and of the associated biological and economic consequences.[1885] We note that the dictionary defines the term "potential" as "the possibility of something happening [...] in the future".[1886]

7.3049 In this context, one relevant document to be examined is the Austrian study on toxicology and allergology of biotech products of March 2003. This study reviews the assessment under Regulation 258/97 of toxic and allergenic risks of food containing or consisting of GMOs. The objective of the study was to investigate risk assessment practices for food derived from biotech plants, and to make proposals to "concretise and standardise the toxicological and allergological risk assessment."[1887] We consider that this study evaluates risk assessment *procedures*, and not the potential for adverse effects on human or animal health arising from the consumption of specific foods containing or consisting of GMOs. We therefore think that the March 2003 study does not meet the definition of a risk assessment as provided in Annex A(4).

7.3050 Regarding Austria's concern about the development of antibiotic resistance, we recall that this concern was raised in the January 2004 document.[1888] However, none of the supporting documents which were provided to the Panel contains a discussion of risks associated with this specific concern in the context of the product at issue. The Austrian study on toxicology and allergology of biotech products of March 2003 reviews procedures for the assessment of risks of food containing or consisting of GMOs; the issue of antibiotic resistance is not included in the analysis. Thus, we are not aware of any pre-August 2003 document which addresses the issue of antibiotic resistance and which meets the definition of a risk assessment provided in Annex A(4).

7.3051 In the light of the foregoing, we conclude that the above-mentioned documents relied on by Austria to justify its safeguard measure are not in themselves risk assessments within the meaning of Annex A(4) and Article 5.1.

[1885] Appellate Body Report, *Australia – Salmon*, footnote 69.

[1886] *The Concise Oxford Dictionary*, 10th edn, J. Pearsall (ed.) (Oxford University Press, 1999), p. 1120.

[1887] Exhibit EC-158/At. 41, p. 19.

[1888] Exhibit EC-158/At. 30.

7.3052 In connection with the documents relied on by Austria, we should also note the European Communities' argument that Austria's safeguard measure was based on an assessment "appropriate to the circumstances" within the meaning of Article 5.1. According to the European Communities, the phrase "as appropriate to the circumstances" makes it clear that Members have a certain degree of flexibility in meeting the requirements of Article 5.1.[1889] The European Communities submits that the circumstances in the case of the Austrian safeguard measure include the fact that, from Austria's perspective, relevant scientific evidence was or is insufficient.

7.3053 We need not determine whether relevant scientific evidence was or is insufficient for Austria, and if so, whether this would be a relevant circumstance. Even if this were the case, the flexibility which the phrase "as appropriate to the circumstances" may in some situations provide does not relieve Austria from the requirement in Article 5.1 to base its safeguard measure on a risk assessment which meets the definition of Annex A(4).[1890] All of the Annex A(4) definition of the term "risk assessment" which are applicable to Austria's safeguard measure, must, in our view, be met. It is useful to recall in this respect that the Appellate Body in *Australia – Salmon* observed that an evaluation of the likelihood of entry, establishment or spread of a pest could be done both quantitatively and qualitatively.[1891] Moreover, in circumstances where there is little available scientific evidence, the phrase "as appropriate to the circumstances" may provide a measure of flexibility in terms of how (but not whether) the applicable elements of the Annex A(4) definition, including the likelihood evaluation, are satisfied. In the case at hand, we have answered in the negative the question of whether the documents which Austria relied on satisfy the applicable elements of the Annex A(4) definition of the term "risk assessment". Therefore, we see no need to examine further the European Communities' argument in relation to the phrase "as appropriate to the circumstances".

7.3054 We have found above that none of the documents relied on by Austria constitute risk assessments. However, the European Communities contends that there is a document other than the documents relied on by Austria which constitutes a risk assessment for T25 maize. The document in question is the "[r]isk assessment [which] was carried out at the time when the original Community consent was given" (hereafter the "original risk assessment").[1892] It is not clear from this assertion whether the European Communities is referring to the risk assessment conducted by the lead CA or to that conducted by the SCP.[1893] In any event, we have noted above that it is not in dispute that both of these documents constitute risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3055 In addition, we note that none of the Parties has argued that, on the date of establishment of this Panel, the risk assessments conducted by the lead CA and the SCP were no longer "appropriate to the circumstances". We also recall in this regard that the SCP confirmed its original risk assessment after reviewing the information relied on by Austria. In the light of this, and in view of our findings below with regard to whether the Austrian safeguard measure is "based on" these risk assessments, we do not need to examine this issue further.

[1889] In support of its statement, the European Communities refers to the Appellate Body report on *EC – Hormones*, para. 129.

[1890] We note in this context the statement by the panel in *Australia – Salmon* to the effect that the phrase "as appropriate to the circumstances" "cannot [...] annul or supersede the substantive obligation resting on Australia to base the sanitary measure in dispute [...] on a risk assessment". Panel Report, *Australia – Salmon*, para. 8.57.

[1891] Appellate Body Report, *Australia – Salmon*, para. 124.

[1892] EC reply to Panel question No. 107.

[1893] Exhibits EC-160/At. 2; CDA-75 and 87; US-56 (referencing original SCP assessment); ARG-45 and 46 (referencing original SCP assessment).

"Based on"

7.3056 As noted, it is not clear whether the original risk assessment referred to by the European Communities is the risk assessment conducted by the lead CA or that conducted by the SCP. In our analysis below, we will examine whether, at the time of establishment of this Panel, the Austrian safeguard measure was "based on" either of these risk assessments.

7.3057 The European Communities presents two main arguments to support its assertion that the Austrian safeguard measure is based on a risk assessment pursuant to Article 5.1. The first argument of the European Communities is that responsible and representative governments may act either on the basis of mainstream scientific opinion or on the basis of a divergent scientific view. Regarding Austria's safeguard measure on T25 maize, the European Communities submits that Austria acted on the basis of new scientific information, which presented a view divergent from the mainstream scientific opinion reflected in the original risk assessment.

7.3058 The Panel notes that in *EC - Hormones*, the Appellate Body observed that a "[r]isk assessment could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view".[1894] It then went on to state that "responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources. By itself, this does not necessarily signal the absence of a reasonable relationship between the SPS measure and the risk assessment, especially where the risk involved is life-threatening in character and is perceived to constitute a clear and imminent threat to public health and safety."[1895]

7.3059 It is important to recall that this statement related to a hypothetical situation where divergent views were expressed as part of, and in, the same risk assessment. In the case at hand, we are not aware, and have not been made aware, of any divergent views that would be expressed in the risk assessments of the lead CA and SCP concerning T25 maize. Therefore, we are presented here with a situation that is different from that described by the Appellate Body in *EC – Hormones*. Furthermore, we note that the contributions of the Panel's experts do not support the view that the potential risks arising from the deliberate release of T25 maize and the other biotech products subject to this dispute can be considered to be risks that are "life-threatening in character" or that "constitute a clear and imminent threat to public health and safety".[1896]

7.3060 Where a given risk assessment sets out a divergent opinion[1897] and this opinion comes from qualified and respected sources, it can be reasonably said that an SPS measure which reflects the divergent opinion is "based on" the risk assessment in question inasmuch as the divergent opinion is expressed in that risk assessment. In contrast, where a given risk assessment sets out a single opinion, it cannot be reasonably said that an SPS measure is "based on" *that* risk assessment if the relevant SPS measure reflects a divergent opinion which is not expressed in the risk assessment in question. *Ex hypothesi*, the opinion expressed in that risk assessment would not "sufficiently warrant", or "reasonably support", the SPS measure taken.

7.3061 In the case of the Austrian safeguard measure, the European Communities asserts that new scientific information became available and that this new information justified Austria's differing

[1894] Appellate Body Report, *EC - Hormones*, para. 194.
[1895] Appellate Body Report, *EC - Hormones*, paras. 193-194.
[1896] *Ibid.*
[1897] We use the term "divergent opinion" or "divergent assessment" to refer to an opinion or assessment which argues for, and supports, a significantly different overall conclusion.

assessment of the risks. Even assuming this were the case, however, this would not alter the fact that we are unaware of any divergent opinions expressed in the risk assessments which were conducted by the lead CA and the SCP. Therefore, it would be clear that, on the date of establishment of this Panel, Austria's safeguard measure would not have been based on these existing risk assessments, but on its own modified version of these assessments, namely, its divergent assessment.

7.3062 Even if the alleged divergent assessment by Austria in a number of respects did not depart from the existing risk assessments, Austria's safeguard measure could not, for that reason alone, be considered to be based on these risk assessments if these assessments reached a different overall conclusion. To be clear, we are not suggesting that Members cannot rely in part on an existing risk assessment which sets out a single opinion. But to the extent they disagree with some or all of the conclusions contained in such an assessment, it would in our view be necessary for Members to explain, by reference to the existing assessment, how and why they assess the risks differently, and to provide their revised or supplemental assessment of the risks. The European Communities or Austria did not do so in relation to the safeguard measure on T25 maize.

7.3063 Since we are unable to accept the European Communities' first argument in support of its view that the Austrian safeguard measure is based on the risk assessments conducted by the lead CA and the SCP, we must go on to examine the European Communities' second argument. The second argument of the European Communities is that the risk assessment carried out before Community-wide marketing approval was given, can serve, at least temporarily, as a basis for both the Community-wide marketing approval and Austria's provisional safeguard measure. In other words, the European Communities contends that the same risk assessment can "sufficiently warrant", or "reasonably support", more than one type of SPS measure, or, as the European Communities puts it, one and the same risk assessment may justify "divergent responses by equally responsible and representative governments".[1898]

7.3064 As a general matter, the Panel agrees with the European Communities that a particular risk assessment might conceivably serve as a basis for different types of SPS measures. Indeed, there may be a range of measures that may be rationally related to a given risk assessment, at least in cases where a risk is determined to exist.[1899] In the present case, the risk assessments conducted by the lead CA and by the SCP with regard to T25 maize were favourable.[1900] These assessments concluded that there was no evidence that T25 maize presents any greater risk to human health or the environment than its conventional (non-biotech) counterpart. Yet, the safeguard measure which Austria allegedly adopted on the basis of these risk assessments provides for a complete prohibition of the product.[1901] In our view, the favourable findings of the risk assessments in question do not naturally lead to the conclusion that what is arguably the strictest type of SPS measure, *i.e.*, a complete prohibition, was warranted in Austria's case to protect human health and the environment. To the contrary, these findings strongly suggest that this type of measure was not sufficiently warranted.

7.3065 The European Communities asserts that each of the safeguard measures at issue in this dispute is based on the precautionary principle. We would agree that the fact that a Member has

[1898] *See* EC reply to Panel question No. 107.

[1899] While there may be a variety of SPS measures that would be rationally related to a given risk assessment, some of these measures may be inconsistent with Article 5.6 of the *SPS Agreement*. In other words, there may be SPS measures which are rationally related to a risk assessment, but more trade-restrictive than required to achieve a Member's appropriate level or protection.

[1900] Exhibits EC-160/At. 2; CDA-75 and 87; US-56 (referencing original SCP risk assessment); ARG-45 and 46 (referencing original SCP risk assessment).

[1901] As we have noted, the prohibition is subject to an exception which applies in cases where the products are meant to be immediately re-exported after handling and repackaging (Exhibit EC-160/At. 3_trans).

decided to follow a precautionary approach could have a bearing on a panel's assessment of whether an SPS measure is "based on" a risk assessment as required by Article 5.1. We consider that if there are factors which affect scientists' level of confidence in a risk assessment they have carried out[1902], a Member may in principle take this into account in determining the measure to be applied for achieving its appropriate level of protection from risks.[1903] Thus, there may conceivably be cases where a Member which follows a precautionary approach, and which confronts a risk assessment that identifies uncertainties[1904] or constraints, would be justified in applying (i) an SPS measure even though another Member might not decide to apply any SPS measure on the basis of the same risk assessment, or (ii) an SPS measure which is stricter than the SPS measure applied by another Member to address the same risk. However, even if a Member follows a precautionary approach, its SPS measures need to be "based on" (*i.e.*, "sufficiently warranted" or "reasonably supported" by) a risk assessment. Or, to put it another way, such an approach needs to be applied in a manner consistent with the requirements of Article 5.1.[1905]

7.3066 In the case of Austria's safeguard measure on T25 maize, the European Communities has not identified possible uncertainties or constraints in the risk assessments in question, much less explained why, in view of any such uncertainties or constraints, Austria's prohibition is warranted by the relevant risk assessments. Therefore, the European Communities' argument about the precautionary approach does not persuade us that Austria's safeguard measure is "sufficiently warranted" by the favourable risk assessments which were performed with regard to T25 maize. In other words, if Austria's safeguard measure reflects a precautionary approach, we consider, based on the evidence before us, that Austria did not implement that approach in a manner consistent with the requirements of Article 5.1.

7.3067 We note the European Communities' argument that "based on" does not mean "conform to". To the extent the European Communities means to argue that Members are free to adopt any kind of SPS measure provided there exists a risk assessment for the product subject to the SPS measure, we

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[1902] *E.g.*, a limited body of relevant scientific evidence may be such a factor.

[1903] This view is consistent with risk assessment techniques established by relevant international organizations. For instance, the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* state that "[t]he report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors". Codex Alimentarius Commission, *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (adopted in June/July 2003), Section III, Codex Procedural Manual, 14th edition, 2004, para. 25. Along similar lines, the Codex *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* state that "[r]isk managers should take into account the uncertainties identified in the risk assessment and implement appropriate measures to manage these uncertainties". Codex Alimentarius Commission, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* (adopted in June/July 2003), CAC/GL 44-2003, para. 18. Similarly, the IPPC's ISPM #11 (2001) states in relevant part that "[t]he uncertainty noted in the assessments of economic consequences and probability of introduction should also be considered and included in the selection of a pest management option". IPPC, ISPM #11: *Pest Risk Analysis for Quarantine Pests*, April 2001, para. 3. The quoted passage stayed the same in the 2004 version of ISPM #11, which applies specifically to living modified organisms.

[1904] We are not referring here to the theoretical uncertainty which inevitably remains because science can never provide absolute certainty that a product will never have adverse effects on human health or the environment. The Appellate Body has made it clear that this theoretical uncertainty is not the kind of risk which is to be assessed under Article 5.1. Appellate Body Report, *EC – Hormones*, para. 186.

[1905] We recall that according to the Appellate Body, the precautionary principle "has not been written into the *SPS Agreement* as a ground for justifying SPS measures that are otherwise inconsistent with the obligations of Members set out in particular provisions of that Agreement". Appellate Body Report, *EC – Hormones*, para. 124.

disagree. It is correct that the Appellate Body in *EC – Hormones* has said that the expression "based on" as it appears in Article 3.1 of the *SPS Agreement*[1906] does not mean "conform to".[1907] However, the Appellate Body also said in *EC – Hormones* that in the specific context of Article 5.1, the expression "based on" should be interpreted to mean "sufficiently warranted by", "reasonably supported by" or "rationally related to".[1908] As we have said, in the case of Austria's safeguard measure on T25 maize, there exists no apparent rational relationship between that measure, which imposes a complete prohibition, and risk assessments which found no evidence that T25 maize presents any greater risk to human health or the environment than its conventional (non-biotech) counterpart.[1909] At any rate, if we were to allow Austria effectively to ignore favourable risk assessments, we would turn these assessments into documents without any substantive importance and the conduct of these assessments into a mere formality. Yet, the requirement in Article 5.1 to "base" an SPS measure on a risk assessment is plainly a substantive requirement, and not simply a formal requirement to accompany an SPS measure by a risk assessment.[1910]

7.3068 In view of the foregoing considerations, while not rejecting the European Communities' second argument generally, we do not agree with the European Communities that Austria's safeguard measure can be considered to be "based on" the risk assessments performed by the lead CA and the SCP in relation to T25 maize.

7.3069 Accordingly, since we are of the view that Austria's safeguard measure cannot be considered to be "based on" the existing (original) risk assessments, and recalling also that no other risk assessment which might reasonably support Austria's safeguard measure has been provided to us, we find that the Austrian measure prohibiting the placing on the market of T25 maize is not based on a risk assessment pursuant to Article 5.1.[1911]

Overall conclusions

7.3070 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on T25 maize is not based on a risk assessment.

[1906] Article 3.1 states in relevant part that "Members shall base their [SPS] measures on international standards, guidelines or recommendations, where they exist [...]".

[1907] Appellate Body Report, *EC - Hormones*, para. 166.

[1908] *Ibid.*, para. 193.

[1909] We note that the Appellate Body in *EC – Hormones* confronted a comparable situation. Specifically, the Appellate Body found that scientific reports which concluded that the use of certain hormones for growth promotion purposes was safe did not rationally support an import prohibition maintained by the European Communities. Appellate Body Report, *EC - Hormones*, paras. 196-197.

[1910] We note that the Appellate Body in *EC – Hormones* also characterized the requirement that an SPS measure be "based on" a risk assessment as a "substantive requirement". Appellate Body Report, *EC - Hormones*, para. 193.

[1911] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the Austrian safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on T25 maize is not based on a risk assessment.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on T25 maize is not based on a risk assessment.

7.3071 In view of our findings in the previous paragraph with regard to DS291 (United States), DS292 (Canada) and DS293 (Argentina), it is necessary to examine, in addition, whether the Austrian safeguard measure on T25 maize is consistent with the requirements of Article 5.7 of the *SPS Agreement*. It is only once we have completed this additional examination that we can come to a final conclusion regarding the consistency of the Austrian safeguard measure on T25 maize with Article 5.1 of the *SPS Agreement*. We undertake the necessary examination under Article 5.7 in the next section.

(iii) Austria – Bt-176 maize

7.3072 The Panel turns to its analysis of Austria's measure on Bt-176 maize. The first issue we will address is whether the documents Austria relies on to justify its safeguard measure meet the definition of a risk assessment.

"Risk assessment"

7.3073 We recall from the Reasons document that Austria's concerns with respect to Bt-176 maize were related in particular to the issues of gene transfer (development of antibiotic resistance) and the development of resistance to *Bt* toxin.[1912] With respect to each of these concerns, Austria presented the scientific reasons for its decision to prohibit Bt-176 maize.[1913]

7.3074 We note that Austria provided additional scientific evidence to the Commission in May 1997 in support of its safeguard measure on Bt-176 maize.[1914] In particular, Austria provided two studies concerning the development of resistance to *Bt* toxin arising from the circumstance that transgenic crops producing insecticidal proteins from *Bt* are being grown commercially (hereafter the "March and April 1997 studies").[1915]

[1912] Exhibit EC-158/At. 7.

[1913] We note that Austria's Reasons document makes reference to a number of scientific studies in support of its safeguard measure. However, since these studies were not submitted to the Panel as evidence, we cannot determine whether any of these studies constitutes in itself a risk assessment on which the safeguard measure might be based. We do note, however, that many of these studies predate the original EC risk assessment and would presumably have been known to and taken into account in the context of that risk assessment.

[1914] Exhibit EC-158/At. 10.

[1915] Exhibit EC-158/Ats. 11-12.

7.3075 Furthermore, in the January 2004 document, Austria invoked recent scientific findings concerning risks related to allergenicity and toxicity, the potential environmental impact of *Bt* toxin, including effects on non-target organisms, as well as antibiotic resistance marker genes.[1916] In relation to the January 2004 document, we recall that our task is to assess whether the Austrian safeguard measure was based on a risk assessment as of 29 August 2003, when this Panel was established. A risk assessment completed after August 2003 in our view would not assist the European Communities in rebutting the Complaining Parties' claim that Austria's safeguard measure was not based on a risk assessment in August 2003. However, we note that one of the studies mentioned by Austria in the January 2004 document was published in March 2003, and we therefore take it into account. The study in question is a joint study by the Federal Ministry of the Environment ("Umweltbundesamt GmbH") and IFF/IFZ – Inter-University Research Centre for Technology, Work and Culture, entitled "*Toxicology and Allergology of GM Products: Investigations into practice and recommendations on the standardization of risk assessment of genetically modified food*" (hereinafter the "March 2003 document").[1917]

7.3076 Having identified the documents which Austria relies on to justify its safeguard measure, we can now go on to determine whether any of these documents constitutes a "risk assessment" within the meaning of the *SPS Agreement*. As with Austria's safeguard measure for T25 maize, given the concerns raised by Austria in the context of Bt-176 maize, we consider that both the first and the second clause of Annex A(4) to the *SPS Agreement* define the "risk assessment" to be carried out for Austria's measure on Bt-176 maize.

7.3077 We begin our analysis with Austria's Reasons document. We note that the Reasons document highlights concerns related to the development of antibiotic resistance and the impacts of the development of insect resistance to Bt toxin. Furthermore, we note that Austria makes reference in the Reasons document to the original risk assessments undertaken by the Scientific Committee for Food (SCF), the Scientific Committee for Animal Nutrition (SCAN) and the Scientific Committee on Pesticides (SCPE). While noting that all the scientific comments and arguments presented in the opinions of these scientific committees are "valid and well taken"[1918], Austria asserts that new scientific results raise questions about the possibility of a conclusive evaluation of the mechanism of gene transfer, as well as the development of resistance to Bt toxin. With regard to these new scientific results, Austria notes that " possible risks are very hard to assess and should be avoided at the present state of the scientific discussion."[1919] In a similar vein, the Reasons document states that "[t]here are adequate maize-products already available which do not comprise these restrictions and by this there is no reason to accept risks which are difficult to assess".[1920] Elsewhere, the Reasons document states that "[t]he impact of a transfer of the *bla* gene to bacteria of humans or animals can not be fully evaluated".[1921] These statements serve to demonstrate that Austria did not "assess" the alleged risks identified in the Reasons document. Therefore, we do not consider that the Reasons document constitutes an "assessment" of risks within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*.

7.3078 We now turn to the two scientific studies that Austria provided to the Commission in May 1997 in support of its safeguard measure on Bt-176 maize.[1922] These studies focused on the

[1916] Exhibit EC-158/At. 30.
[1917] Exhibit EC-158/At. 41_trans.
[1918] Exhibit 158/At. 7, p. 5.
[1919] *Ibid.*
[1920] *Ibid*.
[1921] Exhibit 158/At. 7, p. 6.
[1922] Exhibit EC-158/At. 10.

development of resistance to Bt toxin due to the commercial production of transgenic Bt crops (studies published in the National Academy of Science from March and April 1997).[1923] Both of these studies examine the mechanism through which insects develop resistance to Bt toxin. The first study describes a technique for estimating the likelihood that a particular population of insects would develop resistance to Bt toxin, while the second uses genetic analysis to show that a single insect gene can confer resistance to several different strains of the Bt toxin. The first study focuses on insects feeding on Bt cotton; the second examines the genetics underlying the evolution of resistance through feeding studies of insects on Bt toxins in dust form. While the results of these studies may be of relevance to the assessment of the risks of the potential development of resistance to Bt-176 maize, neither study assesses the likelihood of this risk. For this reason, we do not consider that the March 1997 and April 1997 studies meet the definition of a risk assessment as provided in Annex A(4). We therefore consider that these studies cannot be considered risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3079 We recall that the European Communities provided as evidence a study by Austria on toxicological and allergological risks related to biotech products (the March 2003 document).[1924] As we noted above with respect to T25 maize, we consider that this study evaluates risk assessment *procedures*, and not the potential for adverse effects on human or animal health arising from the consumption of specific foods containing or consisting of GMOs.[1925] We therefore think that this March 2003 study does not constitute a risk assessment within the meaning of Annex A(4) and Article 5.1.

7.3080 In the light of the foregoing, we conclude that the above-mentioned documents relied on by Austria to justify its safeguard measure are not risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3081 Furthermore, in connection with the documents relied on by Austria, we should also note the European Communities' argument that Austria's safeguard measure was based on an assessment "appropriate to the circumstances" within the meaning of Article 5.1. The European Communities submits that the circumstances in the case of the Austrian safeguard measure include the fact that, from Austria's perspective, relevant scientific evidence was or is insufficient. We recall our previous consideration of the European Communities' argument based on the phrase "appropriate to the circumstances" within the meaning of Article 5.1 in paragraphs 7.3052-7.3053 above, and consider that our conclusions there apply *mutatis mutandis* to this measure.

7.3082 We have found above that none of the documents relied on by Austria with regard to its safeguard measure on Bt-176 maize constitute risk assessments. However, the European Communities contends that there is a document other than the documents relied on by Austria which constitutes a risk assessment for Bt-176. The document in question is the "risk assessment [which] was carried out at the time when the original Community consent was given" (hereafter the "original risk assessment").[1926] It is not clear from this assertion whether the European Communities is referring to the risk assessment conducted by the lead CA or any of the risk assessments which were conducted by the Scientific Committee for Pesticides (SCPE), the Scientific Committee for Animal

[1923] Exhibit EC-158/Ats. 11-12.
[1924] *See supra*, para. 7.3037.
[1925] *See supra*, para. 7.3049.
[1926] EC reply to Panel question No. 107.

Nutrition (SCAN) or the SCF.[1927] In any event, we have noted above that it is not in dispute that all of these documents constitute risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3083 In addition, we recall that none of the Parties has argued that, on the date of establishment of this Panel, the risk assessments conducted by the lead CA and the risk assessments which were conducted by the SCPE, the SCAN or the SCF were no longer "appropriate to the circumstances". In the light of this, and in view of our findings below with regard to whether the Austrian safeguard measure on Bt-176 maize is "based on" these risk assessments, we do not need to examine this issue further.

"Based on"

7.3084 We now turn to the question of whether, at the time of establishment of this Panel, the Austrian safeguard measure on Bt-176 maize was "based on" either the risk assessment of the lead CA or any of those conducted by the SCPE, the SCAN or the SCF.[1928]

7.3085 We note that the European Communities' arguments in respect of this issue were the same as those it presented in the context of Austria's safeguard measure on T25 maize. We have addressed these arguments above and have reached the conclusion that Austria's safeguard measure on T25 maize cannot be considered to be "based on" the risk assessments performed by the lead CA and the SCP in relation to T25 maize. This conclusion, and the reasoning supporting it, also apply, *mutatis mutandis*, to Austria's safeguard measure on Bt-176 maize and the risk assessment performed by the lead CA and the risk assessments which were conducted by the SCPE, the SCAN or the SCF in relation to Bt-176. This is because, as in the case of Austria's safeguard measure on T25 maize:

(a) we are not aware of any divergent opinions expressed in the risk assessments which were conducted by the lead CA and the risk assessments which were conducted by the SCPE, the SCAN or the SCF with regard to Bt-176 maize;

(b) the European Communities or Austria did not explain, by reference to these risk assessments, how and why Austria assessed the risks differently, and did not provide a revised or supplemental assessment of the risks;

(c) the European Communities has not identified possible uncertainties or constraints in the risk assessments in question, and has not explained why, in view of any such uncertainties or constraints, Austria's prohibition is warranted by the relevant risk assessments; and

(d) there is no apparent rational relationship between Austria's safeguard measure, which imposes a prohibition, and risk assessments which found no evidence that Bt-176 maize will give rise to any adverse effects on human or animal health and the environment.

7.3086 Thus, in view of our conclusion that Austria's safeguard measure on Bt-176 maize cannot be considered to be "based on" the risk assessment performed by the lead CA or the risk assessments

[1927] Exhibits EC-158/Ats. 1-3; EC-158/At. 4; EC-158/At. 5; EC-158/At. 6.

[1928] As noted, we must examine as part of our analysis whether the safeguard measure is based on any of those risk assessments, as it is not clear whether the original risk assessment referred to by the European Communities is the risk assessment conducted by the lead CA or those conducted by the SCPE, the SCAN or the SCF.

which were conducted by the SCPE, the SCAN or the SCF in relation to Bt-176 maize, and recalling the fact that no other risk assessment which might reasonably support Austria's safeguard measure has been provided to us, we find that the Austrian safeguard measure is not based on a risk assessment pursuant to Article 5.1.[1929]

Overall conclusions

7.3087 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on Bt-176 maize is not based on a risk assessment.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on Bt-176 maize is not based on a risk assessment.

7.3088 In view of our findings in the previous paragraph with regard to DS291 (United States) and DS293 (Argentina), it is necessary to examine, in addition, whether the Austrian safeguard measure on Bt-176 maize is consistent with the requirements of Article 5.7 of the *SPS Agreement*. It is only once we have completed this additional examination that we can come to a final conclusion regarding the consistency of the Austrian safeguard measure on Bt-176 maize with Article 5.1 of the *SPS Agreement*. We undertake the necessary examination under Article 5.7 in the next section.

(iv) Austria – MON810 maize

7.3089 We now turn to the analysis of Austria's measure on MON810 maize. The first issue we will address is whether the documents Austria relies on to justify its safeguard measure meet the definition of a risk assessment.

"Risk assessment"

7.3090 We recall from the Reasons document that Austria's concerns with respect to MON810 maize were related in particular to undesired effects on non-target organisms and the development of resistance to *Bt* toxin in insects.[1930] In relation to each of these concerns, Austria refers to the results of recent scientific studies. We note that only the following scientific studies invoked by Austria in the Reasons document in support of its safeguard measure on MON810 maize were submitted to the Panel:

[1929] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the Austrian safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

[1930] Exhibit EC-159/At. 3.

(i) Study by Losey (1999), "Transgenic pollen harms monarch larvae"[1931];

(ii) Study by Hilbeck *et al.* (1998), "Toxicity of Bacillus thuringiensis Cry1Ab Toxin to the Predator Chrysoperla carnea (Neuroptera: Chrysopidae)"[1932];

(iii) Study by Hilbeck *et al.* (1998), "Effects of transgenic Bacillus thuringiensis corn-fed prey on mortality and development time of immature Chrysoperla carnea (Neuroptera: Chrysopidae)"[1933].

7.3091 Furthermore, we recall that in the January 2004 document, Austria invoked scientific findings concerning risks related to allergenicity and toxicity, the potential environmental impact of *Bt* toxin, as well as antibiotic resistance marker genes.[1934] In relation to the document of January 2004, we recall that our task is to assess whether the Austrian safeguard measure was based on a risk assessment as of 29 August 2003, when this Panel was established. A risk assessment completed after August 2003 in our view would not assist the European Communities in rebutting the Complaining Parties' claim that Austria's safeguard measure was not based on a risk assessment in August 2003. However, we note that one of the studies mentioned by Austria in the January 2004 document was published in March 2003, and we therefore take it into account. The study in question is a joint study by the Federal Ministry of the Environment ("Umweltbundesamt GmbH") and IFF/IFZ – Inter-University Research Centre for Technology, Work and Culture, entitled "*Toxicology and Allergology of GM Products: Investigations into practice and recommendations on the standardization of risk assessment of genetically modified food*" (hereinafter the "March 2003 document").[1935]

7.3092 As with Austria's safeguard measures on T25 maize and Bt-176 maize, given the concerns raised by Austria in the context of MON810 maize, we consider that both the first and the second clause of Annex A(4) to the *SPS Agreement* provide definitions for the "risk assessment" to be carried out for Austria's measure on MON810 maize.

7.3093 We begin our analysis with Austria's Reasons document. In this document, Austria points to new scientific evidence which, according to Austria, raises uncertainty with respect to the potential risks related to MON810 maize, in particular regarding the effects on non-target organisms and the development of resistance in insects. According to Austria, this new scientific evidence raises doubts with regard to the safety of MON810 maize for human health or the environment.

7.3094 However, nothing in the Reasons document indicates that Austria carried out a new assessment of the alleged risks in the light of the scientific evidence mentioned by Austria. We recall in this connection that a risk assessment must evaluate the likelihood or probability of particular risks, or evaluate the potential for adverse effects on animal health arising from the presence of certain substances in food, beverages or feedstuffs.[1936] The Reasons document refers to possibilities of risks arising in respect of MON810 maize, but it does not itself evaluate the potential for adverse health effects or the likelihood of the risk of establishment, entry or spread of a pest. For example, Austria notes that reservations concern the "[p]ossible undesired effects of the Bt toxin on non-target

[1931] Exhibit EC-158/At. 24.
[1932] Exhibit EC-158/At. 26.
[1933] Exhibit EC-158/At. 27.
[1934] Exhibit EC-158/At. 30.
[1935] Exhibit EC-158/At. 41_trans.
[1936] We note that "evaluate" is defined as "form an idea of the amount, number or value of; assess", *Concise Oxford English Dictionary*, Eleventh Ed. 2004, p. 493.

organisms and the possible development of resistance in insects".[1937] The document highlights studies of undesired effects on non-target organisms related to the consumption of Bt maize but does not itself make an evaluation of the potential for adverse health effects or the likelihood of these undesired effects occurring in the event that MON810 maize were to be introduced.[1938] The Reasons document also identified one study which noted that "further effects on the food chain [of consumption of Bt pollen by monarch butterflies] are possible."[1939] Yet, there is no evaluation of the potential for adverse health effects or the likelihood of such effects occurring.

7.3095 Furthermore, we note that with respect to one of the risks identified in the Reasons document, namely the development of resistance to Bt toxin in insects, the Reasons document states that "[t]he risk for related groups of insects [...] cannot be assessed conclusively based on the available data."[1940] This statement further confirms that Austria did not "evaluate" or "assess" the alleged risk.

7.3096 Accordingly, we are of the view that the Reasons document does not meet the definition of a risk assessment as provided in Annex A(4). We therefore consider that the Reasons document cannot be considered a risk assessment within the meaning of Annex A(4) and Article 5.1.

7.3097 We now turn to the scientific studies referred to by Austria in its Reasons document. Each of these studies describes aspects of Bt toxin impacts on insects. The study by Losey, entitled "Transgenic pollen harms monarch larvae"[1941], describes results from a laboratory experiment in which monarch butterfly caterpillars were fed Bt maize pollen. The study focuses on a variety of Bt maize other than MON810 maize. Furthermore, while the Losey study notes that results on larvae consumption and growth rates have "potentially profound implications for the conservation of monarch butterflies" there is no attempt to evaluate these potential implications, rather the study notes that the experimental results point to possible environmental outcomes. For example, in arguing that monarch butterfly caterpillars are at risk from the production of Bt maize, the study states that "[t]he large land area covered by corn in this region *suggests* that a substantial portion of available milkweeds *may be* within range of corn pollen deposition".[1942] Hence, we do not consider that the Losey study in itself constitutes a risk assessment within the meaning of either the first or the second clause of Annex A(4) and Article 5.1.

7.3098 The second study, by Hilbeck *et al.*, on "[t]oxicity of Bacillus thuringiensis Cry1Ab Toxin to the Predator Chrysoperla carnea (Neuroptera: Chrysopidae)"[1943] described a feeding study in which insects were fed a liquid diet containing Bt toxins, rather than being fed Bt plants directly. Thus, we do not consider that this study evaluated the potential for adverse effects associated with the insects eating MON810 maize plants. In addition, in its conclusion it notes that "trials investigating predation efficiency and predator performance under field conditions are necessary before conclusions regarding the potential ecological relevance of the results presented [...] can be drawn."[1944] Hence, like the Losey study, the study by Hilbeck *et al.* does not evaluate the likelihood of an outcome in the field. Accordingly, as with the Losey study, we do not consider that the Hilbeck *et al*. study in itself constitutes a risk assessment within the meaning of either the first or the second clause of Annex A(4) and Article 5.1, although we accept that it may be of relevance for a risk assessment.

[1937] Exhibit EC-159/At. 3_trans p. 5.
[1938] Exhibit EC-159/At. 3_trans pp. 5-6.
[1939] Exhibit EC-159/At. 3_trans p. 6.
[1940] Exhibit EC-159/At. 3_trans p. 8.
[1941] Exhibit EC-158/At. 24.
[1942] Exhibit EC- 158/At. 24 (emphasis added).
[1943] Exhibit EC-158/At. 26.
[1944] Exhibit EC-158/26 p. 7.

7.3099 The third study, also by Hilbeck *et al.*, concerns "[e]ffects of transgenic Bacillus thuringiensis corn-fed prey on mortality and development time of immature *Chrysoperla carnea* (Neuroptera: Chrysopidae)".[1945] This study used a maize hybrid containing a gene from *Bacillus thuringiensis*. The study provides information regarding the impact on non-maize eating insects of eating herbivorous insects raised on Bt maize and thus is aimed at evaluating non-target impacts of Bt crop cultivation. While this study concludes that, in this experiment, differences in mortality exist for insect predators fed prey raised on Bt versus non-Bt maize, the study notes that "[n]o conclusions can be drawn at this point as to how results from [...] laboratory trials might translate in the field".[1946] This statement, in our view, implies that this study *per se* cannot be said to evaluate the alleged risks identified by Austria in its Reasons document. In addition, given the lack of conclusions concerning how the laboratory trials might translate in the field noted above, we do not consider that the second Hilbeck study provides an evaluation of the potential for adverse effects on insect health from the presence of Bt toxin in food or feedstuffs. Therefore, we do not consider that this study in itself constitutes a risk assessment within the meaning of either the first or the second clause of Annex A(4) and Article 5.1, although we accept that it may be of relevance for a risk assessment.

7.3100 Finally, we recall that the European Communities provided as evidence a study by Austria on toxicological and allergological risks related to biotech products (the March 2003 document).[1947] As we noted above with respect to T25 maize, we consider that this study evaluates risk assessment *procedures*, and not the potential for adverse effects on human or animal health arising from the consumption of specific foods containing or consisting of GMOs. We therefore think that this March 2003 study does not constitute a risk assessment within the meaning of Annex A(4) and Article 5.1.

7.3101 In the light of the foregoing, we conclude that the above-mentioned documents relied on by Austria to justify its safeguard measure are not risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3102 Furthermore, in connection with the documents relied on by Austria, we should also note the European Communities' argument that Austria's safeguard measure was based on an assessment "appropriate to the circumstances" within the meaning of Article 5.1. The European Communities submits that the circumstances in the case of the Austrian safeguard measure include the fact that, from Austria's perspective, relevant scientific evidence was or is insufficient. We recall our previous consideration of the European Communities' argument based on the phrase "appropriate to the circumstances" within the meaning of Article 5.1 in paragraphs 7.3031-7.3032 above, and consider that our conclusions there apply *mutatis mutandis* to this measure.

7.3103 We have found above that none of the documents relied on by Austria with regard to its safeguard measure on MON810 maize constitute risk assessments. However, the European Communities contends that there is a document other than the documents relied on by Austria which constitutes a risk assessment for MON810 maize. The document in question is the "risk assessment [which] was carried out at the time when the original Community consent was given" (hereafter the "original risk assessment").[1948] It is not clear from this assertion whether the European Communities is referring to the risk assessment conducted by the lead CA or to that conducted by the SCP.[1949] In

[1945] Exhibit EC-158/At. 27.
[1946] Exhibit EC-158/At. 27 p. 485.
[1947] *See supra*, para. 7.3069.
[1948] EC reply to Panel question No. 107.
[1949] Exhibits EC-159/Ats. 1-2; CDA-82; US-55 (referencing original SCP risk assessment); ARG–44 (referencing original SCP risk assessment).

any event, we have noted above that it is not in dispute that both of these documents constitute risk assessments within the meaning of Annex A(4) and Article 5.1

7.3104 In addition, we note that none of the Parties has argued that, on the date of establishment of this Panel, the risk assessments conducted by the lead CA and the SCP were no longer "appropriate to the circumstances". In the light of this, and in view of our findings below with regard to whether the Austrian safeguard measure on MON810 maize is "based on" these risk assessments, we do not need to examine this issue further.

"Based on"

7.3105 We now turn to the question of whether, at the time of establishment of this Panel, the Austrian safeguard measure on MON810 maize was "based on" either the risk assessment of the lead CA or that conducted by the SCP.[1950]

7.3106 We note that the European Communities' arguments in respect of this issue were the same as those it presented in the context of Austria's safeguard measure on T25 maize. We have addressed these arguments above and have reached the conclusion that Austria's safeguard measure on T25 maize cannot be considered to be "based on" the risk assessments performed by the lead CA and the SCP in relation to T25 maize. This conclusion, and the reasoning supporting it, also apply, *mutatis mutandis*, to Austria's safeguard measure on MON810 maize and the risk assessments performed by the lead CA and the SCP in relation to MON810 maize. This is because, as in the case of Austria's safeguard measure on T25 maize:

(a) we are not aware of any divergent opinions expressed in the risk assessments which were conducted by the lead CA and the SCP with regard to MON810 maize;

(b) the European Communities or Austria did not explain, by reference to these risk assessments, how and why Austria assessed the risks differently, and did not provide a revised or supplemental assessment of the risks;

(c) the European Communities has not identified possible uncertainties or constraints in the risk assessments in question, and has not explained why, in view of any such uncertainties or constraints, Austria's prohibition is warranted by the relevant risk assessments; and

(d) there is no apparent rational relationship between Austria's safeguard measure, which imposes a prohibition, and risk assessments which found no evidence that MON810 maize is likely to cause adverse effects on human or animal health and the environment.

7.3107 Thus, in view of our conclusion that Austria's safeguard measure on MON810 maize cannot be considered to be "based on" the risk assessments performed by the lead CA or the SCP in relation to MON810 maize, and recalling the fact that no other risk assessment which might reasonably

[1950] We recall that we must examine as part of our analysis whether the safeguard measure is based on either risk assessment, as it is not clear whether the original risk assessment referred to by the European Communities is the risk assessment conducted by the lead CA or that conducted by the SCP.

support Austria's safeguard measure has been provided to us, we find that the Austrian safeguard measure is not based on a risk assessment pursuant to Article 5.1.[1951]

Overall conclusions

7.3108 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on MON810 maize is not based on a risk assessment.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on MON810 maize is not based on a risk assessment.

7.3109 In view of our findings in the previous paragraph with regard to DS291 (United States) and DS293 (Argentina), it is necessary to examine, in addition, whether the Austrian safeguard measure on MON810 maize is consistent with the requirements of Article 5.7 of the *SPS Agreement*. It is only once we have completed this additional examination that we can come to a final conclusion regarding the consistency of the Austrian safeguard measure on MON810 maize with Article 5.1 of the *SPS Agreement*. We undertake the necessary examination under Article 5.7 in the next section.

(v) France – MS1/RF1 oilseed rape (EC-161)

7.3110 We now turn to the analysis of France's measure on MS1/RF1 oilseed rape (EC-161). The first issue we will address is whether the documents France relies on to justify its safeguard measure meet the definition of a risk assessment.

"Risk assessment"

7.3111 We recall from the Reasons document that the main concerns of France were related to the risk of contamination of traditional oilseed rape by genetically modified oilseed rape; the likelihood of transfer of the herbicide-tolerance gene to adventitious flora; and the overall impact on the environment or long-term ecological effects of MS1/RF1 oilseed rape (EC-161).[1952] With respect to France's concerns related to gene flow and pollen dispersal, we note that France makes reference to a number of scientific studies. However, these studies were not submitted as evidence to the Panel. We therefore cannot determine whether any of these studies constitutes a risk assessment on which the safeguard measure on MS1/RF1 oilseed rape (EC-161) is based.

[1951] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the Austrian safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

[1952] Exhibits EC-161/At. 2 and EC-162/At. 5.

7.3112 We further recall that the decision by France to extend the suspension of the authorization for placing on the market of MS1/RF1 oilseed rape (EC-161) in July 2001 and July 2003 were allegedly based on the conclusions of opinions delivered by the BEC in 2001 and 2003, respectively. We note that the BEC delivered a further opinion on MS1/RF1 oilseed rape (EC-161) on 13 February 2004.[1953] We recall that we must assess whether the French safeguard measure on MS1/RF1 oilseed rape (EC-161) was based on a risk assessment as of August 2003, when this Panel was established. Since the 2004 opinion of the BEC was delivered after the time of establishment of the Panel, we do not take it into account as part of our analysis.

7.3113 Having identified the documents which France relies on to justify its safeguard measure, we can now go on to determine whether any of these documents constitutes a "risk assessment" within the meaning of the *SPS Agreement*. We recall our previous conclusion that France's concerns fall within the scope of Annex A(1)(a) and/or (d). We consider, therefore, that the first clause of Annex A(4) to the *SPS Agreement* provides the relevant definition for the "risk assessment" to be carried out for France's measure on MS1/RF1 oilseed rape (EC-161) and consider that the requirements for such a risk assessment, as clarified by the Appellate Body in *Australia–Salmon*, apply.

7.3114 The Panel begins its analysis with France's Reasons document. In this document, France points to new scientific evidence which, according to France, raises uncertainty with respect to the potential risks related to MS1/RF1 oilseed rape (EC-161), in particular regarding the environmental effects associated with out-crossing between MS1/RF1 oilseed rape (EC-161) and other plants. According to France, this new scientific evidence raises doubts with regard to the environmental safety of MS1/RF1 oilseed rape (EC-161).

7.3115 We note that nothing in the Reasons document indicates that France has made a new assessment of the alleged risks in the light of the scientific evidence invoked by France. Indeed, we are of the view that the statement in the Reasons document that "these possible developments in agronomic practices must be assessed in terms of their overall impact on the environment"[1954] implies that France is calling for further study rather than presenting a new assessment. Furthermore, the Reasons document notes that a prohibition of MS1/RF1 oilseed rape (EC-161) is justified "pending a clear and full scientific report on these issues".[1955] Consequently, we are of the view that the Reasons document does not itself constitute an "assessment" of risks within the meaning of Annex A(4) and Article 5.1.[1956]

7.3116 We also note that while the Reasons document refers to the likelihood of risks arising in respect of MS1/RF1 oilseed rape (EC-161), the document does not "evaluate" the likelihood of the risk of establishment, entry or spread of a pest (*in casu*, hybrid plants) "according to the [SPS] measures which might be applied". It is merely concluded that "dispersal into the environment [of herbicide tolerance transgenes] is likely".[1957] The discussion in the Reasons document cannot therefore be said to meet the definition of a risk assessment as defined in Annex A(4).

[1953] Exhibit EC-161/At. 10.
[1954] Exhibit EC-161/At. 2 p. 3.
[1955] *Ibid.*, p. 4.
[1956] We note that in its Reasons document, France refers to numerous scientific studies. However, these studies were not submitted to the Panel as evidence. Therefore, we can not evaluate in detail whether any of these documents would constitute a risk assessment within the meaning of Annex A(4) and Article 5.1.
[1957] Exhibit EC-161/At. 2, p. 2.

7.3117 Turning to the BEC opinions, we recall that the BEC apparently issued an opinion in 2001 which allegedly supported France's decision to prolong the safeguard measure for a further two years. As we noted earlier, it is not clear to the Panel whether this opinion of the BEC was submitted to us as evidence. An undated report by the BEC has been provided.[1958] This document makes reference to the French decision to take a safeguard measure in November 1998, and to production data in 2000. The document addresses concerns with regard to both genetically modified sugar beet and oilseed rape. For the sake of our analysis, we will assume that this document is the 2001 opinion of the BEC (hereafter "the 2001 BEC report"). According to this report, the BEC "proceeded to make an expert appraisal of the scientific information which was available for assessing the impacts on the environment of genetically modified oilseed rape and beet plants which were tolerant to a herbicide".[1959] In this context, reference is made to documents appended to the opinion, however these documents were not provided to the Panel. The 2001 BEC report identifies some possible ecological and agronomic impacts of herbicide tolerant oilseed rape. These include the "possible proliferation of the tolerant plants in the ecosystem"; the "possible development of adventitious flora [...]"; and possible changes in the ability of farmers to carry out weed control.[1960]

7.3118 We note that the 2001 BEC report purports to provide some evaluation of likelihood with respect to the "ability of oilseed rape to hybridize".[1961] Specifically, the report indicates that "the hybridizations which have been observed in England and in certain countries in the north of Europe are very unlikely in France".[1962] The report indicates that the studies in France focussed on "the analysis of the probability" of obtaining three types of hybrids, involving wild radish (*Raphanus raphanistrum*), short-pod mustard (*Hirschfeldia incana*) and wild mustard (*Sinapis arvensis*). The report indicates that "oilseed rape hybridizes rarely with wild radish, even more rarely with short-pod mustard and not at all with wild mustard".[1963] With respect to consequences for the environment, the report states: "In the case of genes for tolerance to a herbicide, and in natural environments, there is no information which leads one to suppose that the ability of plants, which have received these genes, to multiply and invade environments should be different from that of any other oilseed rape plant which has escaped from farmed land or from that of any other wild-type crucifer."[1964]

7.3119 The 2001 BEC report goes on to identify a number of areas for further study.[1965] Finally, the report contains the following "general conclusion": "The Biomolecular Engineering Committee is of the opinion that, even if cultivating genetically modified oilseed rapes which are tolerant to herbicides does not present any direct risks for the environment, a transitional phase of two years would make it possible, by carrying out experiments on areas of different scale, to validate the forms of management which are proposed for weed control and for coexistence between two methods of agriculture."[1966]

7.3120 With reference to the requirements for a risk assessment as clarified by the Appellate Body in *Australia–Salmon*[1967], the Panel notes that unlike the Reasons document, the 2001 BEC report does appear to provide some evaluation of the likelihood of entry, establishment or spread of one of the "pests" of concern, that is of hybrids between herbicide tolerant oilseed rape and some wild plants.

[1958] Exhibit EC-161/At. 6, with translations of the summary and body of this document apparently submitted as EC-161/Ats. 7 and 8, respectively. None of these submissions are dated.
[1959] Exhibit EC-161/At. 8, p.5.
[1960] *Ibid*., p.5.
[1961] *Ibid*., p.9
[1962] *Ibid*.
[1963] *Ibid*.
[1964] *Ibid*., p. 10.
[1965] *Ibid*., p. 11.
[1966] Exhibit EC-161/At. 8, p. 19.
[1967] *See supra*, para. 7.3040.

However, this is addressed, in the context of the BEC report, with respect to all herbicide tolerant oilseed rape varieties and not specifically those which are genetically modified. Furthermore, we note that the 2001 BEC report does not provide any analysis of the associated potential biological and economic consequences of these hybrids, nor does it purport to evaluate the likelihood of entry, establishment or spread of these hybrids according to the SPS measures which might be applied. Consequently, we do not consider that the 2001 BEC report fulfils all of the criteria of a risk assessment in accordance with the definition in Annex A(4).

7.3121 The decision by France in July 2003 to further prolong its safeguard measure on MS1/RF1 oilseed rape (EC-161) was allegedly supported by another opinion of the BEC issued in July 2003 (hereafter "the 2003 BEC report").[1968] We note that the 2003 BEC report refers to the concerns identified by France at the time the safeguard measure was first taken. The 2003 BEC report points to some new elements of information and to on-going research which it indicates may shed new light on some of the conclusions of the 2001 BEC report.[1969] However, the 2003 BEC report does not contain any evaluation of new information. Rather, the report calls for further analysis and for the organization of a scientific workshop to consider whether this information might affect the opinions contained in the 2001 BEC report.[1970] We note that this workshop, which was held in November 2003, resulted in the issuance of another report by the BEC in February 2004. As we have previously indicated, we will not take into account the BEC opinion of February 2004.[1971]

7.3122 In the light of the foregoing, we conclude that the above-mentioned documents relied on by France to justify its safeguard measure are not risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3123 Furthermore, in connection with the documents relied on by France, we should also note the European Communities' argument that France's safeguard measure was based on an assessment "appropriate to the circumstances" within the meaning of Article 5.1. The European Communities submits that the circumstances in the case of the French safeguard measure include the fact that, from France's perspective, relevant scientific evidence was or is insufficient. We recall our previous consideration of the European Communities' argument based on the phrase "appropriate to the circumstances" within the meaning of Article 5.1 in 7.3031-7.3032 above, and consider that our conclusions there apply *mutatis mutandis* to this measure.

7.3124 We have found above that none of the documents relied on by France with regard to its safeguard measure on MS1/RF1 oilseed rape (EC-161) constitute risk assessments. However, the European Communities contends that there is a document other than the documents relied on by France which constitutes a risk assessment for MS1/RF1 oilseed rape (EC-161). The document in question is the "risk assessment [which] was carried out at the time when the original Community consent was given" (hereafter the "original risk assessment").[1972] As we understand it, the European Communities in this instance is referring to the risk assessment conducted by the lead CA. This is because the Commission did not consult the SCP before approving MS1/RF1 oilseed rape (EC-161).[1973] As we have noted above, it is not in dispute that the lead CA's assessment constitutes a risk assessment within the meaning of Annex A(4) and Article 5.1.

[1968] Exhibit EC-161/At. 9.
[1969] Exhibit EC-161/At. 9 p. 1.
[1970] Exhibit EC-161/At. 9 p. 3.
[1971] *See supra*, para. 7.3112.
[1972] EC reply to Panel question No. 107.
[1973] The SCP was only established in 1997. Exhibits US-61; CDA-69.

7.3125 In addition, we recall that none of the Parties has argued that, on the date of establishment of this Panel, the risk assessment conducted by the lead CA was no longer "appropriate to the circumstances". In the light of this, and in view of our findings below with regard to whether the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is "based on" this risk assessment, we do not need to examine this issue further.

"Based on"

7.3126 We now turn to the question of whether, at the time of establishment of this Panel, the French safeguard measure on MS1/RF1 oilseed rape (EC-161) was "based on" the risk assessment of the lead CA.

7.3127 We note that the European Communities' arguments in respect of this issue were the same as those it presented in the context of Austria's safeguard measure on T25 maize. We have addressed these arguments above and have reached the conclusion that Austria's safeguard measure on T25 maize cannot be considered to be "based on" the risk assessments performed by the lead CA and the SCP in relation to T25 maize. This conclusion, and the reasoning supporting it, also apply, *mutatis mutandis*, to France's safeguard measure on MS1/RF1 oilseed rape (EC-161) and the risk assessment performed by the lead CA in relation to T25 maize. This is because, as in the case of Austria's safeguard measure on T25 maize:

(a) we are not aware of any divergent opinions expressed in the risk assessments which were conducted by the lead CA and the SCP with regard to MS1/RF1 oilseed rape (EC-161);

(b) the European Communities or France did not explain, by reference to these risk assessments, how and why France assessed the risks differently, and did not provide a revised or supplemental assessment of the risks;

(c) the European Communities has not identified possible uncertainties or constraints in the risk assessments in question, and has not explained why, in view of any such uncertainties or constraints, France's prohibition is warranted by the relevant risk assessments; and

(d) there is no apparent rational relationship between France's safeguard measure, which imposes a prohibition, and risk assessments which found no evidence that MS1/RF1 oilseed rape (EC-161) is likely to cause any adverse effects on human health and the environment.

7.3128 Thus, in view of our conclusion that France's safeguard measure on MS1/RF1 oilseed rape (EC-161) cannot be considered to be "based on" the risk assessments performed by the lead CA or the SCP in relation to MS1/RF1 oilseed rape (EC-161), and recalling the fact that no other risk assessment which might reasonably support France's safeguard measure has been provided to us, we find that the French safeguard measure is not based on a risk assessment pursuant to Article 5.1.[1974]

[1974] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the French safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

Overall conclusions

7.3129 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is not based on a risk assessment.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is not based on a risk assessment.

7.3130 In view of our findings in the previous paragraph with regard to DS291 (United States) and DS292 (Canada), it is necessary to examine, in addition, whether the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is consistent with the requirements of Article 5.7 of the *SPS Agreement*. It is only once we have completed this additional examination that we can come to a final conclusion regarding the consistency of the French safeguard measure on MS1/RF1 oilseed rape (EC-161) with Article 5.1 of the *SPS Agreement*. We undertake the necessary examination under Article 5.7 in the next section.

(vi) France – Topas oilseed rape

7.3131 We now turn to the analysis of France's measure on Topas oilseed rape. The first issue we will address is whether the documents France relies on to justify its safeguard measure meet the definition of a risk assessment.

"Risk assessment"

7.3132 We note that France relied on the same documents with respect to its safeguard measure on Topas oilseed rape as for its measure on MS1/RF1 oilseed rape (EC-161). We recall our analysis of the relevant documents relied on by France in respect of its safeguard measure on MS1/RF1 oilseed rape (EC-161) above. Based on a review of these documents, we found that none constituted a risk assessment within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*. Consistent with our analysis above, we also find in the case of the French safeguard measure on Topas oilseed rape that none of the documents relied on by France constitute a risk assessment.

7.3133 Furthermore, in connection with the documents relied on by France, we should also note the European Communities' argument that France's safeguard measure was based on an assessment "appropriate to the circumstances" within the meaning of Article 5.1. The European Communities submits that the circumstances in the case of the French safeguard measure include the fact that, from France's perspective, relevant scientific evidence was or is insufficient. We recall our previous consideration of the European Communities' argument based on the phrase "appropriate to the circumstances" within the meaning of Article 5.1 in paragraphs 7.3031-7.3032 above, and consider that our conclusions there apply *mutatis mutandis* to this measure.

7.3134 We have found above that none of the documents relied on by France with regard to its safeguard measure on Topas oilseed rape constitute risk assessments. However, the European Communities contends that there is a document other than the documents relied on by France which constitutes a risk assessment for Topas oilseed rape. The document in question is the "risk assessment [which] was carried out at the time when the original Community consent was given" (hereafter the "original risk assessment").[1975] It is not clear from this assertion whether the European Communities is referring to the risk assessment conducted by the lead CA or to that conducted by the SCP.[1976] In any event, we have noted above that it is not in dispute that both of these documents constitute risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3135 In addition, we recall that none of the Parties has argued that, on the date of establishment of this Panel, the risk assessments conducted by the lead CA and the SCP were no longer "appropriate to the circumstances". In the light of this, and in view of our findings below with regard to whether the French safeguard measure on Topas oilseed rape is "based on" these risk assessments, we do not need to examine this issue further.

"Based on"

7.3136 We now turn to the question of whether, at the time of establishment of this Panel, the French safeguard measure on Topas oilseed rape was "based on" either the risk assessment of the lead CA or that conducted by the SCP.[1977]

7.3137 We note that the European Communities' arguments in respect of this issue were the same as those it presented in the context of Austria's safeguard measure on T25 maize. We have addressed these arguments above and have reached the conclusion that Austria's safeguard measure on T25 maize cannot be considered to be "based on" the risk assessments performed by the lead CA and the SCP in relation to T25 maize. This conclusion, and the reasoning supporting it, also apply *mutatis mutandis*, to France's safeguard measure on Topas oilseed rape and the risk assessments performed by the lead CA and the SCP in relation to Topas oilseed rape. This is because, as in the case of Austria's safeguard measure on T25 maize:

(a) we are not aware of any divergent opinions expressed in the risk assessments which were conducted by the lead CA and the SCP with regard to Topas oilseed rape;

(b) the European Communities or France did not explain, by reference to these risk assessments, how and why France assessed the risks differently, and did not provide a revised or supplemental assessment of the risks;

(c) the European Communities has not identified possible uncertainties or constraints in the risk assessments in question, and has not explained why, in view of any such uncertainties or constraints, France's prohibition is warranted by the relevant risk assessments; and

(d) there is no apparent rational relationship between France's safeguard measure, which imposes a prohibition, and risk assessments which found no evidence that Topas

[1975] EC reply to Panel question No. 107.
[1976] Exhibits EC-162/At. 1; CDA-63; US-62 (referencing original SCP risk assessment).
[1977] We recall that we must examine as part of our analysis whether the safeguard measure is based on either risk assessment, as it is not clear whether the original risk assessment referred to by the European Communities is the risk assessment conducted by the lead CA or that conducted by the SCP.

oilseed rape is likely to cause adverse effects on human or animal health and the environment.

7.3138 Thus, in view of our conclusion that France's safeguard measure on Topas oilseed rape cannot be considered to be "based on" the risk assessments performed by the lead CA or the SCP in relation to Topas oilseed rape, and recalling the fact that no other risk assessment which might reasonably support France's safeguard measure has been provided to us, we find that the French safeguard measure is not based on a risk assessment pursuant to Article 5.1.[1978]

Overall conclusions

7.3139 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the French safeguard measure on Topas oilseed rape is not based on a risk assessment.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the French safeguard measure on Topas oilseed rape is not based on a risk assessment.

7.3140 In view of our findings in the previous paragraph with regard to DS291 (United States) and DS292 (Canada), it is necessary to examine, in addition, whether the French safeguard measure on Topas oilseed rape is consistent with the requirements of Article 5.7 of the *SPS Agreement*. It is only once we have completed this additional examination that we can come to a final conclusion regarding the consistency of the French safeguard measure on Topas oilseed rape with Article 5.1 of the *SPS Agreement*. We undertake the necessary examination under Article 5.7 in the next section.

(vii) Germany – Bt-176 maize

7.3141 We now turn to Germany's safeguard measure on Bt-176 maize. We recall that we must determine whether Germany's measure is "based on" a risk assessment pursuant to Article 5.1. In this context, the first issue we will address is whether the documents Germany relies on to justify its safeguard measure meet the definition of a risk assessment.

"Risk assessment"

7.3142 We recall that Germany (Robert Koch Institute) notified its decision to prohibit Bt-176 maize to the Commission in a letter dated 4 April 2000.[1979] In this letter, Germany explained the reasons for

[1978] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the French safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

[1979] Exhibit EC-158/At. 21. We note that the concerns of Germany were also set out in an earlier letter addressed by the Robert Koch Institute to the Commission on 2 March 2000 (Exhibit EC-158/At. 19_trans), as

adopting its safeguard measure on Bt-176 maize. The letter refers to the following scientific studies in support of Germany's safeguard measure:

(i) Study by Losey (1999), "Transgenic pollen harms monarch larvae"[1980];
(ii) Study by Hilbeck *et al.* (January 1999), "Prey-mediated effects of Cry1Ab toxin and protoxin and Cry2A protoxin on the predator *Chrysoperla carnea*"[1981];
(iii) Study by Hilbeck *et al.* (1998), "Toxicity of *Bacillus thuringiensis* Cry1Ab Toxin to the Predator *Chrysoperla carnea* (Neuroptera: Chrysopidae)"[1982];
(iv) Study by Hilbeck *et al.* (1998), "Effects of transgenic *Bacillus thuringiensis* corn-fed prey on mortality and development time of immature *Chrysoperla carnea* (Neuroptera: Chrysopidae)"[1983];
(v) Study by Saxena *et al.* (1999), "Insecticidal toxin in root exudates from *Bt* corn"[1984];
(vi) Öko-Institut e. V. (Dec. 1999) – Study on the "Therapeutical relevance of antibiotics in connection with the use of antibiotic resistance genes in transgenic plants"[1985].

7.3143 Having determined the documents relied on by Germany with respect to its safeguard measure on Bt-176 maize, we must now determine whether one or more of these documents constitutes a "risk assessment" within the meaning of the *SPS Agreement*.

7.3144 We recall our conclusions that the concerns identified by Germany, relating to possible effects on non-target organisms, the development of resistance to Bt toxins in insects, the possible adverse effects of Bt toxin in the soil and potential for development of antibiotic resistance, fall within the scope of Annex A(1)(a), (b) and/or (d) of the *SPS Agreement*. Both clauses of Annex A(4) to the *SPS Agreement* define the "risk assessment" to be carried out for SPS measures which have these types of purposes. As discussed earlier, Germany's concern relating to potential increased development of antibiotic resistance could also fall within the scope of Annex A(1)(b) of the *SPS Agreement*. The second clause of Annex A(4) to the *SPS Agreement* defines the "risk assessment" to be carried out for SPS measures which fall within the scope of Annex A(1)(b).

7.3145 We begin our analysis with Germany's Reasons document. That document includes references to possibilities of risks, but does not evaluate the potential or likelihood of such risks occurring. For example, the document states that "it cannot be excluded that unacceptable adverse effects on other lepidoptera species and on some other insects would occur."[1986] Similarly, the document states that "an ecologically unacceptable development of resistance may occur in the event of unrestricted cultivation"[1987] of Bt maize. With regard to possible effects of Bt-toxin on soil micro-organisms, the Reasons document states that these effects "cannot be excluded".[1988] Finally, the Reasons document notes that increased development of antibiotic resistance following uptake of the antibiotic resistance gene contained in Bt-176 maize "cannot [be] excluded".[1989] As noted by us

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well as in a letter from the Robert Koch Institute to Gaedertz Attorneys-at-Law on 31 March 2000 (Exhibit US-65).

[1980] Exhibit EC-158/At. 24.
[1981] Exhibit EC-158/At. 25.
[1982] Exhibit EC-158/At. 26.
[1983] Exhibit EC-158/At. 27.
[1984] Exhibit EC-158/At. 28.
[1985] Exhibit EC-158/At. 29.
[1986] Exhibit EC-158/At. 21, p.1.
[1987] *Ibid*., p. 2.
[1988] *Ibid*.
[1989] *Ibid*.

above, the Appellate Body in *Australia – Salmon* clarified that a risk assessment as defined in the first clause of Annex A(4) must evaluate the likelihood or probability of relevant risks.[1990]

7.3146 Regarding the concern over the possible development of antibiotic resistance, we further note the statement in the Reasons document to the effect that on the basis of current knowledge, unacceptable adverse effects are not to be expected in view of the already widespread resistance in bacteria to the relevant antibiotics, if, as the EC approval decision envisages, the quantity of Bt-176 maize seeds which may be sown is limited to 12 tonnes/year.[1991] Thus, the Reasons document suggests that there is only a small potential for adverse effects on human or animal health arising from the presence of ARMG in Bt-176 maize. However, the Reasons document does not itself contain and provide the information necessary to an evaluation of the potential for adverse effects on human or animal health. Accordingly, we consider that the Reasons document constitutes, not a complete, self-contained, scientific evaluation of the potential for adverse effects, but only part of such an evaluation. Hence, we are of the view that the Reasons document on its own does not meet the definition of a risk assessment as provided in the second clause of Annex A(4).

7.3147 We now turn to the scientific studies which Germany relied on in respect of its safeguard measure. The first four of these studies relate to impacts of Bt toxins on insects while the fifth examines the use of antibiotic resistance marker genes in transgenic plants. We recall that we have previously examined the Losey study as well as the two 1998 Hilbeck *et al*. studies in the context of our consideration of Austria's safeguard measure on MON810 maize. We recall our conclusions that none of these studies evaluate the potential or likelihood of the occurrence of the adverse effect identified in Germany's Reasons document. We do not consider, therefore, that any of these three studies in themselves constitute a risk assessment, although we accept that they may be of relevance for an eventual risk assessment.

7.3148 The 1999 Hilbeck *et al.* document describes laboratory feeding experiments which were carried out to study the effects of insects feeding on other insects which had had an artificial diet containing Bt proteins. While the study's conclusions highlight the importance of assessing the non-target impacts of Bt toxins, it does not do this in the context of the Bt-176 maize. In particular, this study does not provide an evaluation of the likelihood of risks associated with the insects eating Bt-176 maize plants. Nor does it evaluate the likelihood of an outcome in the field. For example, the study notes "field studies must be conducted to assess the ecological consequences"[1992] of the study's results. We do not consider, therefore, that this study in and of itself constitutes a risk assessment, although we accept that it may be of relevance for an eventual risk assessment.

7.3149 The fifth study, by Saxena *et al.*, examines the potential for Bt toxin to be released into the soil from the roots of Bt maize. The study used a variety of Bt maize called NK4640Bt which differs from the variety which is subject to the German safeguard measure. While the study measured the toxin released into the soil surrounding the roots of maize plants, the authors note that they have "no indication of how soil communities might be affected by Bt toxin in [...] the field" and that "[f]urther investigations will be necessary to shed light on what might happen underground".[1993] Thus, this study neither purports to evaluate the potential consequences associated with the release of Bt exudates into the soil, nor provides information specifically related to the product at issue in this safeguard measure, Bt-176 maize. Therefore, we do not consider that this study, by itself, meets the definition of a risk assessment as provided in Annex A(4).

[1990] Appellate Body Report, *Australia – Salmon*, paras. 123-124.
[1991] Exhibit EC-158/At. 21, p. 3.
[1992] Exhibit EC-158/At. 25 p. 11.
[1993] Exhibit EC-158/At. 28, p. 480.

7.3150 The final study, by the Öko-Institut e.V., provides an overview of the types of antibiotics which could be affected by the possible development of resistance to antibiotics due to the use of antibiotic resistance marker genes in transgenic plants. The study describes the therapeutic importance of a variety of antibiotics, but does not evaluate the likelihood that the consumption of transgenic plants in general, much less of Bt-176 maize specifically, will lead to the spread of diseases due to the development of resistance to the relevant antibiotics. The authors state that "the wide dispersal of [antibiotic resistance] genes via agriculture, animal feeding and in the human food chain provides an additional path for the development of antibiotic resistance" and that "this risk is not negligible" as outside hospitals the resistance problem was still smaller.[1994] The study further states that "particularly worrying" is the fact that "there are indications" that the transfer rate of antibiotic resistance in soils can be furthered by herbicide use.[1995] The study goes on to say that because herbicide applications are the rule in agriculture and because many ARMG in transgenic plants were transferred together with herbicide resistance genes, this "possibly creates conditions which could [...] have a promoting influence on the development of resistance".[1996] The study therefore recommends that ARMG should not be used any more.

7.3151 Hence, the study by the Öko-Institut asserts that there is a potential for adverse effects on human or animal health from the presence of ARMG in transgenic plants used as or in food/feed. However, it does not "evaluate" that potential. Indeed, the study devotes only a few paragraphs to transgenic plants containing ARMG as an additional source of possible development of antibiotic resistance. Moreover, the study does not evaluate the likelihood of spread of diseases due to the presence of ARMG in transgenic plants. As indicated, the study refers to possibilities, but it does not determine likelihoods. We therefore do not consider that this study meets the definition of a risk assessment as provided in Annex A(4).

7.3152 In the light of the foregoing, we conclude that the above-mentioned documents relied on by Germany to justify its safeguard measure are not risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3153 Furthermore, in connection with the documents relied on by Germany, we should also note the European Communities' argument that Germany's safeguard measure was based on an assessment "appropriate to the circumstances" within the meaning of Article 5.1. The European Communities submits that the circumstances in the case of the German safeguard measure include the fact that, from Germany's perspective, relevant scientific evidence was or is insufficient. We recall our previous consideration of the European Communities' argument based on the phrase "appropriate to the circumstances" within the meaning of Article 5.1 in paragraphs 7.3031 and 7.3032 above, and consider that our conclusions there apply *mutatis mutandis* to this measure.

7.3154 We have found above that the documents provided by the Parties in relation to Germany's safeguard measure on Bt-176 maize on which Germany relied on do not constitute a risk assessment. However, the European Communities contends that there is a document other than the documents relied on by Germany which constitutes a risk assessment for Bt-176 maize. The document in question is the "risk assessment [which] was carried out at the time when the original Community consent was given" (hereafter the "original risk assessment").[1997] It is not clear from this assertion whether the European Communities is referring to the risk assessment conducted by the lead CA or to any of the risk assessments which were conducted by the Scientific Committee for Pesticides (SCPE),

[1994] Exhibit EC-158/At. 29, p. 28.
[1995] *Ibid*.
[1996] *Ibid*.
[1997] EC reply to Panel question No. 107.

the Scientific Committee for Animal Nutrition (SCAN) or the SCF.[1998] In any event, we have noted above that it is not in dispute that these documents constitute risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3155 In addition, we note that none of the Parties has argued that, on the date of establishment of this Panel, the risk assessments conducted by the lead CA and the risk assessments which were conducted by the SCPE, the SCAN or the SCF were no longer "appropriate to the circumstances". In the light of this, and in view of our findings below with regard to whether Germany's safeguard measure is "based on" these risk assessments, we do not need to examine this issue further.

"Based on"

7.3156 We now turn to the question of whether, at the time of establishment of this Panel, the German safeguard measure on Bt-176 maize was "based on" either the risk assessment of the lead CA or any of those conducted by the SCPE, the SCAN or the SCF.[1999]

7.3157 We note that the European Communities' arguments in respect of this issue were the same as those it presented in the context of Austria's safeguard measure on T25 maize. We have addressed these arguments above and have reached the conclusion that Austria's safeguard measure on T25 maize cannot be considered to be "based on" the risk assessments performed by the lead CA and the SCP in relation to T25 maize. This conclusion, and the reasoning supporting it, also apply, *mutatis mutandis*, to Germany's safeguard measure on Bt-176 maize and the risk assessment performed by the lead CA and the risk assessments which were conducted by the Scientific Committee for Pesticides (SCPE), the Scientific Committee for Animal Nutrition (SCAN) or the SCF in relation to Bt-176 maize. This is because, as in the case of Austria's safeguard measure on T25 maize:

(a) we are not aware of any divergent opinions expressed in the risk assessments which were conducted by the lead CA and those which were conducted by the SCPE, the SCAN or the SCF with regard to Bt-176 maize;

(b) the European Communities or Germany did not explain, by reference to these risk assessments, how and why Germany assessed the risks differently, and did not provide a revised or supplemental assessment of the risks;

(c) the European Communities has not identified possible uncertainties or constraints in the risk assessments in question, and has not explained why, in view of any such uncertainties or constraints, Germany's prohibition is warranted by the relevant risk assessments; and

(d) there is no apparent rational relationship between Germany's safeguard measure, which imposes a prohibition, and risk assessments which found no evidence that Bt-176 maize will give rise to any adverse effects on human or animal health and the environment.

[1998] Exhibit EC-158/Ats. 1-3; EC-158/At. 4; EC-158/At. 5; EC-158/At. 6.

[1999] We recall that we must examine as part of our analysis whether the safeguard measure is based on any of those risk assessments, as it is not clear whether the original risk assessment referred to by the European Communities is the risk assessment conducted by the lead CA or those conducted by the SCPE, the SCAN or the SCF.

7.3158 Thus, in view of our conclusion that Germany's safeguard measure on Bt-176 maize cannot be considered to be "based on" the risk assessment performed by the lead CA or the risk assessments which were conducted by the SCPE, the SCAN or the SCF in relation to Bt-176 maize, and recalling the fact that no other risk assessment which might reasonably support Germany's safeguard measure has been provided to us, we find that the German safeguard measure is not based on a risk assessment pursuant to Article 5.1.[2000]

Overall conclusions

7.3159 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the German safeguard measure on Bt-176 maize is not based on a risk assessment.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the German safeguard measure on Bt-176 maize is not based on a risk assessment.

7.3160 In view of our findings in the previous paragraph with regard to DS291 (United States) and DS293 (Argentina), it is necessary to examine, in addition, whether the German safeguard measure on Bt-176 maize is consistent with the requirements of Article 5.7 of the *SPS Agreement*. It is only once we have completed this additional examination that we can come to a final conclusion regarding the consistency of the German safeguard measure on Bt-176 maize with Article 5.1 of the *SPS Agreement*. We undertake the necessary examination under Article 5.7 in the next section.

(viii) Greece – Topas oilseed rape

7.3161 We now turn to the Greek safeguard measure on Topas oilseed rape. We recall that we must determine whether Greece's measure is "based on" a risk assessment pursuant to Article 5.1. In this context, the first issue we will address is whether the documents Greece relies on to justify its safeguard measure meet the definition of a risk assessment.

"Risk assessment"

7.3162 We start by recalling the documents on record in respect of this safeguard measure. We recall that Greece notified its Ministerial Decision to prohibit Topas oilseed rape to the Commission in a document dated 3 November 1998 (hereafter the "Reasons document"). In this document, Greece explained the reasons for adopting its safeguard measure on Topas oilseed rape. [2001]

[2000] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the German safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

[2001] Exhibit EC-162/At. 4

7.3163 Furthermore, in a letter of 3 March 2004 to the Commission, Greece provides further justification for its safeguard measure on Topas oilseed rape.[2002] In relation to this letter, we recall that our task is to assess whether the Greek safeguard measure was based on a risk assessment as of 29 August 2003, when this Panel was established. A risk assessment completed after August 2003 in our view would not assist the European Communities in rebutting the Complaining Parties' claim that the Greek safeguard measure was not based on a risk assessment in August 2003. We note that the March 2004 letter makes reference to two scientific studies. The first study was not submitted to the Panel. It is from the European Environment Agency and is entitled "Genetically Modified Organisms: The significance of gene flow through pollen transfer" and dated 21 March 2002. According to the March 2004 letter, the study characterizes oilseed rape as a high risk crop as far as gene transfer between crops and wild relative species is concerned. The second study is from the UK Advisory Committee on Releases to the Environment (ACRE) and is dated January 2004.[2003] According to the letter, the study concerns spring oilseed rape and confirms the March 2002 study. The ACRE study apparently refers to adverse effects on biodiversity, a significant decrease of the wild weed population and harmful effects on the higher levels of the food chain of the crop in question as compared to conventional crops. Considering that the first study was not submitted to us and that the second study dates from after August 2003, we do not review these studies with a view to determining whether they constitute a risk assessment within the meaning of Annex A(4) and Article 5.1.

7.3164 Finally, we note that in a letter of 17 March 2004 to the Commission, Greece refers to additional documents in support of its safeguard measure on Topas oilseed rape.[2004] The following documents were submitted to us and will be taken into account:

(i) Study by the Office of the Gene Technology Regulator (July 2002), "The biology and ecology of canola (Brassica napus)"[2005];
(ii) Several studies that constitute part of the Farm Scale Evaluations of spring-sown genetically modified crops (October 2003)[2006];
(iii) Study by Wilkinson *et al.* (2003), "Hybridization Between *Brassica napus* and *B. rapa* on a National Scale in the United Kingdom"[2007].

7.3165 Having determined the documents relied on by Greece with respect to its safeguard measure on Topas oilseed rape, we must now determine whether any of these documents constitutes a "risk assessment" within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*.

7.3166 As with Austria's safeguard measure for T25 maize, given the concerns raised by Greece in the context of Topas oilseed rape relating to environmental risks and consumer health, we consider that both the first and the second clause of Annex A(4) to the *SPS Agreement* define the "risk assessment" to be carried out for Greece's measure on Topas oilseed rape.

7.3167 We start our examination with the Reasons document notified by Greece in respect of its safeguard measure on Topas oilseed rape. The Reasons document alleges risks for the natural environment of Greece from spillage of seeds of Topas oilseed rape during transport. Specifically, the

[2002] Exhibit EC-162/At. 6_transl.
[2003] Exhibit EC-40.
[2004] Exhibit EC-162/At. 7.
[2005] Exhibit EC-162/At. 13.
[2006] Exhibit EC-162/At. 9-11. Although the Farm Scale Evaluations were published in October 2003, they contain the results of evaluations conducted over the 3-year period from 2000-2002.
[2007] Exhibit EC-162/At. 12.

Reasons document asserts that "it is certain that the seeds will escape into the environment and will give viable plants".[2008] It also asserts that "it is certain that [...] there will arise hybrid plants [weeds] bearing the glufosinate tolerance gene".[2009] It further asserts that glufosinate tolerant weeds "will" have a selective advantage over other weeds and consequently "will" dominate.[2010] Also, "there exists the risk" that, following the release of other herbicide tolerant GM plants, multiresistant weeds will arise.[2011] Finally, the resistant weeds "will" spread not only in the agricultural environment but also in the natural environment.[2012] As noted above, the Appellate Body in *Australia – Salmon* clarified that a risk assessment must evaluate the likelihood or probability of particular risks.[2013] The Reasons document reaches conclusions regarding the likelihood of the spread of certain pests, but it reaches these conclusions without any prior "evaluation" of relevant data and information. The relevant passages in the Reasons document are only a few paragraphs long and no results from studies or tests are contained in, or annexed to, the document. Additionally, we note that the Reasons document does not evaluate the likelihood of the spread of pests according to the SPS measures which might be applied. The document only addresses the likelihood of risks in the situation where no SPS measure is applied, *i.e.*, where Topas oilseed rape is released into the environment. For these reasons, we are of the view that the discussion in the Reasons document of potential environmental risks does not constitute a risk assessment within the meaning of Annex A(4) and Article 5.1.

7.3168 The Reasons document further notes that some of the wild plant varieties at issue are collected and consumed in Greece as food. Greece points out in this regard that if out-crossing were to confer on these wild plant varieties the herbicide resistance trait, the consequences of the consumption of these varieties would be unpredictable. Greece observes that these consequences have not been considered in the original risk assessment prior to the approval of Topas oilseed rape. Thus, while the Reasons document refers to unspecified adverse effects on human health arising from the consumption of hybrid plants, it does not provide any evaluation of the potential for such adverse effects to occur. We therefore do not consider that the discussion in the Reasons document of potential risks for the health of consumers constitutes a risk assessment within the meaning of Annex A(4) and Article 5.1.

7.3169 We now turn to the scientific studies relied on by Greece in respect of its safeguard measure. The first study, by the Office of the Gene Technology Regulator, focuses on the biology and ecology of a particular variety of oilseed rape – canola, or *Brassica napus* – and highlights the potential for outcrossing between this type of plant and its weedy relatives. The study states that while "the probability of outcrossing appears to be low", the biology of canola "ensures that a substantial number of outcrossed seeds can still be produced".[2014] Thus, the study evaluates the likelihood of outcrossing from canola. However, it does not do so for Topas oilseed rape, but for canola in general, including for canola which is not genetically modified. Also, consistent with its stated objective of addressing the biology and ecology of canola, the study does not evaluate the likelihood of the entry, establishment or spread of undesired cross-breeds according to the SPS measures which might be applied. We therefore do not consider that this study meets the definition of a risk assessment as provided in Annex A(4).

[2008] Exhibit EC-162/At. 4.
[2009] *Ibid*.
[2010] *Ibid*.
[2011] *Ibid*.
[2012] *Ibid*.
[2013] Appellate Body Report, *Australia – Salmon*, paras. 123-124.
[2014] Exhibit EC-162/At. 13 p. 13.

7.3170 The second set of studies report results from the Farm Scale Evaluations (FSEs) conducted in the United Kingdom. The first of these studies, by Squire *et al.*, summarizes the methods and results of the FSEs. This study emphasizes the difficulty of predicting the impact of growing GM crop varieties which are tolerant to herbicides (hereafter "GMHT crops"), due to the uncertainty about farmer management decisions. The study notes that "predictions [...] are particularly difficult since what happens will be strongly affected by the preference of farmers and by current economics."[2015] Another FSE study, by Haughton *et al.*, reports results regarding the impacts of the management of GMHT varieties on arthropods with particular reference to the weed vegetation that supports them. The study summarizes the effects on arthropods across a variety of GMHT crops, and notes that "the effects were indirect and related to herbicide management".[2016] The third study referenced by Greece, by Hawes *et al.*, seeks to determine whether differences in weed populations and biomass due to the impact of GMHT cropping result in changes in population trends of particular insects. The study's conclusions notes that "commercialization of GMHT crops would [...] be likely to have a range of effects on plant and invertebrate functional groups in the long-term".[2017] Each of these studies discusses GMHT crops in general rather than focusing specifically on the Topas oilseed rape, and none of these studies evaluates the likelihood of adverse effects from the entry, establishment or spread of GMHT crops according to the SPS measures which might be taken by Greece to reduce any potential risks. We therefore do not consider that these studies meets the definition of a risk assessment as provided in Annex A(4).

7.3171 The Wilkinson *et al.* study reports results regarding hybridization between two varieties of oilseed rape, *Brassica napus* and *B. rapa.*[2018] The study provides an estimate of GM hybrid abundance for the United Kingdom and notes that its findings help "set targets for strategies to eliminate hybridization and represent the first step toward quantitative risk assessment on a national scale."[2019] It also states that the presence of GM hybrids is not a risk in itself and does not imply inevitable ecological change. It notes that hybrid fitness and other factors affecting the likelihood of ecological change should also be assessed.[2020] These statements serve to demonstrate that the study does not take into account all factors that are relevant to an evaluation of the likelihood of environmental change caused by gene flow. Accordingly, we consider that the study does not constitute a risk assessment as defined in Annex A(4) and required by Article 5.1. We also note that the study does not claim that the estimates it provides are valid outside mainland Britain. We therefore do not consider that this study meets the definition of a risk assessment as provided in Annex A(4).

7.3172 In the light of the foregoing, we conclude that the above-mentioned documents relied on by Greece to justify its safeguard measure are not risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3173 Furthermore, in connection with the documents relied on by Greece, we should also note the European Communities' argument that Greece's safeguard measure was based on an assessment "appropriate to the circumstances" within the meaning of Article 5.1. The European Communities submits that the circumstances in the case of the Greek safeguard measure include the fact that, from Greece's perspective, relevant scientific evidence was or is insufficient. We recall our previous

[2015] Exhibit EC-162/At. 9 p. 1795.
[2016] Exhibit EC-162/At. 10 p. 1875.
[2017] Exhibit EC-162/At. 11 p. 1912.
[2018] We understand from the application for the deliberate release of this product that *Brassica napus* is the species of oilseed rape which has been modified to produce Topas oilseed rape.
[2019] Exhibit EC-162/At. 12, p. 457.
[2020] *Ibid*., p. 459.

consideration of the European Communities' argument based on the phrase "appropriate to the circumstances" within the meaning of Article 5.1 in paragraphs 7.3031-7.3032 above, and consider that our conclusions there apply *mutatis mutandis* to this measure.

7.3174 We have found above that the documents provided by the Parties in relation to Greece's safeguard measure on Topas oilseed rape on which Greece relied do not constitute a risk assessment. However, the European Communities contends that there is a document other than the documents relied on by Greece which constitutes a risk assessment for Topas oilseed rape. The document in question is the "risk assessment [which] was carried out at the time when the original Community consent was given" (hereafter the "original risk assessment").[2021] It is not clear from this assertion whether the European Communities is referring to the risk assessment conducted by the lead CA or to that conducted by the SCP.[2022] In any event, we have noted above that it is not in dispute that both of these documents constitute risk assessments within the meaning of Annex A(4) and Article 5.1

7.3175 In addition, we note that none of the Parties has argued that, on the date of establishment of this Panel, the risk assessments conducted by the lead CA and the SCP were no longer "appropriate to the circumstances". In the light of this, and in view of our findings below with regard to whether Greece's safeguard measure is "based on" these risk assessments, we do not need to examine this issue further.

"Based on"

7.3176 We now turn to the question of whether, at the time of establishment of this Panel, the Greek safeguard measure on Topas oilseed rape was "based on" either the risk assessment of the lead CA or that conducted by the SCP.[2023]

7.3177 We note that the European Communities' arguments in respect of this issue were the same as those it presented in the context of Austria's safeguard measure on T25 maize. We have addressed these arguments and have reached the conclusion that Austria's safeguard measure on T25 maize cannot be considered to be "based on" the risk assessments performed by the lead CA and the SCP in relation to T25 maize. This conclusion, and the reasoning supporting it, also apply, *mutatis mutandis*, to Greece's safeguard measure on Topas oilseed rape and the risk assessments performed by the lead CA and the SCP in relation to Topas oilseed rape. This is because, as in the case of Austria's safeguard measure on T25 maize:

(a) we are not aware of any divergent opinions expressed in the risk assessments which were conducted by the lead CA and the SCP with regard to Topas oilseed rape;

(b) the European Communities or Greece did not explain, by reference to these risk assessments, how and why Greece assessed the risks differently, and did not provide a revised or supplemental assessment of the risks;

(c) the European Communities has not identified possible uncertainties or constraints in the risk assessments in question, and has not explained why, in view of any such

[2021] EC reply to Panel question No. 107.
[2022] Exhibits EC-162/At. 1; CDA-63; US-70 (referencing original SCP risk assessment).
[2023] We recall that we must examine as part of our analysis whether the safeguard measure is based on either risk assessment, as it is not clear whether the original risk assessment referred to by the European Communities is the risk assessment conducted by the lead CA or that conducted by the SCP.

uncertainties or constraints, Greece's prohibition is warranted by the relevant risk assessments; and

(d) there is no apparent rational relationship between Greece's safeguard measure, which imposes a prohibition, and risk assessments which we understand found no evidence that Topas oilseed rape will give rise to any adverse effects on human or animal health and the environment.

7.3178 Thus, in view of our conclusion that Greece's safeguard measure on Topas oilseed rape cannot be considered to be "based on" the risk assessments performed by the lead CA or the SCP in relation to Topas oilseed rape, and recalling the fact that no other risk assessment which might reasonably support Greece's safeguard measure has been provided to us, we find that the Greek safeguard measure is not based on a risk assessment pursuant to Article 5.1.[2024]

Overall conclusions

7.3179 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Greek safeguard measure on Topas oilseed rape is not based on a risk assessment.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Greek safeguard measure on Topas oilseed rape is not based on a risk assessment.

7.3180 In view of our findings in the previous paragraph with regard to DS291 (United States) and DS292 (Canada), it is necessary to examine, in addition, whether the Greek safeguard measure on Topas oilseed rape is consistent with the requirements of Article 5.7 of the *SPS Agreement*. It is only once we have completed this additional examination that we can come to a final conclusion regarding the consistency of the Greek safeguard measure on Topas oilseed rape with Article 5.1 of the *SPS Agreement*. We undertake the necessary examination under Article 5.7 in the next section.

(ix) Italy – T25 maize, MON810 maize, MON809 maize, Bt-11 maize (EC-163)

7.3181 We now turn to the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163). We recall that we must determine whether Italy's measure is "based on" a risk assessment pursuant to Article 5.1. In this context, the first issue we will address is whether the documents Italy relies on to justify its safeguard measure meet the definition of a risk assessment.

[2024] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the Greek safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

"Risk assessment"

7.3182 We start by summarizing the documents on record in respect of this safeguard measure. We recall that Italy issued a decree on 4 August 2000 suspending the trade and use of T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163).[2025] As stated in the Decree, the decision by Italy to apply a safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) was based on opinions issued by the Italian Superior Council of Health and Superior Institute of Health. We recall that only the 28 July 2000 opinion of the Superior Institute of Health referred to in the Italian Decree was provided to the Panel.[2026] The relevant conclusions of the opinion of the Superior Institute of Health set out in the Decree were summarized above.

7.3183 Having determined the documents relied on by Italy with respect to its safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163), we must now determine whether any of these documents constitutes a "risk assessment" within the meaning of the *SPS Agreement*.

7.3184 We recall that the concerns identified by Italy relate to the protection of human health from potential risks associated with the consumption of the relevant GM maize products as well as potential risks arising from the "environmental release" of the relevant GMOs or their products. Regarding the latter category of risks, we consider that the first clause of Annex A(4) to the *SPS Agreement* provides the applicable definition for the "risk assessment" to be carried out for Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163). Regarding the former category of risks – risks associated with the consumption of the relevant GM maize products – we consider that the second clause of Annex A(4) to the *SPS Agreement* provides the applicable definition. We note that, unlike for the definition of risk assessment contained in the first clause of Annex A(4), WTO jurisprudence provides little guidance on the meaning of key concepts contained in the definition provided in the second clause. The Appellate Body merely observed in this respect that the first clause is substantially different from the second clause, and that the second clause requires "only" the evaluation of the "potential" for adverse effects on human or animal health arising from the presence of certain substances in foods, whereas the first clause requires an evaluation of the "likelihood" of entry, establishment or spread of a pest or disease and of the associated biological and economic consequences.[2027] We note that the dictionary defines the term "potential" as "the possibility of something happening [...] in the future".[2028]

7.3185 We start with the Decree notified by Italy in respect of its safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163). This Decree makes reference to "an exposé by an environmentalist association regarding to the simplified authorization procedure for the placing on the market"[2029] of these four maize products, and assertions by the environmentalist association that the condition of "substantial equivalence" required for the use of the simplified procedure was not met for these products. The Decree also makes reference to an opinion by the Italian Superior Institute of Health which it says found (i) that residues of genetically modified components (proteins) remain in the four products in question and (ii) that the technical documentation available does not examine the relevant GMOs in comparison to their conventional counterparts with regard to the presence of these components. Although the Decree reports the

[2025] Exhibit EC-157/At. 1.
[2026] Exhibit EC-157/At. 2.
[2027] Appellate Body Report, *Australia – Salmon*, footnote 69.
[2028] *The Concise Oxford Dictionary*, 10th edn, J. Pearsall (ed.) (Oxford University Press, 1999), p. 1120.
[2029] Exhibit EC-157/At. 1.

ultimate conclusion of the Italian Superior Institute of Health that "there are no apparent risks to the health of humans or livestock from the consumption of derivatives of the aforementioned GMOs"[2030], the Decree states that this conclusion was reached in a context in which there were inadequacies in the applicable risk assessment procedures. The Decree further states that since it had been established that residues of modified components remain in the four products, the information available from the simplified procedure was also inadequate with regard to the risks arising from "environmental release" of the GMOs in question, or their products.

7.3186 In our view, it is clear that the Decree does not itself provide an "evaluation" of the potential for adverse effects on human or animal health arising from the presence of certain substances/components (toxins, additives, etc.) in the four products in question. Similarly, the Decree does not itself evaluate the likelihood of the establishment or spread of a pest due to the "environmental release" of the relevant GMOs or their products. We therefore consider that the Decree is not in itself a risk assessment within the meaning of Annex A(4) and Article 5.1.

7.3187 We turn next to the opinion by the Italian Superior Institute of Health of July 2000.[2031] In assessing the possible food safety risks associated with the consumption of the four maize products, the Institute comments on composition (noting an expressed presence of protein deriving from the genetic modifications), toxicity of the products of "extraneous" genes (including Bt toxin), herbicide residues and antibiotic resistance. The report concludes that "in the light of current scientific knowledge it is this Institute's opinion that there are no risks to human or animal health due to the consumption of derivatives of the GMOs indicated in the table".[2032] Finally, the Institute declined to express an opinion regarding the risk of possible "environmental release" of the GMOs in question, or of their products.

7.3188 In considering the Institute's opinion, we note that in relation to herbicide residues, the Institute stated that this issue would need to be "evaluated" by the Phyto-pharmaceutical Commission in order to determine whether regulatory action would be appropriate. Thus, it is apparent that the Institute's opinion does not itself evaluate the potential for any adverse effects. Regarding toxicity and antibiotic resistance, we note that the opinion draws conclusions regarding the potential for adverse effects from the results of available studies and tests. These studies and tests are not annexed to the opinion, however. The opinion merely indicates their results and critical conclusions.[2033] Hence, it is clear that the text of the opinion does not itself contain and provide all the information necessary to an evaluation of the potential for the relevant adverse effects to occur. Accordingly, we consider that the Institute's opinion constitutes, not a complete, self-contained, scientific evaluation of the potential for adverse effects on human or animal health due to toxicity and the development of antibiotic resistance, but only part of such an evaluation. We are therefore of the view that the Institute's opinion does not meet the definition of a risk assessment as provided in the second clause of Annex A(4). Moreover, since none of the studies or tests referenced or mentioned in the opinion were provided to us, we cannot, and do not, express a view on whether the opinion and these studies and tests taken together would satisfy the Annex A(4) definition of a "risk assessment".

7.3189 Regarding potential risks arising from the "environmental release" of the relevant GMOs or their products, we recall that the Institute's opinion explicitly states that it does not address such risks.

[2030] *Ibid*.
[2031] Exhibit EC-157/At. 2.
[2032] *Ibid*.
[2033] It is pertinent to note that that the entirety of the discussion concerning toxicity and antibiotic resistance extends over no more than one page.

It follows that the opinion does not provide an assessment of such risks which would meet the definition of Annex A(4).

7.3190 In the light of the foregoing, we conclude that the above-mentioned documents relied on by Italy to justify its safeguard measure are not risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3191 Furthermore, in connection with the documents relied on by Italy, we should also note the European Communities' argument that Italy's safeguard measure was based on an assessment "appropriate to the circumstances" within the meaning of Article 5.1. The European Communities submits that the circumstances in the case of the Italian safeguard measure include the fact that, from Italy's perspective, relevant scientific evidence was or is insufficient We recall our previous consideration of the European Communities' argument based on the phrase "appropriate to the circumstances" in paragraphs 7.3052-7.3053 above and consider that our conclusions there apply *mutatis mutandis* to this measure.

7.3192 We have found above that the documents provided by the Parties in relation to Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) on which Italy relied do not constitute a risk assessment. However, the European Communities contends that there is a document other than the documents relied on by Italy which constitutes a risk assessment for T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163). The document in question is the "risk assessment [which] was carried out at the time when the original Community consent was given" (hereafter the "original risk assessment").[2034] It is not clear from this assertion whether the European Communities is referring to the risk assessment conducted by the lead CA or to those conducted by the SCP.[2035] In any event, we have noted above that it is not in dispute that both of these documents constitute risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3193 In addition, we note that none of the Parties has argued that, on the date of establishment of this Panel, the risk assessments conducted by the lead CA and the SCP were no longer "appropriate to the circumstances". In the light of this, and in view of our findings below with regard to whether Italy's safeguard measure is "based on" these risk assessments, we do not need to examine this issue further.

"Based on"

7.3194 We now turn to the question of whether, at the time of establishment of this Panel, the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) was "based on" either the risk assessment of the lead CA or those conducted by the SCP.[2036]

7.3195 We note that the European Communities' arguments in respect of this issue were the same as those it presented in the context of Austria's safeguard measure on T25 maize. We have addressed these arguments above and have reached the conclusion that Austria's safeguard measure on T25 maize cannot be considered to be "based on" the risk assessments performed by the lead CA and the

[2034] EC reply to Panel question No. 107.

[2035] Exhibits EC-159/Ats. 1-2; EC-160/At. 1-2; EC-163/At. 1; CDA-82, CDA-83, CDA-84 and CDA-85; US-68 (referencing original SCP risk assessments); ARG-47 (referencing original SCP risk assessments).

[2036] We recall that we must examine as part of our analysis whether the safeguard measure is based on either risk assessment, as it is not clear whether the original risk assessment referred to by the European Communities is the risk assessment conducted by the lead CA or those conducted by the SCP.

SCP in relation to T25 maize. This conclusion, and the reasoning supporting it, also apply, *mutatis mutandis*, to Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) and the risk assessments performed by the lead CA and the SCP in relation to T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163). This is because, as in the case of Austria's safeguard measure on T25 maize:

(a) we are not aware of any divergent opinions expressed in the risk assessments which were conducted by the lead CA and the SCP with regard to T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163);

(b) the European Communities or Italy did not explain, by reference to these risk assessments, how and why Italy assessed the risks differently, and did not provide a revised or supplemental assessment of the risks;

(c) the European Communities has not identified possible uncertainties or constraints in the risk assessments in question, and has not explained why, in view of any such uncertainties or constraints, Italy's prohibition is warranted by the relevant risk assessments; and

(d) there is no apparent rational relationship between Italy's safeguard measure, which imposes a prohibition, and risk assessments which we understand found no grounds for considering that the use of T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) endangers human health or the environment.

7.3196 Thus, in view of our conclusion that Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) cannot be considered to be "based on" the risk assessments performed by the lead CA or the SCP in relation to T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) and recalling the fact that no other risk assessment which might reasonably support Italy's safeguard measure has been provided to us, we find that the Italian safeguard measure is not based on a risk assessment pursuant to Article 5.1.[2037]

7.3197 We add that even if the favourable opinion[2038] by the Superior Institute of Health of July 2000 was considered to provide a risk assessment regarding the concerns over toxicity and development of antibiotic resistance, Italy's decision to prohibit the marketing of the four GM maize products at issue could not, in our view, be said to be based on the Institute's favourable opinion. The reasons which we have given above in relation to the risk assessments performed by the lead CA or the SCP apply, *mutatis mutandis*, also to the Institute's opinion.

[2037] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the Italian safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

[2038] We recall that the Institute's conclusion was to the effect that there are no risks to human health due to the consumption of these products.

Overall conclusions

7.3198 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is not based on a risk assessment.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is not based on a risk assessment.

(iii) DS293 (Argentina)[2039]

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Italian safeguard measure on T25 maize, MON810 maize and Bt-11 maize (EC-163) is not based on a risk assessment.

7.3199 In view of our findings in the previous paragraph with regard to DS291 (United States), DS292 (Canada) and DS293 (Argentina), it is necessary to examine, in addition, whether the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is consistent with the requirements of Article 5.7 of the *SPS Agreement*. It is only once we have completed this additional examination that we can come to a final conclusion regarding the consistency of the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) with Article 5.1 of the *SPS Agreement*. We undertake the necessary examination under Article 5.7 in the next section.

(x) Luxembourg – Bt-176 maize

7.3200 We now turn to Luxembourg's safeguard measure on Bt-176 maize. We recall that we must determine whether Luxembourg's measure is "based on" a risk assessment pursuant to Article 5.1. In this context, the first issue we will address is whether the document Luxembourg relies on to justify its safeguard measure meet the definition of a risk assessment.

[2039] We recall that unlike the complaints by the other Complaining Parties, Argentina's complaint with regard to the Italian safeguard measure covers only three products subject to the Italian decree of August 2000, *i.e.*, T25 maize, MON810 maize and Bt-11 maize.

"Risk assessment"

7.3201 We recall that only one document was submitted by the Parties in relation to Luxembourg's safeguard measure on Bt-176 maize, namely the Reasons document.[2040] Thus, we must determine whether this document constitutes a "risk assessment" within the meaning of the *SPS Agreement*.

7.3202 As with Austria's safeguard measure for Bt-176 maize, given the concerns raised by Luxembourg in the context of Bt-176 maize, we consider that both the first and the second clause of Annex A(4) to the *SPS Agreement* define the "risk assessment" to be carried out for Luxembourg's measure on Bt-176 maize.

7.3203 In the Reasons document, Luxembourg alleges that Bt-176 maize poses risks in relation to the development of antibiotic resistance and the development of insect resistance to Bt toxin. Regarding the development of antibiotic resistance, the Reasons document refers to scientific advice from EC scientific committees and other scientific experts. Although Luxembourg acknowledges that these experts indicated that there was only a small risk that antibiotic resistance would develop due to gene transfer to bacteria in the gut of humans or animals, Luxembourg insists that a small risk exists, notably in situations where the maize in question is used as animal feed, and argues that there is a need for further study regarding the mechanism of gene transfer.

7.3204 With regard to the development of insect resistance to Bt toxin, the Reasons document refers to the "possible" emergence of insects resistant to the Bt toxin as "a real risk factor".[2041] It emphasizes the lack of understanding of the long-term impacts of Bt toxin on the evolution of insect resistance. It also refers to a case of development of insect resistance in the United States in the wake of the introduction of GM cotton with an insecticidal trait. The Reasons document argues in this respect that as long as the causes of the insect resistance in the United States have not been elucidated, Bt maize should not be cultivated.

7.3205 Thus, the Reasons document calls for, but does not itself provide, further evaluation of the mechanism of gene transfer which might lead to the development of antibiotic resistance and of the risk of development of insects resistant to Bt toxin. More particularly, the Reasons document does not make a further evaluation of the likelihood of the spread of diseases or target insects. Nor does it make a further evaluation of the potential for adverse effects on human or animal health arising from the presence of ARMG in food. Given this, we consider that the Reasons document does not meet the definition of a risk assessment as provided in Annex A(4).

7.3206 In the light of the foregoing, we conclude that the Reasons document, being the document relied on by Luxembourg to justify its safeguard measure, does not constitute a risk assessment within the meaning of Annex A(4) and Article 5.1.

7.3207 Furthermore, in connection with the document relied on by Luxembourg, we should also note the European Communities' argument that Luxembourg's safeguard measure was based on an assessment "appropriate to the circumstances" within the meaning of Article 5.1. The European Communities submits that the circumstances in the case of Luxembourg's safeguard measure include the fact that, from Luxembourg's perspective, relevant scientific evidence was or is insufficient We recall our previous consideration of the European Communities' argument based on the phrase "appropriate to the circumstances" within the meaning of Article 5.1 in paragraphs 7.3031-7.3032 above, and consider that our conclusions there apply *mutatis mutandis* to this measure.

[2040] Exhibit EC-158/At. 9.
[2041] *Ibid*.

7.3208 We have found above that the only document which was provided by the Parties in relation to Luxembourg's safeguard measure on Bt-176 maize and which Luxembourg relied on does not constitute a risk assessment. However, the European Communities contends that there is a document other than the document relied on by Luxembourg which constitutes a risk assessment for Bt-176. The document in question is the "risk assessment [which] was carried out at the time when the original Community consent was given" (hereafter the "original risk assessment").[2042] It is not clear from this assertion whether the European Communities is referring to the risk assessment conducted by the lead CA or any of the risk assessments which were conducted by the Scientific Committee for Pesticides (SCPE), the Scientific Committee for Animal Nutrition (SCAN) or the SCF.[2043] In any event, it is not in dispute that these documents constitute risk assessments within the meaning of Annex A(4) and Article 5.1.

7.3209 In addition, we note that none of the Parties has argued that, on the date of establishment of this Panel, the risk assessments conducted by the lead CA and the risk assessments which were conducted by the SCPE, the SCAN or the SCF were no longer "appropriate to the circumstances". In the light of this, and in view of our findings below with regard to whether Luxembourg's safeguard measure is "based on" these risk assessments, we do not need to examine this issue further.

"Based on"

7.3210 We now turn to the question of whether, at the time of establishment of this Panel, Luxembourg's safeguard measure on Bt-176 maize was "based on" either the risk assessment of the lead CA or that conducted by the SCPE, the SCAN or the SCF.[2044]

7.3211 We note that the European Communities' arguments in respect of this issue were the same as those it presented in the context of Austria's safeguard measure on T25 maize. We have addressed these arguments above and have reached the conclusion that Austria's safeguard measure on T25 maize cannot be considered to be "based on" the risk assessments performed by the lead CA and the SCP in relation to T25 maize. This conclusion, and the reasoning supporting it, also apply, *mutatis mutandis*, to Luxembourg's safeguard measure on Bt-176 maize and the risk assessments performed by the lead CA and the SCPE, the SCAN and the SCF in relation to Bt-176 maize. This is because, as in the case of Austria's safeguard measure on T25 maize:

(a) we are not aware of any divergent opinions expressed in the risk assessments which were conducted by the lead CA and the SCPE, the SCAN or the SCF with regard to Bt-176 maize;

(b) the European Communities or Luxembourg did not explain, by reference to these risk assessments, how and why Luxembourg assessed the risks differently, and did not provide a revised or supplemental assessment of the risks;

(c) the European Communities has not identified possible uncertainties or constraints in the risk assessments in question, and has not explained why, in view of any such

[2042] EC reply to Panel question No. 107.

[2043] Exhibits EC-158/Ats. 1-3; EC-158/At. 4; EC-158/At. 5; EC-158/At. 6.

[2044] As noted, we must examine as part of our analysis whether the safeguard measure is based on either risk assessment, as it is not clear whether the original risk assessment referred to by the European Communities is the risk assessment conducted by the lead CA or that conducted by the SCPE, the SCAN or the SCF.

uncertainties or constraints, Luxembourg's prohibition is warranted by the relevant risk assessments; and

(d) there is no apparent rational relationship between Luxembourg's safeguard measure, which imposes a prohibition, and risk assessments which found no evidence that Bt-176 maize will give rise to any adverse effects on human or animal health and the environment.

7.3212 Thus, in view of our conclusion that Luxembourg's safeguard measure on Bt-176 maize cannot be considered to be "based on" the risk assessments performed by the lead CA or the SCPE, the SCAN or the SCF in relation to Bt-176 maize, and recalling the fact that no other risk assessment which might reasonably support Luxembourg's safeguard measure has been provided to us, we find that Luxembourg's safeguard measure is not based on a risk assessment pursuant to Article 5.1.[2045]

Overall conclusions

7.3213 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, Luxembourg's safeguard measure on Bt-176 maize is not based on a risk assessment.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, Luxembourg's safeguard measure on Bt-176 maize is not based on a risk assessment.

7.3214 In view of our findings in the previous paragraph with regard to DS291 (United States) and DS293 (Argentina), it is necessary to examine, in addition, whether Luxembourg's safeguard measure on Bt-176 maize is consistent with the requirements of Article 5.7 of the *SPS Agreement*. It is only once we have completed this additional examination that we can come to a final conclusion regarding the consistency of Luxembourg's safeguard measure on Bt-176 maize with Article 5.1 of the *SPS Agreement*. We undertake the necessary examination under Article 5.7 in the next section.

(d) Consistency with Article 5.7 of the *SPS Agreement* and final conclusion regarding consistency with Article 5.1 of the *SPS Agreement*

7.3215 We have found above that none of the relevant safeguard measures meets the requirements set out in the text of Article 5.1. As we have said, in view of this finding, it is necessary to go on to examine whether the safeguard measures are consistent with the requirements of Article 5.7 of the *SPS Agreement*.

[2045] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, Luxembourg's safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

7.3216 To recall, Article 5.7 provides as follows:

> "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

7.3217 We have explained earlier that if we were to find that a safeguard measure is consistent with the requirements of Article 5.7, Article 5.1 would not be applicable and we would consequently need to conclude that the European Communities has not acted inconsistently with its obligations under Article 5.1. Conversely, if we were to find that a safeguard measure is inconsistent with the requirements of Article 5.7, Article 5.1 would be applicable and, in view of our finding that none of the safeguard measures meets the requirements set out in the text of Article 5.1, we would need to conclude that the European Communities has acted inconsistently with its obligations under Article 5.1 in respect of the relevant measure.

7.3218 Before embarking on an examination of the individual safeguard measures under Article 5.7, it is well to recall that the Appellate Body in *Japan – Agricultural Products II* found that there are four requirements in Article 5.7 that must be met in order for a Member to adopt and maintain a provisional SPS measure. More specifically, the Appellate Body stated that:[2046]

> "Pursuant to the first sentence of Article 5.7, a Member may provisionally adopt an SPS measure if this measure is:
>
> (1) imposed in respect of a situation where "relevant scientific information is insufficient"; and
>
> (2) adopted "on the basis of available pertinent information".
>
> Pursuant to the second sentence of Article 5.7, such a provisional measure may not be maintained unless the Member which adopted the measure:
>
> (1) "seek[s] to obtain the additional information necessary for a more objective assessment of risk"; and
>
> (2) 'review[s] the … measure accordingly within a reasonable period of time'."

7.3219 Furthermore, we note that, according to the Appellate Body, the four requirements contained in Article 5.7 are "clearly cumulative in nature".[2047] In other words, "[w]henever one of these four requirements is not met, the measure at issue is inconsistent with Article 5.7."[2048]

7.3220 The Appellate Body further stated that Article 5.7 reflects the precautionary principle, and that the precautionary principle as such has not been written into the *SPS Agreement* as a ground for

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[2046] Appellate Body Report, *Japan – Agricultural Products II*, para. 89. *See also* Appellate Body Report, *Japan – Apples*, para. 176. We note regarding the first requirement that the Appellate Body referred to "relevant scientific information" instead of "relevant scientific evidence".

[2047] Appellate Body Report, *Japan – Agricultural Products II*, para. 89.

[2048] *Ibid*.

justifying an SPS measure that is otherwise inconsistent with that Agreement.[2049] The European Communities asserts that each of the safeguard measures at issue in this dispute is based on the precautionary principle. Since we examine below whether the relevant safeguard measures are consistent with the requirements of Article 5.7, in view of the aforementioned statement by the Appellate Body, we see no need separately to examine the European Communities' argument that these measures are based on the precautionary principle.

7.3221 With this in mind, we now turn to examine the first member State safeguard measure, Austria's safeguard measure on T25 maize. As always, we begin with a summary of the Parties' main arguments.

(i) Austria – T25 maize

7.3222 The **United States** argues that the Austrian safeguard measure on T25 maize fails to meet any of the four requirements set out in Article 5.7. *First*, the scientific evidence is sufficient to perform a risk assessment, since the European Communities itself has conducted positive risk assessments on T25 maize. *Second*, the safeguard measure was not adopted on the basis of "available pertinent information". The SCP reviewed the safeguard measure and concluded that the information provided by Austria did not warrant any change in the earlier risk assessment. *Third*, Austria has not sought "to obtain the additional information necessary for a more objective assessment of risk", and there is no information on record that Austria has sought to perform a risk assessment that would support its measure on T25 maize. *Finally*, the United States alleges that neither Austria nor the Commission have reviewed the Austrian safeguard measure within a reasonable period of time.

7.3223 **Canada** argues that a review of the Austrian safeguard measure and the factual and scientific circumstances surrounding its adoption and maintenance reveal that the measure fails to satisfy any of the four elements of Article 5.7. *First*, the measure was not imposed in respect of a situation where relevant scientific information was insufficient. The opinion of the European Communities' own scientific experts demonstrate that there was sufficient scientific evidence to conduct a complete and objective risk assessment. In Canada's view, what was insufficient was the scientific evidence put forward by the European Communities or Austria to support the safeguard measure. *Second*, the measure was not adopted on the basis of "available pertinent information", since this would include the scientific opinions of the lead CA and of the relevant EC scientific committee, which all confirmed the safety of the product.

7.3224 With respect to the *third* element of Article 5.7, the requirement that the Member seek to obtain the additional information necessary for a more objective assessment of risk, Canada notes that this element is irrelevant in this case, given the sufficiency of the scientific evidence available from the European Communities' own sources. *Finally*, with regard to the fourth requirement, namely that the measure must be reviewed within a reasonable period of time, Canada recalls that the European Communities' own legislation requires that such a review take place. However, given the absence of "pertinent information" to support the safeguard measure, Canada draws the conclusion that the measure would have been lifted if such a review had been conducted. Furthermore, according to the Appellate Body, what constitutes a "reasonable period of time" will be influenced by the emergence of the additional information necessary to make a more objective assessment of the risk. In Canada's view, new or additional information was not necessary in the present case to conduct a risk assessment, as sufficient scientific evidence was in existence even at the time the safeguard measure was taken.

[2049] Appellate Body Report, *EC – Hormones*, para. 124.

7.3225 **Argentina** argues that the Austrian safeguard measure does not meet any of the four requirements of Article 5.7. *First*, the scientific evidence was not insufficient, since at least two positive scientific opinions were expressed on T25 maize, including one which specifically rejected the information provided by Austria in support of the measure. *Second*, Austria did not base its measure on the "available pertinent information", since it disregarded the positive scientific opinions of the scientific committee. *Third*, Austria has not sought to obtain further information necessary for a more objective risk assessment, because the information provided in this case is not consistent with the positive scientific opinions given by the scientific committee. *Finally*, with respect to the fourth requirement of Article 5.7, Argentina notes that Austria did not review its safeguard measure.

7.3226 The **European Communities** argues that the Austrian safeguard measure meets the four requirements of Article 5.7. *First*, the European Communities asserts that relevant scientific evidence was insufficient. According to the European Communities, the concept of "insufficiency" in Article 5.7 is "relational" and must therefore refer to the matters of concern to the legislator. Specifically, "insufficient" means "insufficient" for the production of a risk assessment adequate for the purposes of the legislator who must decide whether a measure should be applied, provisionally or otherwise, for one of the reasons enumerated in Annex A(1) of the *SPS Agreement*. The European Communities defines a risk assessment which is adequate as one which has been "delivered by a reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised".[2050]

7.3227 In support of its view, the European Communities submits that the sufficiency of the evidence cannot be examined in a vacuum, but has to be examined in relation to the protection goals sought by legislators. The European Communities argues that it is artificial to suppose that there is some kind of magic moment at which the available science becomes sufficient for all purposes. In the European Communities' view, the actions of a legislator in response to available scientific evidence are a function of what that particular legislator is concerned about. Thus, in the European Communities' view, the higher the level of acceptable risk, the more likely it is that the legislator may conclude, within a relatively short period of time, that the scientific evidence is sufficient and that no provisional measure is therefore necessary. The lower the level of acceptable risk, the more likely it may be that the legislator may continue to consider, for a relatively long period of time, that the scientific evidence is insufficient, and that a measure is warranted.[2051] In other words, according to the European Communities, the sufficiency of the scientific evidence must be examined in relation to the level of acceptable risk of the legislators.

7.3228 Applying these considerations to the Austrian safeguard measure on T25 maize, the European Communities submits that, having regard to the specific concerns of Austria's legislators in adopting that measure, Austria's legislators were entitled to conclude that relevant scientific evidence was insufficient for their purposes.

7.3229 Furthermore, the European Communities contends that Austria has adopted and maintained its safeguard measure on the basis of "available pertinent information", which includes, *inter alia*, the information contained in the original notification, as well as the various relevant scientific discussions, papers and opinions. With respect to the *third* requirement of Article 5.7, the European Communities argues that both Austria and the European Communities are engaged in an ongoing process by which they are seeking to obtain additional information necessary for a more objective assessment of the risk through ongoing research and the constant development of science.

[2050] EC first written submission, para. 604.

[2051] The European Communities considers that this analysis is confirmed by the words "reasonable period of time" in Article 5.7.

7.3230 Finally, the European Communities notes that the measure is subject to a process of review within a reasonable period of time, and that such review is still ongoing both at Community and member State levels.[2052] According to the European Communities, the determination of what constitutes a "reasonable period of time" pursuant to Article 5.7 depends on all the circumstances. In the present case, for instance, assessments are being made of long-term effects, in relation to changes that may have a permanent effect, and that are being introduced at an exponential rate as compared to the past. These circumstances may justify a Member requiring a relatively long period of time to review its provisional measure.[2053] The European Communities finds support for this view in the Appellate Body's statement that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, *e.g.* life-terminating, damage to human health are concerned".[2054] The European Communities differentiates the present case from *Japan-Apples*, arguing that GMO technology is still at the frontiers of science and its future consequences (compared to a case like fire blight) are highly uncertain – and potentially more far-reaching. The European Communities argues that the relevant risks are more than the mere theoretical uncertainty that always remains simply because science can never provide absolute certainty that a given substance will never have adverse effects.[2055]

7.3231 The **Panel** notes that in presenting arguments with respect to the four requirements of Article 5.7, the Parties started with the first requirement, *i.e.* whether the Austrian safeguard measure was imposed in respect of a situation where "relevant scientific evidence [was] insufficient". The Panel, too, will begin its analysis with the first requirement.[2056]

"Insufficiency of relevant scientific evidence"

7.3232 We recall that pursuant to the first requirement, a Member must not provisionally adopt an SPS measure except in a case "where relevant scientific evidence is insufficient". Before examining the Austrian safeguard measure in the light of this requirement, we need to address two issues: (i) whether the sufficiency of the scientific evidence must be assessed by reference to Austria's appropriate level of sanitary or phytosanitary protection and (ii) whether the sufficiency of the scientific evidence is to be judged at the time of adoption of the Austrian safeguard measure or at the

[2052] We recall that the US argument that a requirement that measures be "constantly subject to review" does not meet the requirement that the measures be reviewed within a reasonable period of time of their adoption. US second written submission, para. 100.

[2053] The European Communities submits that the present case is very different, for example, from that before the panel in *Japan – Apples*.

[2054] Appellate Body Report, *EC – Hormones*, para. 124.

[2055] The European Communities notes in its first written submission (para. 608) that "[t]he present case is, for example, very different from the circumstances of the *Japan – Apples* case. That case concerned a disease (fire blight) with a relatively narrow spectrum of possible consequences (compared to GMOs generally). The panel found that the disease had been known and studied for some 200 years – the GMO techniques with which this case is concerned are far more recent than that. The panel also found that there was a high quantity and quality of scientific evidence expressing strong and increasing confidence in the conclusion. In other words, the matter could fairly be described as no longer being at the frontiers of science, but rather to have passed into the realms of conventional scientific wisdom – an operational hypothesis unlikely to be disturbed other than by some revolutionary and currently totally unforeseeable new scientific discovery. That is not at all the circumstances of the present case. GMO technology is still at or close to the frontiers of science and its future consequences (compared to a case like fire blight) highly uncertain – and potentially much more far reaching."

[2056] We note that the panel in *Japan – Apples* also began its inquiry with the first requirement, an approach not faulted by the Appellate Body. Panel Report, *Japan – Apples*, para. 8.214.

time of review by this Panel, *i.e.*, at the time this Panel's terms of reference were fixed. We will examine these issues in turn.

Relevance of the appropriate level of sanitary or phytosanitary protection from risks

7.3233 We recall the European Communities' contention in paragraph 7.3227 above that in assessing the sufficiency of relevant scientific evidence, regard must be had to the protection goals pursued by legislators. In considering this contention, we recall as an initial matter that the Appellate Body in *Japan – Apples* clarified the meaning of the phrase "where relevant scientific evidence is insufficient". According to the Appellate Body, the notion of "insufficiency" implies a relationship between the scientific evidence and something else. On that basis, the Appellate Body determined that "'relevant scientific evidence' will be 'insufficient' within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as required under Article 5.1 and as defined in Annex A to the *SPS Agreement*".[2057] It appears that in the Appellate Body's view scientific evidence could be considered to be insufficient in qualitative terms for instance when it is inconclusive or unreliable.[2058]

7.3234 The European Communities argues that the concept of "insufficiency" in Article 5.7 is "relational" and must, therefore refer to the matters of concern to the legislator. We are not persuaded by this argument. While the Appellate Body has said that the notion of "insufficiency" implies a "relationship" between the scientific evidence and something else, it nowhere said that the notion of "insufficiency" implies a relationship between the scientific evidence and the matters of concern to the legislator. The Appellate Body identified, and acknowledged the existence of, only one relevant relationship: that between the scientific evidence and the obligation to perform a risk assessment under Article 5.1.

7.3235 We note that the Appellate Body in *Japan – Apples* referred to the insufficiency of available scientific evidence to perform an "adequate" assessment of risks. The European Communities appears to rely on the Appellate Body's use of the term "adequate", for it argues that an "adequate" assessment of risks is one which is "adequate for the purposes of the legislator". The Appellate Body failed to define or explain the term "adequate". Moreover, the term "adequate" nowhere appears in Article 5.1, Article 5.7 or Annex A(4). In these circumstances, we are not convinced that we should attach much significance to this term.[2059] Indeed, the term "adequate" may have been intended as nothing more than a reference to the definition in Annex A(4). On this view, a risk assessment would be "adequate" if it meets the standard and definition provided in Annex A(4).

7.3236 If we were nonetheless to try to give independent meaning to the term "adequate", the second sentence of Article 5.7 appears to us to be instructive. That sentence makes clear that in circumstances where relevant scientific evidence is insufficient and a Member has provisionally adopted an SPS measure, the Member concerned must seek to obtain the additional information necessary for a "more objective assessment of risk". We have observed earlier that we take the phrase "a more objective assessment of risk", considered as a whole, to refer to a risk assessment which satisfies the definition provided in Annex A(4), or at least which is closer to satisfying the definition in Annex A(4) than consideration of "available pertinent information". Also, Article 5.1 requires SPS measures to be based on a risk assessment within the meaning of Annex A(4). On that basis, it can be

[2057] Appellate Body Report, *Japan – Apples*, para. 179.
[2058] *Ibid.*, para. 185.
[2059] This view is supported by the fact that three paragraphs later in its report on *Japan – Apples*, the Appellate Body dropped the term "adequate", referring only to "an assessment of risks, as required under Article 5.1 and as defined in Annex A". Appellate Body Report, *Japan – Apples*, para. 182.

argued that the Appellate Body's reference to "an *adequate* assessment of risks as required by Article 5.1 and as defined in Annex A" (emphasis added) should be understood as a reference to "a *more objective* assessment of risks as required by Article 5.1 and as defined in Annex A".

7.3237 Clearly, neither of the two above-noted interpretations of the term "adequate" supports the conclusion that in referring to an "adequate" risk assessment, the Appellate Body intended to suggest that a risk assessment had to be adequate for the purposes of a Member's legislator. The two above-noted interpretations support the conclusion that, in the view of the Appellate Body, relevant scientific evidence is insufficient within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). At any rate, this is the interpretation of the concept of "insufficiency" in Article 5.7 which we believe to be correct.

7.3238 The European Communities argues that it is artificial to suppose that there is some kind of magic moment at which the available science becomes sufficient for all purposes. In the European Communities' view, the actions of a legislator in response to available scientific evidence are a function of what that particular legislator is concerned about. We would agree that it must be determined on a case-by-case basis whether the body of available scientific evidence is insufficient to permit the performance of a risk assessment. But we are not convinced that the protection goals pursued by a legislator are relevant to such a determination. The protection goals of a legislator may have a bearing on the question of which risks a Member decides to assess with a view to taking regulatory action, if necessary. And a legislator's protection goals are certainly relevant to the determination of the measure – or as the European Communities puts it, the "actions" – to be taken for achieving a Member's level of protection against risk. Yet there is no apparent link between a legislator's protection goals and the task of assessing the existence and magnitude of potential risks.

7.3239 We note that the European Communities defines a risk assessment which is adequate for the purposes of a Member's legislator as one which has been "delivered by a reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised".[2060] We have already expressed the view that the question to be answered in an Article 5.7 inquiry is not whether relevant scientific evidence permits the performance of a risk assessment adequate for the purposes of a legislator, but whether it permits the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). Nonetheless, we must examine whether the kind of risk assessment the European Communities considers adequate is consistent with the kind of risk assessment required under Article 5.1 and defined in Annex A(4).

7.3240 We note in this respect that a risk assessment as required under Article 5.1 and as defined in Annex A(4) may set forth diverging scientific opinions coming from qualified and respected sources and, to that extent, need not necessarily inform a Member "unequivocally" about risks. A risk assessment as defined in Annex A(4) should normally address the "degree of precision", or level of confidence, with which the relevant risks can be, or have been, assessed and the circumstances in which the assessment may need to be "revised".[2061] Also, the "passage of time" may be a limiting

[2060] *Ibid.*

[2061] It is instructive to note what is stated in this regard in pertinent risk assessment techniques developed by relevant international organizations. Thus, the Codex *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* provide that "[c]onstraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner". Codex Alimentarius Commission, *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* (adopted in June/July 2003),

factor which might warrant a revision of an existing risk assessment. However, where a risk assessment has been performed, and that risk assessment meets the standard and definition of Annex A(4), it does not cease to be a risk assessment within the meaning of Annex A(4) merely because a particular Member judges that the risks have not been assessed with a "sufficient" degree of precision, that the assessment has not "withstood" the passage of time, and that it is "likely" that the assessment may need to be revised at some point in the future. If there are factors which affect scientists' level of confidence in a risk assessment they have carried out[2062], this may be taken into account by a Member in determining the measure to be applied for achieving its appropriate level of protection from risks. Thus, consistent with the foregoing remarks, we consider that it would be improper to apply the European Communities' definition of an "adequate" risk assessment for the purposes of an analysis of whether relevant scientific evidence is insufficient to perform a risk assessment. We observe that this view is consistent with risk assessment techniques established by relevant international organizations. For instance, the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* state that "[t]he report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors".[2063] Along similar lines, the Codex *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* state that "[r]isk managers should take into account the uncertainties identified in the risk assessment and implement appropriate measures to manage these uncertainties".[2064] Similarly, the IPPC's ISPM #11 (2001) states in relevant part that "[t]he uncertainty noted in the assessments of economic consequences and probability of introduction should also be considered and included in the selection of a pest management option".[2065] The quoted passage stayed the same in the 2004 version of ISPM #11, which applies specifically to living modified organisms.

7.3241 Based on its view that a risk assessment must be adequate for the purposes of a Member's legislator, the European Communities argues that a Member with a high appropriate level of protection may justifiably consider that the available body of scientific evidence is insufficient to permit the assessment of risks with a degree of precision which it would find adequate, while a Member with a lower appropriate level of protection may consider that the same body of evidence is sufficient to perform an adequate risk assessment. In other words, the European Communities argues that in determining whether relevant scientific evidence is insufficient within the meaning of Article 5.7, regard must be had to a Member's appropriate level of protection.

Section III, Codex Procedural Manual, 14th edition, 2004, para. 23. Similarly, the IPPC's ISPM #11 (2001) states in relevant part that "[e]stimation of the probability of introduction of a pest and of its economic consequences involves many uncertainties. [...] It is important to document the areas of uncertainty and the degree of uncertainty in the assessment, and to indicate where expert judgement has been used". IPPC, ISPM #11 : *Pest Risk Analysis for Quarantine Pests*, April 2001, para. 2.4. The quoted passage stayed the same in the 2004 version of ISPM #11, which applies specifically to living modified organisms. Finally, the principles of risk assessment of the OIE *Terrestrial Animal Health Code* provide in relevant part that "[r]isk assessments should document the uncertainties, the assumptions made, and the effect on these on the final risk estimate". OIE, *Terrestrial Animal Health Code*, 2002, Article 1.3.2.3, para. 5.

[2062] *E.g.*, a limited body of relevant scientific evidence may be such a factor.

[2063] Codex Alimentarius Commission, *Working Principles for Risk Analysis for Application in the Framework of the Codex* Alimentarius (adopted in June/July 2003), Section III, Codex Procedural Manual, 14th edition, 2004, para. 25.

[2064] Codex Alimentarius Commission, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* (adopted in June/July 2003), CAC/GL 44-2003, para. 18.

[2065] IPPC, ISPM #11: *Pest Risk Analysis for Quarantine Pests*, April 2001, para. 3.

7.3242 There can be no doubt that a Member's appropriate level of protection is relevant to determining the SPS measure to be applied, if any, to protect that Member from risks. Article 5.3 of the *SPS Agreement* refers to the determination of "the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from [...] risk", and Article 5.6 relates to the establishment or maintenance of "[SPS] measures to achieve the appropriate level of sanitary or phytosanitary protection".

7.3243 In contrast, the definition of the term "risk assessment" in Annex A(4) does not indicate that a Member's appropriate level of protection is pertinent to an assessment of the existence and magnitude of risks.[2066] Also, Annex A(5) to the *SPS Agreement* states that the concept of the appropriate level of protection is referred to by some Members as the concept of the "acceptable level of risk". We do not think that scientists need to know a Member's "acceptable level of risk" in order to assess objectively the existence and magnitude of a risk.[2067] Furthermore, neither Article 5.2[2068] nor Article 5.3[2069] suggests that a Member's appropriate level of protection may be relevant to the assessment of risks.

7.3244 We note that Article 5.1 provides that SPS measures must be based on an assessment of risks which is "appropriate to the circumstances". The European Communities appears to suggest that an importing Member's appropriate level of protection is a relevant circumstance within the meaning of Article 5.1.[2070] In our view, an importing Member may not reject an existing risk assessment which meets the definition of Annex A(4) as not "appropriate to [its] circumstances" on the basis that this risk assessment indicates constraints or uncertainties, and that this would not enable the Member concerned to determine "with a sufficient degree of precision" whether a particular type of measure would in fact achieve its appropriate level of protection. As we have said, if there are factors which affect scientists' level of confidence in a risk assessment they have carried out, an importing Member may take this into account in determining the measure to be applied for achieving its appropriate level of protection.[2071]

7.3245 Finally, we note the European Communities' argument that the phrase "within a reasonable period of time" in the second sentence of Article 5.7 supports its view that the importing Member's appropriate level of protection is relevant to determining whether available scientific evidence is

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[2066] We note that Annex A(4) in part defines a "risk assessment" as "the evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied". We are not convinced that a Member's appropriate level of protection is relevant to identifying "the sanitary or phytosanitary measures which might be applied". In any event, even if this were the case, we do not see how this could affect whether an assessment of the existence and magnitude of risks could be carried out.

[2067] We note in this regard that in *Australia – Salmon* the Appellate Body also underlined the importance of distinguishing carefully "between the evaluation of 'risk' in a risk assessment and the determination of the appropriate level of protection". Appellate Body Report, *Australia – Salmon*, para. 125.

[2068] Article 5.2 provides that "[i]n the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment".

[2069] Article 5.3 provides in relevant part that "[i]n assessing the risk to animal or plant life or health [...], Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks".

[2070] EC reply to Panel question No. 107.

[2071] It should also be recalled that to the extent a risk assessment sets out a minority opinion from a qualified and respected source, an importing Member may also be justified in basing a measure to achieve its appropriate level of protection on that minority opinion.

insufficient within the meaning of Article 5.7 to perform a risk assessment. The second sentence of Article 5.7 requires that Members seek to obtain the information necessary for a more objective assessment of risk and review provisional SPS measures accordingly within a reasonable period of time. In *Japan – Agricultural Products II*, the Appellate Body stated that what constitutes a "reasonable period of time" depends, *inter alia*, on the difficulty of obtaining the information necessary for a more objective assessment of risk.[2072] We think that in cases where additional information obtained by a Member is objectively sufficient to perform "a more objective assessment of risk", the phrase "review [...] within a reasonable period of time" would not provide a justification for delaying the performance of such an assessment on the grounds that an assessment incorporating the additional information would not allow the importing Member to determine "with a sufficient degree of precision" whether a measure different from its provisional measure would achieve its appropriate level of protection. Here again, we consider that if there are factors which affect scientists' level of confidence in "a more objective assessment of risk" they have performed, the importing Member may take this into account when reviewing its provisional measure in the light of the "more objective assessment". Thus, we are unable to accept the European Communities' argument concerning the phrase "within a reasonable period of time".

7.3246 Based on the above considerations, we are unable to agree with the European Communities that in the context of Article 5.7 the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member. More particularly, we do not agree that we need to have regard to Austria's appropriate level of protection in examining whether relevant scientific evidence was sufficient to perform a risk assessment for T25 maize as required under Article 5.1 and as defined in Annex A(4).

Time at which insufficiency of relevant scientific evidence is to be assessed

7.3247 We now turn to analyse the second issue, *i.e.*, whether the insufficiency of relevant scientific evidence, which is a prerequisite for invoking the exception under Article 5.7, is to be judged at the time of adoption of the Austrian safeguard measure or at the time this Panel's terms of reference were fixed.

7.3248 The first sentence of Article 5.7 provides that "[i]n cases where relevant scientific evidence is insufficient", a Member may provisionally "adopt" an SPS measure on the basis of available pertinent information. Thus, the text of the first sentence establishes a clear link between the required insufficiency of relevant scientific evidence and the adoption of a provisional SPS measure which is based on available pertinent information.

7.3249 The second sentence of Article 5.7 provides that "[i]n such circumstances", *i.e.*, in circumstances where an SPS measure has been provisionally adopted consistently with the requirements of the first sentence of Article 5.7, the relevant Member must seek to obtain the additional information necessary for a more objective assessment of risk and review the measure accordingly within a reasonable period of time. It is apparent from the conjunction "[i]n such circumstances" as well as the nature of the requirements laid down in the second sentence of Article 5.7 that that sentence establishes under what conditions an SPS measure which has been provisionally adopted may be maintained.

7.3250 The Appellate Body appears to share the view that the first sentence of Article 5.7 is concerned with the adoption of provisional SPS measures while the second sentence is concerned with the maintenance of such measures. In *Japan – Agricultural Products II*, the Appellate Body

[2072] Appellate Body Report, *Japan – Agricultural Products II*, para. 93.

stated that "[p]ursuant to the first sentence of Article 5.7, a Member may provisionally *adopt* an SPS measure if this measure [meets the two requirements set out in the first sentence]" and that "[p]ursuant to the second sentence of Article 5.7, such a provisional measure may not be *maintained* unless the Member which adopted the measure [complies with the two requirements set out in the second sentence]".[2073] Subsequently, in *Japan – Apples*, the Appellate Body confirmed that the two requirements set out in the second sentence of Article 5.7 "relate to the *maintenance* of a provisional [SPS] measure and highlight the *provisional* nature of measures adopted pursuant to Article 5.7".[2074]

7.3251 Reinforcing our view that the first sentence of Article 5.7 relates to the adoption of provisional SPS measures, but not to their maintenance, is the immediate context of Article 5.7. Article 5.6 provides in relevant part that "when *establishing or maintaining* [SPS] measures to achieve the appropriate level of [...] protection, Members shall ensure that such measures are not more trade-restrictive than required" (emphasis added). Likewise, Article 5.8 stipulates in relevant part that "[w]hen a Member has reason to believe that a specific [SPS] measure *introduced or maintained* by another Member is constraining [...] its exports and the measure is not based on the relevant international standards, guidelines or recommendations [...], an explanation of the reasons for such [SPS] measure may be requested and shall be provided" (emphasis added). Since Articles 5.6 and 5.8 explicitly refer to the "maintenance" of SPS measures in addition to the "establishment" or "introduction" of SPS measures, we think it may be justifiably assumed that the absence of a reference to the "maintenance" of a provisional SPS measure in the first sentence is intentional, and that "maintenance" is indeed covered by the second sentence of Article 5.7.

7.3252 Article 2.2 of the *SPS Agreement* is also part of the context of the first sentence of Article 5.7. To recall, Article 2.2 states in part that SPS measures may not be "*maintained* without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5" (emphasis added). We note the absence of a reference to the "adoption" of SPS measures without sufficient scientific evidence. Logic suggests that if an SPS measure may not be maintained without sufficient scientific evidence, it may also not be adopted without sufficient scientific evidence. This view draws support from the first sentence of Article 5.7, which explicitly refers to the "adoption" of provisional SPS measures. We recall in this respect that Article 5.7 provides for a qualified exemption from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence. Having said this, we do not consider that, conversely, it may be deduced from the reference to the "maintenance" of an SPS measure in Article 2.2 that the first sentence of Article 5.7 implies a reference to the "maintenance" of a provisional SPS measure. As we have noted, we think that the second sentence of Article 5.7 sets forth the applicable requirements relating to the maintenance of a provisional SPS measure. Moreover, we have noted that in marked contrast with the first sentence of Article 5.7, other provisions of the same Article – we have identified Article 5.6 and Article 5.8 – explicitly refer to both the establishment, or introduction, of SPS measures in addition to their maintenance.

7.3253 Since the phrase "[i]n cases where relevant scientific evidence is insufficient" is part of the first sentence of Article 5.7, and since the above considerations lead us to conclude that the requirements contained in the first sentence relate only to the adoption of a provisional SPS measure, we are of the view that a determination of whether a particular case is a case "where relevant scientific evidence is insufficient" must be made by reference to the time the relevant provisional SPS measure was adopted.

7.3254 Consideration of the alternative view strengthens rather than undermines our view. Indeed, if it were assumed that, contrary to our view, it is to be assessed at the time of review by a panel whether

[2073] Appellate Body Report, *Japan – Agricultural Products II*, para. 89 (emphasis added).
[2074] Appellate Body Report, *Japan – Apples*, footnote 318 (emphasis in original).

"relevant scientific evidence is insufficient", the second sentence of Article 5.7 would effectively become redundant. If a Member invoking the exception set out in Article 5.7 had to demonstrate that at the time of review by a panel relevant scientific evidence was insufficient to perform a risk assessment as required under Article 5.1 and as defined in Annex A(4), there would be no apparent need to require that Member to seek to obtain additional information and to review its provisional SPS measure; the Member concerned would have every incentive to do so even in the absence of a requirement as it might be called on to defend its measure at any time.[2075] What is more, if that Member succeeded in demonstrating that relevant scientific evidence was insufficient, we fail to see what purpose would be served by requiring that Member to demonstrate, in addition, that at some earlier point in time it had sought additional information and reviewed its measure.

7.3255 We have concluded that the sufficiency of relevant scientific evidence should be assessed at the time a provisional measure was adopted. This conclusion warrants some elaboration, to avoid possible misinterpretation. *First of all*, we are not suggesting that evidence which establishes that, at some point between the time of adoption of a provisional SPS measure and the time a panel's terms of reference were fixed, relevant scientific evidence became sufficient, or was still insufficient, to perform a risk assessment as required under Article 5.1 and as defined in Annex A(4), is *a priori* irrelevant to an Article 5.7 inquiry. To the contrary, such evidence may be relevant to an inquiry under the second sentence of Article 5.7. It may shed light on whether the Member invoking the exception under Article 5.7 has complied with the requirement to "seek to obtain the additional information necessary for a more objective risk assessment". Alternatively, such evidence may be relevant to a determination of whether the Member invoking the exception under Article 5.7 has conducted a "review" of its provisional measure "within a reasonable period of time".

7.3256 *Secondly*, there is no incongruity between our approach to the European Communities' claim under Article 5.7 and our approach to the Complaining Parties' claim under Article 5.1 and their consequential claim under Article 2.2. It is true that in analysing these latter claims, we have reviewed the situation as it existed at the time the Panel's terms of reference were fixed. However, our approach to Article 5.7 is in keeping with, and gives meaning to, the two sentences of Article 5.7. As we see it, a Member maintaining a provisional SPS measure cannot make a successful claim of justification under Article 5.7 if that measure has not been adopted consistently with the requirements of the first sentence of Article 5.7. Furthermore, if in our analysis we reach the issue of whether the Austrian safeguard measure meets the requirements of the second sentence of Article 5.7, which relates to the maintenance of a provisional SPS measure, we will examine this issue in the light of the situation as it existed when our terms of reference were set. In other words, in the context of any inquiry under the second sentence of Article 5.7, we will follow the approach we adopted in respect of the Complaining Parties' claims under Article 5.1 and 2.2.

7.3257 *Thirdly*, our approach does not have as a consequence that a provisional SPS measure which has been adopted consistently with the requirements of the first sentence of Article 5.7 may be maintained indefinitely. The requirement in the second sentence of Article 5.7 that a Member "review" a provisional SPS measure in our view implies that once sufficient relevant scientific evidence has been obtained and a risk assessment meeting the definition of Annex A(4) has been

[2075] In contrast, if, as we think, the sufficiency of scientific evidence is to be assessed at the time a provisional SPS measure was adopted, a Member which could demonstrate that, at the time it adopted its provisional SPS measure, relevant scientific evidence was insufficient would not have an obvious incentive to seek additional information and review its measure in the absence of a requirement to do so. Our view gives purpose to the inclusion of such explicit requirements in the second sentence of Article 5.7.

carried out[2076], the provisional SPS measure must be withdrawn or modified if it cannot be "based on" the risk assessment in question. We note in this regard that the dictionary defines the noun "review" as "a formal assessment of something with the intention of instituting change if necessary".[2077] We also recall that the Appellate Body in *Japan – Apples* observed that the requirement to review provisional SPS measures "highlights the *provisional* nature of measures adopted pursuant to Article 5.7".[2078] This observation implies that a Member is required to withdraw or modify a provisional measure if the review establishes that the measure is no longer justified. Indeed, were it otherwise, the requirement to review a provisional SPS measure would be inconsequential and meaningless.

(ii) Austria's safeguard measure on T25 maize

7.3258 Turning now to Austria's safeguard measure on T25 maize, we note the Complaining Parties' argument that relevant scientific evidence could not have been insufficient to conduct a risk assessment at the time of adoption of the Austrian safeguard measure, since a risk assessment was conducted by the SCP on the basis of the information provided by Austria in support of its measure.

7.3259 We recall that Austria adopted its safeguard measure on T25 maize in April 2000. Following Austria's notification of the measure, the Commission requested the SCP to analyse the information provided by Austria in support of its measure in order to determine whether this information would cause the SCP to consider that the product constituted a risk to human health or the environment. The SCP in its opinion of November 2000 concluded that the information provided by Austria did not constitute new scientific information which would change the original risk assessment which it had carried out in the context of the EC approval procedure concerning T25 maize.[2079] Thus, as we understand it, the SCP effectively reviewed its original risk assessment in the light of the information presented by Austria and confirmed its original risk assessment. [2080]

7.3260 We have found above that both the SCP opinions delivered in the context of relevant EC approval procedures – the original assessments– and the SCP opinions delivered after the adoption of the relevant member State safeguard measures – the review assessments – are risk assessments within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*.[2081] We recall in this regard that the European Communities does not suggest otherwise.[2082] In the light of this, we agree with the

[2076] We recall that a risk assessment as required under Article 5.1 and as defined in Annex A(4) could also be carried out by another Member or an international organization.

[2077] *The Concise Oxford Dictionary*, 10th edn, J. Pearsall (ed.) (Oxford University Press, 1999), p. 1225.

[2078] Appellate Body Report, *Japan – Apples*, footnote 318 (emphasis in original).

[2079] Exhibits US-56; CDA-77 and 87; ARG-45 and ARG-46.

[2080] Exhibits US-56 (referencing original SCP assessment); CDA-75 and -87; ARG-45 and -46 (referencing original SCP assessment).

[2081] We recall that the review assessments are generally in the nature of supplemental assessments and thus need to be read in conjunction with the original assessments.

[2082] It is pertinent to recall in this context that in defending the Austrian safeguard measure against the Complaining Parties' claims under Article 5.1, the European Communities essentially argued that Austria acted on the basis of new scientific information which presented a view divergent from the mainstream scientific opinion reflected in the original risk assessment. It may be that in making this argument the European Communities meant to refer to the SCP's original risk assessment. However, the fact that Austria may have disagreed with the SCP's original assessment, and possibly also with the SCP's subsequent review assessment, would not imply that the SCP's review and original assessments are not risk assessments as required under Article 5.1 and as defined in Annex A(4). The Appellate Body has made it clear that a risk assessment as required under Article 5.1 "[c]ould set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view". Appellate Body Report, *EC – Hormones*,

Complaining Parties that the SCP's review assessment of T25 maize, and the SCP's original assessment of T25 maize (which, as noted, was confirmed by the SCP's review assessment), serves to demonstrate that at the time of adoption of the Austrian safeguard measure, the body of available scientific evidence permitted the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). We consider, therefore, that the Complaining Parties have established a presumption that Austria's safeguard measure was imposed in respect of a situation where relevant scientific evidence was not insufficient. This presumption has not been effectively rebutted by the European Communities.[2083]

7.3261 As we pointed out above, the Appellate Body found that whenever one of the requirements of Article 5.7 is not met, the measure at issue is inconsistent with this provision. Thus, as it has been established that Austria's safeguard measure on T25 maize was not adopted consistently with the first requirement of Article 5.7, we conclude that that measure is inconsistent with Article 5.7.

Overall conclusions

7.3262 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that the Austrian safeguard measure on T25 maize is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on T25 maize is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel finds that the Austrian safeguard measure on T25 maize is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on T25 maize is not based on a risk assessment, the Panel reaches the final conclusion

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para. 184. Thus, the mere fact that the scientists taking a divergent view do not agree with the majority view does not necessarily mean that the majority view is based on a risk assessment which does not meet the standard and definition set out in Annex A(4). In any event, as noted, the European Communities does not argue that the SCP's original and review assessments of T25 maize are not risk assessments as required under Article 5.1 and as defined in Annex A(4).

[2083] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the Austrian safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that the Austrian safeguard measure on T25 maize is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on T25 maize is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(iii) Austria – Bt-176 maize

7.3263 We now turn to Austria's safeguard measure applied with respect to Bt-176 maize. We note the arguments of the Parties in respect of this measure.

7.3264 The **United States** argues that the Austrian safeguard measure on Bt-176 maize fails to meet any of the four requirements set out in Article 5.7. *First*, the scientific evidence is sufficient to perform a risk assessment, since the European Communities itself has conducted positive risk assessments on Bt-176 maize. *Second*, the safeguard measure was not adopted on the basis of "available pertinent information". The SCF and the Scientific Committee for Pesticides, Food and Animal Nutrition (SCPE) reviewed the safeguard measure and concluded that the information provided by Austria did not warrant any change in the earlier risk assessment. *Third*, Austria has not sought "to obtain the additional information necessary for a more objective assessment of risk", and there is no information on record that Austria has sought to perform a risk assessment that would support its measure on Bt-176 maize. *Finally*, the United States alleges that neither Austria nor the Commission have reviewed the Austrian safeguard measure within a reasonable period of time.

7.3265 **Argentina** argues that the Austrian safeguard measure does not meet any of the four requirements of Article 5.7. *First*, the scientific evidence was not insufficient, since at least two positive scientific opinions were expressed on Bt-176 maize, including one which specifically rejected the information provided by Austria in support of the measure. *Second*, Austria did not base its measure on the "available pertinent information", since it disregarded the positive scientific opinions of the scientific committee. *Third*, Austria has not sought to obtain further information necessary for a more objective risk assessment, because the information provided in this case is not consistent with the positive scientific opinions given by the scientific committee. *Finally*, with respect to the fourth requirement of Article 5.7, Argentina notes that Austria did not review its safeguard measure.

7.3266 The **European Communities** argues that the Austrian safeguard measure meets the four requirements of Article 5.7. *First*, the European Communities asserts that relevant scientific evidence was insufficient. According to the European Communities, the concept of "insufficiency" in Article 5.7 is "relational" and must therefore refer to the matters of concern to the legislator. Specifically, "insufficient" means "insufficient" for the production of a risk assessment adequate for the purposes of the legislator who must decide whether a measure should be applied, provisionally or otherwise, for one of the reasons enumerated in Annex A(1) of the *SPS Agreement*. The European Communities defines a risk assessment which is adequate as one which has been "delivered by a

reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised.[2084]

7.3267 In support of its view, the European Communities submits that the sufficiency of the evidence cannot be examined in a vacuum, but has to be examined in relation to the protection goals sought by legislators. The European Communities argues that it is artificial to suppose that there is some kind of magic moment at which the available science becomes sufficient for all purposes. In the European Communities' view, the actions of a legislator in response to available scientific evidence are a function of what that particular legislator is concerned about. Thus, in the European Communities' view, the higher the level of acceptable risk, the more likely it is that the legislator may conclude, within a relatively short period of time, that the scientific evidence is sufficient and that no provisional measure is therefore necessary. The lower the level of acceptable risk, the more likely it may be that the legislator may continue to consider, for a relatively long period of time, that the scientific evidence is insufficient, and that a measure is warranted.[2085] In other words, according to the European Communities, the sufficiency of the scientific evidence must be examined in relation to the level of acceptable risk of the legislators.

7.3268 Applying these considerations to the Austrian safeguard measure on Bt-176 maize, the European Communities submits that, having regard to the specific concerns of Austria's legislators in adopting that measure, Austria's legislators were entitled to conclude that relevant scientific evidence was insufficient for their purposes.

7.3269 *Second*, the European Communities contends that Austria has adopted and maintained its safeguard measure on the basis of "available pertinent information", which includes, *inter alia*, the information contained in the original notification, as well as the various relevant scientific discussions, papers and opinions. With respect to the *third* requirement of Article 5.7, the European Communities argues that both Austria and the European Communities are engaged in an ongoing process by which they are seeking to obtain additional information necessary for a more objective assessment of the risk through ongoing research and the constant development of science.

7.3270 Finally, the European Communities notes that the measure is subject to a process of review within a reasonable period of time, and that such review is still ongoing both at Community and member State levels.[2086] According to the European Communities, the determination of what constitutes a "reasonable period of time" pursuant to Article 5.7 depends on all the circumstances. In the present case, for instance, assessments are being made of long-term effects, in relation to changes that may have a permanent effect, and that are being introduced at an exponential rate as compared to the past. These circumstance may justify a Member requiring a relatively long period of time to review its provisional measure.[2087] The European Communities finds support for this view in the Appellate Body's statement that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned".[2088] The European Communities differentiates the present case from *Japan-Apples*, arguing that GMO technology is still at the frontiers of science and its future

[2084] EC first written submission, para. 604.

[2085] The European Communities considers that this analysis is confirmed by the words "reasonable period of time" in Article 5.7.

[2086] We recall that the US arguments that a requirement that measures be "constantly subject to review" does not meet the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption. US second written submission, para. 100.

[2087] The European Communities submits that the present case is very different, for example, from that before the panel in *Japan – Apples*.

[2088] Appellate Body Report, *EC – Hormones*, para. 124.

consequences (compared to a case like fire blight) are highly uncertain – and potentially more far-reaching. The European Communities argues that the relevant risks are more than the mere theoretical uncertainty that always remains simply because science can never provide absolute certainty that a given substance will never have adverse effects.[2089]

"Insufficiency of relevant scientific evidence"

7.3271 The **Panel** will begin its analysis with the first requirement of Article 5.7.[2090] In other words, we will consider whether the safeguard measure in question was imposed in respect of a situation where "relevant scientific evidence [was] insufficient". Initially, we recall that we do not agree with the European Communities that in the context of Article 5.7, the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member. We also recall our view that the sufficiency of relevant scientific evidence should be assessed at the time a provisional measure was adopted, not at the time of review by this Panel. The United States and Argentina argue in this regard that in the case of Austria's safeguard measure on Bt-176 maize, relevant scientific evidence could not have been insufficient to conduct a risk assessment at the time of adoption of the Austrian safeguard measure, since risk assessments were conducted by EC scientific committees on the basis of the information provided by Austria in support of its measure.

7.3272 We recall that Austria adopted its safeguard measure on Bt-176 maize in February 1997. Following Austria's notification of the measure, the Commission requested the SCF, the Scientific Committee for Animal Nutrition (SCAN) and the Scientific Committee for Pesticides (SCPE) to analyse the information provided by Austria in support of its measure in order to determine whether this information would cause these Committees to consider that the product constituted a risk to human health or the environment. The SCF in its opinion of March 1997, the SCAN in its opinion of April 1997 and the SCPE in its opinion of May 1997 concluded that the information provided by Austria did not constitute new scientific information which would change the original risk assessments which they had carried out in the context of the EC approval procedure concerning Bt-176 maize.[2091]

7.3273 We have found above that both the opinions by EC scientific committees which were delivered in the context of relevant EC approval procedures – the original assessments – and the opinions by EC scientific committees which were delivered after the adoption of the relevant member State safeguard measures – the review assessments – are risk assessments within the meaning of

[2089] The European Communities notes in its first written submission (para. 608) that "[t]he present case is, for example, very different from the circumstances of the Japan – Apples case. That case concerned a disease (fire blight) with a relatively narrow spectrum of possible consequences (compared to GMOs generally). The panel found that the disease had been known and studied for some 200 years – the GMO techniques with which this case is concerned are far more recent than that. The panel also found that there was a high quantity and quality of scientific evidence expressing strong and increasing confidence in the conclusion. In other words, the matter could fairly be described as no longer being at the frontiers of science, but rather to have passed into the realms of conventional scientific wisdom – an operational hypothesis unlikely to be disturbed other than by some revolutionary and currently totally unforeseeable new scientific discovery. That is not at all the circumstances of the present case. GMO technology is still at or close to the frontiers of science and its future consequences (compared to a case like fire blight) highly uncertain – and potentially much more far reaching."

[2090] We note that the panel in *Japan – Apples* also began its inquiry with the first requirement, an approach not faulted by the Appellate Body. Panel Report, *Japan – Apples*, para. 8.214.

[2091] Exhibits US-57, -58 and -66; ARG-43.

Annex A(4) and Article 5.1 of the *SPS Agreement*.[2092] We recall in this regard that the European Communities does not suggest otherwise[2093]. In the light of this, we agree with the United States and Argentina that the 1997 SCF, SCAN and SCPE review assessments of Bt-176 maize, and the SCF, SCAN and SCPE original assessments of Bt-176 maize (which, as noted, were confirmed by the review assessments), serve to demonstrate that at the time of adoption of the Austrian safeguard measure, the body of available scientific evidence permitted the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). We consider, therefore, that the United States and Argentina have established a presumption that Austria's safeguard measure was imposed in respect of a situation where relevant scientific evidence was not insufficient. This presumption has not been effectively rebutted by the European Communities[2094].

7.3274 As we pointed out above, the Appellate Body found that whenever one of the requirements of Article 5.7 is not met, the measure at issue is inconsistent with this provision. Thus, as it has been established that Austria's safeguard measure on Bt-176 maize was not adopted consistently with the first requirement of Article 5.7, we conclude that that measure is inconsistent with Article 5.7.

Overall conclusions

7.3275 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that the Austrian safeguard measure on Bt-176 maize is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on Bt-176 maize is not based on a risk assessment, the Panel reaches the final conclusion

[2092] We recall that the review assessments are generally in the nature of supplemental assessments and thus need to be read in conjunction with the original assessments.

[2093] It is pertinent to recall in this context that in defending the Austrian safeguard measure against the Complaining Parties' claims under Article 5.1, the European Communities essentially argued that Austria acted on the basis of new scientific information which presented a view divergent from the mainstream scientific opinion reflected in the original risk assessments. It may be that in making this argument the European Communities meant to refer to the original risk assessments by the SCF, the SCAN and the SCPE. However, the fact that Austria may have disagreed with these' original assessments, and possibly also with the subsequent review assessment by the SCP, would not imply that these committees' assessments are not risk assessments as required under Article 5.1 and as defined in Annex A(4). The Appellate Body has made it clear that a risk assessment as required under Article 5.1 "could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view". Appellate Body Report, *EC – Hormones*, para. 184. Thus, the mere fact that the scientists taking a divergent view do not agree with the majority view does not necessarily mean that the majority view is based on a risk assessment which does not meet the standard and definition set out in Annex A(4). In any event, as noted, the European Communities does not argue that the original and review assessments of Bt-176 maize are not risk assessments as required under Article 5.1 and as defined in Annex A(4).

[2094] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the Austrian safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that the Austrian safeguard measure on Bt-176 maize is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on Bt-176 maize is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(iv) Austria – MON810 maize

7.3276 We now turn to Austria's safeguard measure applied with respect to MON810 maize. We note the arguments of the Parties in respect of this measure.

7.3277 The **United States** argues that the Austrian safeguard measure on MON810 maize fails to meet any of the four requirements set out in Article 5.7. *First*, the scientific evidence is sufficient to perform a risk assessment, since the European Communities itself has conducted positive risk assessments on MON810 maize. *Second*, the safeguard measure was not adopted on the basis of "available pertinent information". The SCP reviewed the safeguard measure and concluded that the information provided by Austria did not warrant any change in the earlier risk assessment. *Third*, Austria has not sought "to obtain the additional information necessary for a more objective assessment of risk", and there is no information on record that Austria has sought to perform a risk assessment that would support its measure on MON810 maize. *Finally*, the United States alleges that neither Austria nor the Commission have reviewed the Austrian safeguard measure within a reasonable period of time.

7.3278 **Argentina** argues that the Austrian safeguard measure does not meet any of the four requirements of Article 5.7. *First*, the scientific evidence was not insufficient, since at least two positive scientific opinions were expressed on MON810 maize, including one which specifically rejected the information provided by Austria in support of the measure. *Second*, Austria did not base its measure on the "available pertinent information", since it disregarded the positive scientific opinions of the scientific committee. *Third*, Austria has not sought to obtain further information necessary for a more objective risk assessment, because the information provided in this case is not consistent with the positive scientific opinions given by the scientific committee. *Finally*, with respect to the fourth requirement of Article 5.7, Argentina notes that Austria did not review its safeguard measure.

7.3279 The **European Communities** argues that the Austrian safeguard measure meets the four requirements of Article 5.7. *First*, the European Communities asserts that relevant scientific evidence was insufficient. According to the European Communities, the concept of "insufficiency" in Article 5.7 is "relational" and must therefore refer to the matters of concern to the legislator. Specifically, "insufficient" means "insufficient" for the production of a risk assessment adequate for the purposes of the legislator who must decide whether a measure should be applied, provisionally or otherwise, for one of the reasons enumerated in Annex A(1) of the *SPS Agreement*. The European

Communities defines a risk assessment which is adequate as one which has been "delivered by a reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised.[2095]

7.3280 In support of its view, the European Communities submits that the sufficiency of the evidence cannot be examined in a vacuum, but has to be examined in relation to the protection goals sought by legislators. The European Communities argues that it is artificial to suppose that there is some kind of magic moment at which the available science becomes sufficient for all purposes. In the European Communities' view, the actions of a legislator in response to available scientific evidence are a function of what that particular legislator is concerned about. Thus, in the European Communities' view, the higher the level of acceptable risk, the more likely it is that the legislator may conclude, within a relatively short period of time, that the scientific evidence is sufficient and that no provisional measure is therefore necessary. The lower the level of acceptable risk, the more likely it may be that the legislator may continue to consider, for a relatively long period of time, that the scientific evidence is insufficient, and that a measure is warranted.[2096] In other words, according to the European Communities, the sufficiency of the scientific evidence must be examined in relation to the level of acceptable risk of the legislators.

7.3281 Applying these considerations to the Austrian safeguard measure on MON810 maize, the European Communities submits that, having regard to the specific concerns of Austria's legislators in adopting that measure, Austria's legislators were entitled to conclude that relevant scientific evidence was insufficient for their purposes.

7.3282 *Second*, the European Communities contends that Austria has adopted and maintained its safeguard measure on the basis of "available pertinent information", which includes, *inter alia*, the information contained in the original notification, as well as the various relevant scientific discussions, papers and opinions. With respect to the *third* requirement of Article 5.7, the European Communities argues that both Austria and the European Communities are engaged in an ongoing process by which they are seeking to obtain additional information necessary for a more objective assessment of the risk through ongoing research and the constant development of science.

7.3283 Finally, the European Communities notes that the measure is subject to a process of review within a reasonable period of time, and that such review is still ongoing both at Community and member State levels.[2097] According to the European Communities, the determination of what constitutes a "reasonable period of time" pursuant to Article 5.7 depends on all the circumstances. In the present case, for instance, assessments are being made of long-term effects, in relation to changes that may have a permanent effect, and that are being introduced at an exponential rate as compared to the past. These circumstance may justify a Member requiring a relatively long period of time to review its provisional measure.[2098] The European Communities finds support for this view in the Appellate Body's statement that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned".[2099] The European Communities differentiates the present case from

[2095] EC first written submission, para. 604.

[2096] The European Communities considers that this analysis is confirmed by the words "reasonable period of time" in Article 5.7.

[2097] We recall that the United States' argument that a requirement that measures be "constantly subject to review" does not meet the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption. US second written submission, para. 100.

[2098] The European Communities submits that the present case is very different, for example, from that before the panel in *Japan – Apples*.

[2099] Appellate Body Report, *EC – Hormones*, para. 124.

Japan - Apples, arguing that GMO technology is still at the frontiers of science and its future consequences (compared to a case like fire blight) are highly uncertain – and potentially more far-reaching. The European Communities argues that the relevant risks are more than the mere theoretical uncertainty that always remains simply because science can never provide absolute certainty that a given substance will never have adverse effects.[2100]

"Insufficiency of relevant scientific evidence"

7.3284 The **Panel** will begin its analysis with the first requirement of Article 5.7.[2101] In other words, we will consider whether the safeguard measure in question was imposed in respect of a situation where "relevant scientific evidence [was] insufficient". Initially, we recall that we do not agree with the European Communities that in the context of Article 5.7, the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member. We also recall our view that the sufficiency of relevant scientific evidence should be assessed at the time a provisional measure was adopted, not at the time of review by this Panel. The United States and Argentina argue in this regard that in the case of Austria's safeguard measure on MON810 maize, relevant scientific evidence could not have been insufficient to conduct a risk assessment at the time of adoption of the Austrian safeguard measure, since risk assessments were conducted by the EC scientific committees on the basis of the information provided by Austria in support of its measure.

7.3285 We recall that Austria adopted its safeguard measure on MON810 maize in June 1999. Following Austria's notification of the measure, the Commission requested the SCP to analyse the information provided by Austria in support of its measure in order to determine whether this information would cause the SCP to consider that the product constituted a risk to human health or the environment. The SCP in its opinion of September 1999 concluded that the information provided by Austria did not constitute new scientific information which would change the original risk assessment which it had carried out in the context of the EC approval procedure concerning MON810 maize.[2102] Thus, as we understand it, the SCP effectively reviewed its original risk assessment in the light of the information presented by Austria and confirmed its original risk assessment.

7.3286 We have found above that both the opinions by the EC scientific committees which were delivered in the context of relevant EC approval procedures – the original assessments – and the opinions by EC scientific committees which were delivered after the adoption of the relevant member State safeguard measures – the review assessments – are risk assessments within the meaning of

[2100] The European Communities notes in its first written submission (para. 608) that "[t]he present case is, for example, very different from the circumstances of the *Japan – Apples* case. That case concerned a disease (fire blight) with a relatively narrow spectrum of possible consequences (compared to GMOs generally). The panel found that the disease had been known and studied for some 200 years – the GMO techniques with which this case is concerned are far more recent than that. The panel also found that there was a high quantity and quality of scientific evidence expressing strong and increasing confidence in the conclusion. In other words, the matter could fairly be described as no longer being at the frontiers of science, but rather to have passed into the realms of conventional scientific wisdom – an operational hypothesis unlikely to be disturbed other than by some revolutionary and currently totally unforeseeable new scientific discovery. That is not at all the circumstances of the present case. GMO technology is still at or close to the frontiers of science and its future consequences (compared to a case like fire blight) highly uncertain – and potentially much more far reaching."

[2101] We note that the panel in *Japan – Apples* also began its inquiry with the first requirement, an approach not faulted by the Appellate Body. Panel Report, *Japan – Apples*, para. 8.214.

[2102] Exhibits US-55 and ARG-44.

Annex A(4) and Article 5.1 of the *SPS Agreement*.[2103] We recall in this regard that the European Communities does not suggest otherwise.[2104] In the light of this, we agree with the United States and Argentina that the SCP's 1999 review assessment of MON810 maize, and the SCP's original assessment of MON810 maize (which, as noted, were confirmed by the review assessments), serve to demonstrate that at the time of adoption of the Austrian safeguard measure, the body of available scientific evidence permitted the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). We consider, therefore, that the United States and Argentina have established a presumption that Austria's safeguard measure was imposed in respect of a situation where relevant scientific evidence was not insufficient. This presumption has not been effectively rebutted by the European Communities.[2105]

7.3287 As we pointed out above, the Appellate Body found that whenever one of the requirements of Article 5.7 is not met, the measure at issue is inconsistent with this provision. Thus, as it has been established that Austria's safeguard measure on MON810 maize was not adopted consistently with the first requirement of Article 5.7, we conclude that that measure is inconsistent with Article 5.7.

Overall conclusions

7.3288 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that the Austrian safeguard measure on MON810 maize is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on MON810 maize is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

[2103] We recall that the review assessments are generally in the nature of supplemental assessments and thus need to be read in conjunction with the original assessments.

[2104] It is pertinent to recall in this context that in defending the Austrian safeguard measure against the Complaining Parties' claims under Article 5.1, the European Communities essentially argued that Austria acted on the basis of new scientific information which presented a view divergent from the mainstream scientific opinion reflected in the original risk assessment. It may be that in making this argument the European Communities meant to refer to the SCP's original risk assessment. However, the fact that Austria may have disagreed with the SCP's original assessment, and possibly also with the SCP's subsequent review assessment, would not imply that the SCP's review and original assessments are not risk assessments as required under Article 5.1 and as defined in Annex A(4). The Appellate Body has made it clear that a risk assessment as required under Article 5.1 "could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view". Appellate Body Report, *EC – Hormones*, para. 184. Thus, the mere fact that the scientists taking a divergent view do not agree with the majority view does not necessarily mean that the majority view is based on a risk assessment which does not meet the standard and definition set out in Annex A(4). In any event, as noted, the European Communities does not argue that the SCP's original and review assessments of MON810 maize are not risk assessments as required under Article 5.1 and as defined in Annex A(4).

[2105] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the Austrian safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that the Austrian safeguard measure on MON810 maize is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on MON810 maize is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(v) France – MS1/RF1 oilseed rape (EC-161)

7.3289 We now turn to France's safeguard measure applied with respect to MS1/RF1 oilseed rape (EC-161). We note the arguments of the Parties in respect of this measure.

7.3290 The **United States** argues that the French safeguard measure on MS1/RF1 oilseed rape (EC-161) fails to meet any of the four requirements set out in Article 5.7. *First*, the scientific evidence is sufficient to perform a risk assessment, since the European Communities itself has conducted positive risk assessments on MS1/RF1 oilseed rape (EC-161). *Second*, the safeguard measure was not adopted on the basis of "available pertinent information". The SCP reviewed the safeguard measure and concluded that the information provided by France did not warrant any change in the earlier risk assessment. *Third*, France has not sought "to obtain the additional information necessary for a more objective assessment of risk", and there is no information on record that France has sought to perform a risk assessment that would support its measure on MS1/RF1 oilseed rape (EC-161). *Finally*, the United States alleges that neither France nor the Commission have reviewed the French safeguard measure within a reasonable period of time.

7.3291 **Canada** argues that a review of the French safeguard measure and the factual and scientific circumstances surrounding its adoption and maintenance reveal that the measure fails to satisfy any of the four elements of Article 5.7. *First*, the measure was not imposed in respect of a situation where relevant scientific information was insufficient. The opinion of the European Communities' own scientific experts demonstrate that there was sufficient scientific evidence to conduct a complete and objective risk assessment. In Canada's view, what was insufficient was the scientific evidence put forward by the European Communities or France to support the safeguard measure. *Second*, the measure was not adopted on the basis of "available pertinent information", since this would include the scientific opinions of the lead CA and of the relevant EC scientific committee, which all confirmed the safety of the product.

7.3292 With respect to the *third* element of Article 5.7, the requirement that the Member seek to obtain the additional information necessary for a more objective assessment of risk, Canada notes that this element is irrelevant in this case, given the sufficiency of the scientific evidence available from the European Communities' own sources. *Finally*, with regard to the fourth requirement, namely that the measure must be reviewed within a reasonable period of time, Canada recalls that the European Communities' own legislation requires that such a review take place. However, given the absence of "pertinent information" to support the safeguard measure, Canada draws the conclusion that the measure would have been lifted if such a review had been conducted. Furthermore, according to the Appellate Body, what constitutes a "reasonable period of time" will be influenced by the emergence

of the additional information necessary to make a more objective assessment of the risk. In Canada's view, new or additional information was not necessary in the present case to conduct a risk assessment, as sufficient scientific evidence was in existence even at the time the safeguard measure was taken.

7.3293 The **European Communities** argues that the French safeguard measure meets the four requirements of Article 5.7. *First*, the European Communities asserts that relevant scientific evidence was insufficient. According to the European Communities, the concept of "insufficiency" in Article 5.7 is "relational" and must therefore refer to the matters of concern to the legislator. Specifically, "insufficient" means "insufficient" for the production of a risk assessment adequate for the purposes of the legislator who must decide whether a measure should be applied, provisionally or otherwise, for one of the reasons enumerated in Annex A(1) of the *SPS Agreement*. The European Communities defines a risk assessment which is adequate as one which has been "delivered by a reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised.[2106]

7.3294 In support of its view, the European Communities submits that the sufficiency of the evidence cannot be examined in a vacuum, but has to be examined in relation to the protection goals sought by legislators. The European Communities argues that it is artificial to suppose that there is some kind of magic moment at which the available science becomes sufficient for all purposes. In the European Communities' view, the actions of a legislator in response to available scientific evidence are a function of what that particular legislator is concerned about. Thus, in the European Communities' view, the higher the level of acceptable risk, the more likely it is that the legislator may conclude, within a relatively short period of time, that the scientific evidence is sufficient and that no provisional measure is therefore necessary. The lower the level of acceptable risk, the more likely it may be that the legislator may continue to consider, for a relatively long period of time, that the scientific evidence is insufficient, and that a measure is warranted.[2107] In other words, according to the European Communities, the sufficiency of the scientific evidence must be examined in relation to the level of acceptable risk of the legislators.

7.3295 Applying these considerations to the French safeguard measure on MS1/RF1 oilseed rape (EC-161), the European Communities submits that, having regard to the specific concerns of France's legislators in adopting that measure, France's legislators were entitled to conclude that relevant scientific evidence was insufficient for their purposes.

7.3296 *Second*, the European Communities contends that France has adopted and maintained its safeguard measure on the basis of "available pertinent information", which includes, *inter alia*, the information contained in the original notification, as well as the various relevant scientific discussions, papers and opinions. With respect to the *third* requirement of Article 5.7, the European Communities argues that both France and the European Communities are engaged in an ongoing process by which they are seeking to obtain additional information necessary for a more objective assessment of the risk through ongoing research and the constant development of science.

7.3297 Finally, the European Communities notes that the measure is subject to a process of review within a reasonable period of time, and that such review is still ongoing both at Community and

[2106] EC first written submission, para. 604.

[2107] The European Communities considers that this analysis is confirmed by the words "reasonable period of time" in Article 5.7.

member State levels.[2108] According to the European Communities, the determination of what constitutes a "reasonable period of time" pursuant to Article 5.7 depends on all the circumstances. In the present case, for instance, assessments are being made of long-term effects, in relation to changes that may have a permanent effect, and that are being introduced at an exponential rate as compared to the past. These circumstances may justify a Member requiring a relatively long period of time to review its provisional measure.[2109] The European Communities finds support for this view in the Appellate Body's statement that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned".[2110] The European Communities differentiates the present case from *Japan-Apples*, arguing that GMO technology is still at the frontiers of science and its future consequences (compared to a case like fire blight) are highly uncertain – and potentially more far-reaching. The European Communities argues that the relevant risks are more than the mere theoretical uncertainty that always remains simply because science can never provide absolute certainty that a given substance will never have adverse effects.[2111]

"Insufficiency of relevant scientific evidence"

7.3298 The **Panel** will begin its analysis with the first requirement of Article 5.7.[2112] In other words, we will consider whether the safeguard measure in question was imposed in respect of a situation where "relevant scientific evidence [was] insufficient". Initially, we recall that we do not agree with the European Communities that in the context of Article 5.7, the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member. We also recall our view that the sufficiency of relevant scientific evidence should be assessed at the time a provisional measure was adopted, not at the time of review by this Panel. The United States and Canada argue in this regard that in the case of France's safeguard measure on MS1/RF1 oilseed rape (EC-161), relevant scientific evidence could not have been insufficient to conduct a risk assessment at the time of adoption of the French safeguard measure, since risk assessment were conducted by EC scientific committees on the basis of the information provided by France in support of its measure.

[2108] We recall that the United States' argument that a requirement that measures be "constantly subject to review" does not meet the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption. US second written submission, para. 100.

[2109] The European Communities submits that the present case is very different, for example, from that before the panel in *Japan – Apples*.

[2110] Appellate Body Report, *EC – Hormones*, para. 124.

[2111] The European Communities notes in its first written submission (para. 608) that "[t]he present case is, for example, very different from the circumstances of the Japan – Apples case. That case concerned a disease (fire blight) with a relatively narrow spectrum of possible consequences (compared to GMOs generally). The panel found that the disease had been known and studied for some 200 years – the GMO techniques with which this case is concerned are far more recent than that. The panel also found that there was a high quantity and quality of scientific evidence expressing strong and increasing confidence in the conclusion. In other words, the matter could fairly be described as no longer being at the frontiers of science, but rather to have passed into the realms of conventional scientific wisdom – an operational hypothesis unlikely to be disturbed other than by some revolutionary and currently totally unforeseeable new scientific discovery. That is not at all the circumstances of the present case. GMO technology is still at or close to the frontiers of science and its future consequences (compared to a case like fire blight) highly uncertain – and potentially much more far reaching."

[2112] We note that the panel in *Japan – Apples* also began its inquiry with the first requirement, an approach not faulted by the Appellate Body. Panel Report, *Japan – Apples*, para. 8.214.

7.3299 We recall that France adopted its safeguard measure on MS1/RF1 oilseed rape (EC-161) in November 1998. Following France's notification of the measure, the Commission requested the SCP to analyse the information provided by France in support of its measure in order to determine whether this information would cause the SCP to consider that the product constituted a risk to human health and the environment. The SCP in its opinion of May 1999 concluded that the information provided by France did not change the environmental assessment provided by the SCP in 1998 in the context of the approval procedure concerning a similar hybrid oilseed rape, MS8/RF3 oilseed rape.[2113] Thus, as we understand it, the SCP effectively reviewed its earlier risk assessment for MS8/RF3 oilseed rape in the light of the information presented by France and confirmed that assessment.

7.3300 We have found above that both the opinions by the EC scientific committees which were delivered in the context of relevant EC approval procedures – the original assessments – and the opinions by EC scientific committees which were delivered after the adoption of the relevant member State safeguard measures – the review assessments – are risk assessments within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*.[2114] We recall in this regard that the European Communities does not suggest otherwise.[2115] In the light of this, we agree with the United States and Canada that the SCP's 1999 review assessment of MS1/RF1 oilseed rape (EC-161), serves to demonstrate that at the time of adoption of the French safeguard measure, the body of available scientific evidence permitted the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). We consider, therefore, that the United States and Canada have established a presumption that France's safeguard measure was imposed in respect of a situation where relevant scientific evidence was not insufficient. This presumption has not been effectively rebutted by the European Communities.[2116]

7.3301 As we pointed out above, the Appellate Body found that whenever one of the requirements of Article 5.7 is not met, the measure at issue is inconsistent with this provision. Thus, as it has been established that France's safeguard measure on MS1/RF1 oilseed rape (EC-161) was not adopted consistently with the first requirement of Article 5.7, we conclude that that measure is inconsistent with Article 5.7.

[2113] We recall that the SCP was not consulted by the Commission before MS1/RF1 oilseed rape was approved, hence the SCP's reliance on the assessment concerning MS8/RF3 oilseed rape. Exhibits US-61 and CDA-69.

[2114] We recall that the review assessments are generally in the nature of supplemental assessments and thus need to be read in conjunction with the original assessments.

[2115] It is pertinent to recall in this context that in defending the French safeguard measure against the Complaining Parties' claims under Article 5.1, the European Communities essentially argued that France acted on the basis of new scientific information which presented a view divergent from the mainstream scientific opinion reflected in the original risk assessment. It may be that in making this argument the European Communities meant to refer to the SCP's original risk assessment with regard to MS8/RF3 oilseed rape. However, the fact that France may have disagreed with the SCP's original assessment, and possibly also with the SCP's subsequent review assessment, would not imply that the SCP's review and original assessments are not risk assessments as required under Article 5.1 and as defined in Annex A(4). The Appellate Body has made it clear that a risk assessment as required under Article 5.1 "could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view". Appellate Body Report, *EC – Hormones*, para. 184. Thus, the mere fact that the scientists taking a divergent view do not agree with the majority view does not necessarily mean that the majority view is based on a risk assessment which does not meet the standard and definition set out in Annex A(4). In any event, as noted, the European Communities does not argue that the relevant SCP assessments of MS1/RF1 oilseed rape are not risk assessments as required under Article 5.1 and as defined in Annex A(4).

[2116] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the French safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

Overall conclusions

7.3302 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel finds that the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the French safeguard measure on MS1/RF1 oilseed rape (EC-161) is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(vi) France – Topas oilseed rape

7.3303 We now turn to France's safeguard measure applied with respect to Topas oilseed rape. We recall the arguments of the Parties in respect of this measure.

7.3304 The **United States** argues that the French safeguard measure on Topas oilseed rape fails to meet any of the four requirements set out in Article 5.7. *First*, the scientific evidence is sufficient to perform a risk assessment, since the European Communities itself has conducted positive risk assessments on Topas oilseed rape. *Second*, the safeguard measure was not adopted on the basis of "available pertinent information". The SCP reviewed the safeguard measure and concluded that the information provided by France did not warrant any change in the earlier risk assessment. *Third*, France has not sought "to obtain the additional information necessary for a more objective assessment of risk", and there is no information on record that France has sought to perform a risk assessment that would support its measure on Topas oilseed rape. *Finally*, the United States alleges that neither France nor the Commission have reviewed the French safeguard measure within a reasonable period of time.

7.3305 **Canada** argues that a review of the French safeguard measure and the factual and scientific circumstances surrounding its adoption and maintenance reveal that the measure fails to satisfy any of the four elements of Article 5.7. *First*, the measure was not imposed in respect of a situation where relevant scientific information was insufficient. The opinion of the European Communities' own

scientific experts demonstrate that there was sufficient scientific evidence to conduct a complete and objective risk assessment. In Canada's view, what was insufficient was the scientific evidence put forward by the European Communities or France to support the safeguard measure. *Second*, the measure was not adopted on the basis of "available pertinent information", since this would include the scientific opinions of the lead CA and of the relevant EC scientific committee, which all confirmed the safety of the product.

7.3306 With respect to the *third* element of Article 5.7, the requirement that the Member seek to obtain the additional information necessary for a more objective assessment of risk, Canada notes that this element is irrelevant in this case, given the sufficiency of the scientific evidence available from the European Communities' own sources. *Finally*, with regard to the fourth requirement, namely that the measure must be reviewed within a reasonable period of time, Canada recalls that the European Communities' own legislation requires that such a review take place. However, given the absence of "pertinent information" to support the safeguard measure, Canada draws the conclusion that the measure would have been lifted if such a review had been conducted. Furthermore, according to the Appellate Body, what constitutes a "reasonable period of time" will be influenced by the emergence of the additional information necessary to make a more objective assessment of the risk. In Canada's view, new or additional information was not necessary in the present case to conduct a risk assessment, as sufficient scientific evidence was in existence even at the time the safeguard measure was taken.

7.3307 The **European Communities** argues that the French safeguard measure meets the four requirements of Article 5.7. *First*, the European Communities asserts that relevant scientific evidence was insufficient. According to the European Communities, the concept of "insufficiency" in Article 5.7 is "relational" and must therefore refer to the matters of concern to the legislator. Specifically, "insufficient" means "insufficient" for the production of a risk assessment adequate for the purposes of the legislator who must decide whether a measure should be applied, provisionally or otherwise, for one of the reasons enumerated in Annex A(1) of the *SPS Agreement*. The European Communities defines a risk assessment which is adequate as one which has been "delivered by a reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised.[2117]

7.3308 In support of its view, the European Communities submits that the sufficiency of the evidence cannot be examined in a vacuum, but has to be examined in relation to the protection goals sought by legislators. The European Communities argues that it is artificial to suppose that there is some kind of magic moment at which the available science becomes sufficient for all purposes. In the European Communities' view, the actions of a legislator in response to available scientific evidence are a function of what that particular legislator is concerned about. Thus, in the European Communities' view, the higher the level of acceptable risk, the more likely it is that the legislator may conclude, within a relatively short period of time, that the scientific evidence is sufficient and that no provisional measure is therefore necessary. The lower the level of acceptable risk, the more likely it may be that the legislator may continue to consider, for a relatively long period of time, that the scientific evidence is insufficient, and that a measure is warranted.[2118] In other words, according to the European Communities, the sufficiency of the scientific evidence must be examined in relation to the level of acceptable risk of the legislators.

[2117] EC first written submission, para. 604.

[2118] The European Communities considers that this analysis is confirmed by the words "reasonable period of time" in Article 5.7.

7.3309 Applying these considerations to the French safeguard measure on Topas oilseed rape, the European Communities submits that, having regard to the specific concerns of France's legislators in adopting that measure, France's legislators were entitled to conclude that relevant scientific evidence was insufficient for their purposes.

7.3310 *Second*, the European Communities contends that France has adopted and maintained its safeguard measure on the basis of "available pertinent information", which includes, *inter alia*, the information contained in the original notification, as well as the various relevant scientific discussions, papers and opinions. With respect to the *third* requirement of Article 5.7, the European Communities argues that both France and the European Communities are engaged in an ongoing process by which they are seeking to obtain additional information necessary for a more objective assessment of the risk through ongoing research and the constant development of science.

7.3311 Finally, the European Communities notes that the measure is subject to a process of review within a reasonable period of time, and that such review is still ongoing both at Community and member State levels.[2119] According to the European Communities, the determination of what constitutes a "reasonable period of time" pursuant to Article 5.7 depends on all the circumstances. In the present case, for instance, assessments are being made of long-term effects, in relation to changes that may have a permanent effect, and that are being introduced at an exponential rate as compared to the past. These circumstances may justify a Member requiring a relatively long period of time to review its provisional measure.[2120] The European Communities finds support for this view in the Appellate Body's statement that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned".[2121] The European Communities differentiates the present case from *Japan - Apples*, arguing that GMO technology is still at the frontiers of science and its future consequences (compared to a case like fire blight) are highly uncertain – and potentially more far-reaching. The European Communities argues that the relevant risks are more than the mere theoretical uncertainty that always remains simply because science can never provide absolute certainty that a given substance will never have adverse effects.[2122]

[2119] We recall that the US arguments that a requirement that measures be "constantly subject to review" does not meet the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption. US second written submission, para. 100.

[2120] The European Communities submits that the present case is very different, for example, from that before the panel in *Japan – Apples*.

[2121] Appellate Body Report, *EC – Hormones*, para. 124.

[2122] The European Communities notes in its first written submission (para. 608) that "[t]he present case is, for example, very different from the circumstances of the Japan – Apples case. That case concerned a disease (fire blight) with a relatively narrow spectrum of possible consequences (compared to GMOs generally). The panel found that the disease had been known and studied for some 200 years – the GMO techniques with which this case is concerned are far more recent than that. The panel also found that there was a high quantity and quality of scientific evidence expressing strong and increasing confidence in the conclusion. In other words, the matter could fairly be described as no longer being at the frontiers of science, but rather to have passed into the realms of conventional scientific wisdom – an operational hypothesis unlikely to be disturbed other than by some revolutionary and currently totally unforeseeable new scientific discovery. That is not at all the circumstances of the present case. GMO technology is still at or close to the frontiers of science and its future consequences (compared to a case like fire blight) highly uncertain – and potentially much more far reaching."

"Insufficiency of relevant scientific evidence"

7.3312 The **Panel** will begin its analysis with the first requirement of Article 5.7.[2123] In other words, we will consider whether the safeguard measure in question was imposed in respect of a situation where "relevant scientific evidence [was] insufficient". Initially, we recall that we do not agree with the European Communities that in the context of Article 5.7, the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member. We also recall our view that the sufficiency of relevant scientific evidence should be assessed at the time a provisional measure was adopted, not at the time of review by this Panel. The United States and Canada argue in this regard that in the case of France's safeguard measure on Topas oilseed rape, relevant scientific evidence could not have been insufficient to conduct a risk assessment at the time of adoption of the French safeguard measure, since a risk assessment was conducted by the SCP on the basis of the information provided by France in support of its measure.

7.3313 We recall that France adopted its safeguard measure on Topas oilseed rape in November 1998. Following France's notification of the measure, the Commission requested the SCP to analyse the information provided by France in support of its measure in order to determine whether this information would cause the SCP to consider that the product constituted a risk to human health or the environment. The SCP in its opinion of May 1999 concluded that the information provided by France did not constitute new scientific information which would change the original risk assessment carried out by the SCP in the context of the EC approval procedure concerning Topas oilseed rape.[2124] Thus, as we understand it, the SCP effectively reviewed its original risk assessment in the light of the information presented by France and confirmed its original risk assessment.

7.3314 We have found above that both the SCP opinions delivered in the context of relevant EC approval procedures – the original assessments – and the SCP opinions delivered after the adoption of the relevant member State safeguard measures – the review assessments – are risk assessments within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*. [2125] We recall in this regard that the European Communities does not suggest otherwise.[2126] In the light of this, we agree with the United States and Canada that the SCP's 1999 review assessment of Topas oilseed rape and the SCP's original assessment of Topas oilseed rape (which, as noted, was confirmed by the SCP's review

[2123] We note that the panel in *Japan – Apples* also began its inquiry with the first requirement, an approach not faulted by the Appellate Body. Panel Report, *Japan – Apples*, para. 8.214.

[2124] Exhibits US-62; CDA-65.

[2125] We recall that the review assessments are generally in the nature of supplemental assessments and thus need to be read in conjunction with the original assessments.

[2126] It is pertinent to recall in this context that in defending the French safeguard measure against the Complaining Parties' claims under Article 5.1, the European Communities essentially argued that France acted on the basis of new scientific information which presented a view divergent from the mainstream scientific opinion reflected in the original risk assessment. It may be that in making this argument the European Communities meant to refer to the SCP's original risk assessment. However, the fact that France may have disagreed with the SCP's original assessment, and possibly also with the SCP's subsequent review assessment, would not imply that the SCP's review and original assessments are not risk assessments as required under Article 5.1 and as defined in Annex A(4). The Appellate Body has made it clear that a risk assessment as required under Article 5.1 "could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view". Appellate Body Report, *EC – Hormones*, para. 184. Thus, the mere fact that the scientists taking a divergent view do not agree with the majority view does not necessarily mean that the majority view is based on a risk assessment which does not meet the standard and definition set out in Annex A(4). In any event, as noted, the European Communities does not argue that the SCP's original and review assessments of Topas oilseed rape are not risk assessments as required under Article 5.1 and as defined in Annex A(4).

assessment), serve to demonstrate that at the time of adoption of the French safeguard measure, the body of available scientific evidence permitted the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). We consider, therefore, that the United States and Canada have established a presumption that France's safeguard measure was imposed in respect of a situation where relevant scientific evidence was not insufficient. This presumption has not been effectively rebutted by the European Communities.[2127]

7.3315 As we pointed out above, the Appellate Body found that whenever one of the requirements of Article 5.7 is not met, the measure at issue is inconsistent with this provision. Thus, as it has been established that France's safeguard measure on Topas oilseed rape was not adopted consistently with the first requirement of Article 5.7, we conclude that that measure is inconsistent with Article 5.7.

Overall conclusions

7.3316 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that the French safeguard measure on Topas oilseed rape is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the French safeguard measure on Topas oilseed rape is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel finds that the French safeguard measure on Topas oilseed rape is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the French safeguard measure on Topas oilseed rape is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(vii) Germany – Bt-176 maize

7.3317 We now turn to Germany's safeguard measure applied with respect to Bt-176 maize. We recall the arguments of the Parties in respect of this measure.

[2127] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the French safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

7.3318 The **United States** argues that the German safeguard measure on Bt-176 maize fails to meet any of the four requirements set out in Article 5.7. *First*, the scientific evidence is sufficient to perform a risk assessment, since the European Communities itself has conducted positive risk assessments on Bt-176 maize. *Second*, the safeguard measure was not adopted on the basis of "available pertinent information". The SCP reviewed the safeguard measure and concluded that the information provided by Germany did not warrant any change in the earlier risk assessment. *Third*, Germany has not sought "to obtain the additional information necessary for a more objective assessment of risk", and there is no information on record that Germany has sought to perform a risk assessment that would support its measure on Bt-176 maize. *Finally*, the United States alleges that neither Germany nor the Commission have reviewed the German safeguard measure within a reasonable period of time.

7.3319 **Argentina** argues that the German safeguard measure does not meet any of the four requirements of Article 5.7. *First*, the scientific evidence was not insufficient, since at least two positive scientific opinions were expressed on Bt-176 maize, including one which specifically rejected the information provided by Germany in support of the measure. *Second*, Germany did not base its measure on the "available pertinent information", since it disregarded the positive scientific opinions of the scientific committee. *Third*, Germany has not sought to obtain further information necessary for a more objective risk assessment, because the information provided in this case is not consistent with the positive scientific opinions given by the scientific committee. *Finally*, with respect to the fourth requirement of Article 5.7, Argentina notes that Germany did not review its safeguard measure.

7.3320 The **European Communities** argues that the German safeguard measure meets the four requirements of Article 5.7. *First*, the European Communities asserts that relevant scientific evidence was insufficient. According to the European Communities, the concept of "insufficiency" in Article 5.7 is "relational" and must therefore refer to the matters of concern to the legislator. Specifically, "insufficient" means "insufficient" for the production of a risk assessment adequate for the purposes of the legislator who must decide whether a measure should be applied, provisionally or otherwise, for one of the reasons enumerated in Annex A(1) of the *SPS Agreement*. The European Communities defines a risk assessment which is adequate as one which has been "delivered by a reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised.[2128]

7.3321 In support of its view, the European Communities submits that the sufficiency of the evidence cannot be examined in a vacuum, but has to be examined in relation to the protection goals sought by legislators. The European Communities argues that it is artificial to suppose that there is some kind of magic moment at which the available science becomes sufficient for all purposes. In the European Communities' view, the actions of a legislator in response to available scientific evidence are a function of what that particular legislator is concerned about. Thus, in the European Communities' view, the higher the level of acceptable risk, the more likely it is that the legislator may conclude, within a relatively short period of time, that the scientific evidence is sufficient and that no provisional measure is therefore necessary. The lower the level of acceptable risk, the more likely it may be that the legislator may continue to consider, for a relatively long period of time, that the scientific evidence is insufficient, and that a measure is warranted.[2129] In other words, according to the European Communities, the sufficiency of the scientific evidence must be examined in relation to the level of acceptable risk of the legislators.

[2128] EC first written submission, para. 604.

[2129] The European Communities considers that this analysis is confirmed by the words "reasonable period of time" in Article 5.7.

7.3322 Applying these considerations to the German safeguard measure on Bt-176 maize, the European Communities submits that, having regard to the specific concerns of Germany's legislators in adopting that measure, Germany's legislators were entitled to conclude that relevant scientific evidence was insufficient for their purposes.

7.3323 *Second*, the European Communities contends that Germany has adopted and maintained its safeguard measure on the basis of "available pertinent information", which includes, *inter alia*, the information contained in the original notification, as well as the various relevant scientific discussions, papers and opinions. With respect to the *third* requirement of Article 5.7, the European Communities argues that both Germany and the European Communities are engaged in an ongoing process by which they are seeking to obtain additional information necessary for a more objective assessment of the risk through ongoing research and the constant development of science.

7.3324 Finally, the European Communities notes that the measure is subject to a process of review within a reasonable period of time, and that such review is still ongoing both at Community and member State levels.[2130] According to the European Communities, the determination of what constitutes a "reasonable period of time" pursuant to Article 5.7 depends on all the circumstances. In the present case, for instance, assessments are being made of long-term effects, in relation to changes that may have a permanent effect, and that are being introduced at an exponential rate as compared to the past. These circumstance may justify a Member requiring a relatively long period of time to review its provisional measure.[2131] The European Communities finds support for this view in the Appellate Body's statement that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned".[2132] The European Communities differentiates the present case from *Japan-Apples*: arguing that GMO technology is still at the frontiers of science and its future consequences (compared to a case like fire blight) are highly uncertain – and potentially more far-reaching. The European Communities argues that the relevant risks are more than the mere theoretical uncertainty that always remains simply because science can never provide absolute certainty that a given substance will never have adverse effects.[2133]

[2130] We recall that the United States' arguments that a requirement that measures be "constantly subject to review" does not meet the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption. *See* US second written submission, para. 100.

[2131] The European Communities submits that the present case is very different, for example, from that before the panel in *Japan – Apples*.

[2132] Appellate Body Report, *EC – Hormones*, para. 124.

[2133] The European Communities notes in its first written submission (para. 608) that "[t]he present case is, for example, very different from the circumstances of the Japan – Apples case. That case concerned a disease (fire blight) with a relatively narrow spectrum of possible consequences (compared to GMOs generally). The panel found that the disease had been known and studied for some 200 years – the GMO techniques with which this case is concerned are far more recent than that. The panel also found that there was a high quantity and quality of scientific evidence expressing strong and increasing confidence in the conclusion. In other words, the matter could fairly be described as no longer being at the frontiers of science, but rather to have passed into the realms of conventional scientific wisdom – an operational hypothesis unlikely to be disturbed other than by some revolutionary and currently totally unforeseeable new scientific discovery. That is not at all the circumstances of the present case. GMO technology is still at or close to the frontiers of science and its future consequences (compared to a case like fire blight) highly uncertain – and potentially much more far reaching."

"Insufficiency of relevant scientific evidence"

7.3325 The **Panel** will begin its analysis with the first requirement of Article 5.7.[2134] In other words, we will consider whether the safeguard measure in question was imposed in respect of a situation where "relevant scientific evidence [was] insufficient". Initially, we recall that we do not agree with the European Communities that in the context of Article 5.7, the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member. We also recall our view that the sufficiency of relevant scientific evidence should be assessed at the time a provisional measure was adopted, not at the time of review by this Panel. The United States and Argentina argue in this regard that in the case of Germany's safeguard measure on Bt-176 maize, relevant scientific evidence could not have been insufficient to conduct a risk assessment at the time of adoption of the German safeguard measure, since a risk assessment was conducted by the SCP on the basis of the information provided by Germany in support of its measure.

7.3326 We recall that Germany adopted its safeguard measure on Bt-176 maize in March 2000. Following Germany's notification of the measure, the Commission requested the SCP to analyse the information provided by Germany in support of its measure in order to determine whether this information would cause the SCP to consider that the product constituted a risk to human health or the environment. The SCP in its opinion of September 2000 concluded that the information provided by Germany did not constitute new scientific information which would change the original risk assessment which the SCPE had carried out in the context of the EC approval procedure concerning Bt-176 maize.[2135] Thus, as we understand it, the SCP effectively reviewed its original risk assessment in the light of the information presented by Germany and confirmed its original risk assessment.

7.3327 We have found above that both the opinions by the EC scientific committees which were delivered in the context of relevant EC approval procedures – the original assessments – and the opinions by EC scientific committees which were delivered after the adoption of the relevant member State safeguard measures – the review assessments – are risk assessments within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*.[2136] We recall in this regard that the European Communities does not suggest otherwise.[2137] In the light of this, we agree with the United States and Argentina that the SCP's 2000 review assessment of Bt-176 maize, and the SCPE's original

[2134] We note that the panel in *Japan – Apples* also began its inquiry with the first requirement, an approach not faulted by the Appellate Body. Panel Report, *Japan – Apples*, para. 8.214.

[2135] Exhibits US-66; ARG-43.

[2136] We recall that the review assessments are generally in the nature of supplemental assessments and thus need to be read in conjunction with the original assessments.

[2137] It is pertinent to recall in this context that in defending the German safeguard measure against the Complaining Parties' claims under Article 5.1, the European Communities essentially argued that Germany acted on the basis of new scientific information which presented a view divergent from the mainstream scientific opinion reflected in the original risk assessment. It may be that in making this argument the European Communities meant to refer to the SCPE's original risk assessment. However, the fact that Germany may have disagreed with the SCPE's original assessment, and possibly also with the SCP's subsequent review assessment, would not imply that the SCP's review and original assessments are not risk assessments as required under Article 5.1 and as defined in Annex A(4). The Appellate Body has made it clear that a risk assessment as required under Article 5.1 "could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view". Appellate Body Report, *EC – Hormones*, para. 184. Thus, the mere fact that the scientists taking a divergent view do not agree with the majority view does not necessarily mean that the majority view is based on a risk assessment which does not meet the standard and definition set out in Annex A(4). In any event, as noted, the European Communities does not argue that the SCP's original and review assessments of Bt-176 maize are not risk assessments as required under Article 5.1 and as defined in Annex A(4).

assessment of Bt-176 maize (which, as noted, was confirmed by the SCP's review assessment), serve to demonstrate that at the time of adoption of the German safeguard measure, the body of available scientific evidence permitted the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). We consider, therefore, that the United States and Argentina have established a presumption that Germany's safeguard measure was imposed in respect of a situation where relevant scientific evidence was not insufficient. This presumption has not been effectively rebutted by the European Communities.[2138]

7.3328 As we pointed out above, the Appellate Body found that whenever one of the requirements of Article 5.7 is not met, the measure at issue is inconsistent with this provision. Thus, as it has been established that Germany's safeguard measure on Bt-176 maize was not adopted consistently with the first requirement of Article 5.7, we conclude that that measure is inconsistent with Article 5.7.

Overall conclusions

7.3329 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that the German safeguard measure on Bt-176 maize is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the German safeguard measure on Bt-176 maize is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that the German safeguard measure on Bt-176 maize is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the German safeguard measure on Bt-176 maize is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(viii) Greece – Topas oilseed rape

7.3330 We now turn to Greece's safeguard measure applied with respect to Topas oilseed rape. We recall the arguments of the Parties in respect of this measure.

[2138] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the German safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure

7.3331 The **United States** argues that the Greek safeguard measure on Topas oilseed rape fails to meet any of the four requirements set out in Article 5.7. *First*, the scientific evidence is sufficient to perform a risk assessment, since the European Communities itself has conducted positive risk assessments on Topas oilseed rape. *Second*, the safeguard measure was not adopted on the basis of "available pertinent information". The SCP reviewed the safeguard measure and concluded that the information provided by Greece did not warrant any change in the earlier risk assessment. *Third*, Greece has not sought "to obtain the additional information necessary for a more objective assessment of risk", and there is no information on record that Greece has sought to perform a risk assessment that would support its measure on Topas oilseed rape. *Finally*, the United States alleges that neither Greece nor the Commission have reviewed the Greek safeguard measure within a reasonable period of time.

7.3332 **Canada** argues that a review of the Greek safeguard measure and the factual and scientific circumstances surrounding its adoption and maintenance reveal that the measure fails to satisfy any of the four elements of Article 5.7. *First*, the measure was not imposed in respect of a situation where relevant scientific information was insufficient. The opinion of the European Communities' own scientific experts demonstrate that there was sufficient scientific evidence to conduct a complete and objective risk assessment. In Canada's view, what was insufficient was the scientific evidence put forward by the European Communities or France to support the safeguard measure. *Second*, the measure was not adopted on the basis of "available pertinent information", since this would include the scientific opinions of the lead CA and of the relevant EC scientific committee, which all confirmed the safety of the product.

7.3333 With respect to the *third* element of Article 5.7, the requirement that the Member seek to obtain the additional information necessary for a more objective assessment of risk, Canada notes that this element is irrelevant in this case, given the sufficiency of the scientific evidence available from the European Communities' own sources. *Finally*, with regard to the fourth requirement, namely that the measure must be reviewed within a reasonable period of time, Canada recalls that the European Communities' own legislation requires that such a review take place. However, given the absence of "pertinent information" to support the safeguard measure, Canada draws the conclusion that the measure would have been lifted if such a review had been conducted. Furthermore, according to the Appellate Body, what constitutes a "reasonable period of time" will be influenced by the emergence of the additional information necessary to make a more objective assessment of the risk. In Canada's view, new or additional information was not necessary in the present case to conduct a risk assessment, as sufficient scientific evidence was in existence even at the time the safeguard measure was taken.

7.3334 The **European Communities** argues that the Greek safeguard measure meets the four requirements of Article 5.7. *First*, the European Communities asserts that relevant scientific evidence was insufficient. According to the European Communities, the concept of "insufficiency" in Article 5.7 is "relational" and must therefore refer to the matters of concern to the legislator. Specifically, "insufficient" means "insufficient" for the production of a risk assessment adequate for the purposes of the legislator who must decide whether a measure should be applied, provisionally or otherwise, for one of the reasons enumerated in Annex A(1) of the *SPS Agreement*. The European Communities defines a risk assessment which is adequate as one which has been "delivered by a reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised.[2139]

[2139] EC first written submission, para. 604.

7.3335 In support of its view, the European Communities submits that the sufficiency of the evidence cannot be examined in a vacuum, but has to be examined in relation to the protection goals sought by legislators. The European Communities argues that it is artificial to suppose that there is some kind of magic moment at which the available science becomes sufficient for all purposes. In the European Communities' view, the actions of a legislator in response to available scientific evidence are a function of what that particular legislator is concerned about. Thus, in the European Communities' view, the higher the level of acceptable risk, the more likely it is that the legislator may conclude, within a relatively short period of time, that the scientific evidence is sufficient and that no provisional measure is therefore necessary. The lower the level of acceptable risk, the more likely it may be that the legislator may continue to consider, for a relatively long period of time, that the scientific evidence is insufficient, and that a measure is warranted.[2140] In other words, according to the European Communities, the sufficiency of the scientific evidence must be examined in relation to the level of acceptable risk of the legislators.

7.3336 Applying these considerations to the Greek safeguard measure on Topas oilseed rape, the European Communities submits that, having regard to the specific concerns of Greece's legislators in adopting that measure, Greece's legislators were entitled to conclude that relevant scientific evidence was insufficient for their purposes.

7.3337 *Second*, the European Communities contends that Greece has adopted and maintained its safeguard measure on the basis of "available pertinent information", which includes, *inter alia*, the information contained in the original notification, as well as the various relevant scientific discussions, papers and opinions. With respect to the *third* requirement of Article 5.7, the European Communities argues that both Greece and the European Communities are engaged in an ongoing process by which they are seeking to obtain additional information necessary for a more objective assessment of the risk through ongoing research and the constant development of science.

7.3338 Finally, the European Communities notes that the measure is subject to a process of review within a reasonable period of time, and that such review is still ongoing both at Community and member State levels.[2141] According to the European Communities, the determination of what constitutes a "reasonable period of time" pursuant to Article 5.7 depends on all the circumstances. In the present case, for instance, assessments are being made of long-term effects, in relation to changes that may have a permanent effect, and that are being introduced at an exponential rate as compared to the past. These circumstances may justify a Member requiring a relatively long period of time to review its provisional measure.[2142] The European Communities finds support for this view in the Appellate Body's statement that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned".[2143] The European Communities differentiates the present case from *Japan - Apples*, arguing that GMO technology is still at the frontiers of science and its future consequences (compared to a case like fire blight) are highly uncertain – and potentially more far-reaching. The European Communities argues that the relevant risks are more than the mere

[2140] The European Communities considers that this analysis is confirmed by the words "reasonable period of time" in Article 5.7.

[2141] We recall that the US arguments that a requirement that measures be "constantly subject to review" does not meet the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption. US second written submission, para. 100.

[2142] The European Communities submits that the present case is very different, for example, from that before the panel in *Japan – Apples*.

[2143] Appellate Body Report, *EC – Hormones*, para. 124.

theoretical uncertainty that always remains simply because science can never provide absolute certainty that a given substance will never have adverse effects.[2144]

"Insufficiency of relevant scientific evidence"

7.3339 The **Panel** will begin its analysis with the first requirement of Article 5.7.[2145] In other words, we will consider whether the safeguard measure in question was imposed in respect of a situation where "relevant scientific evidence [was] insufficient". Initially, we recall that we do not agree with the European Communities that in the context of Article 5.7, the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member. We also recall our view that the sufficiency of relevant scientific evidence should be assessed at the time a provisional measure was adopted, not at the time of review by this Panel. The United States and Canada argue in this regard that in the case of Greece's safeguard measure on Topas oilseed rape, relevant scientific evidence could not have been insufficient to conduct a risk assessment at the time of adoption of the Greek safeguard measure, since a risk assessment was conducted by the SCP on the basis of the information provided by Greece in support of its measure.

7.3340 We recall that Greece adopted its safeguard measure on Topas oilseed rape in September 1998. Following Greece's notification of the measure, the Commission requested the SCP to analyse the information provided by Greece in support of its measure in order to determine whether this information would cause the SCP to consider that the product constituted a risk to human health or the environment. The SCP in its opinion of May 1999 concluded that the information provided by Greece did not constitute new scientific information which would change the original risk assessment carried out by the SCP in the context of the EC approval procedure concerning Topas oilseed rape.[2146] Thus, as we understand it, the SCP effectively reviewed its original risk assessment in the light of the information presented by Greece and confirmed its original risk assessment.

7.3341 We have found above that both the SCP opinions delivered in the context of relevant EC approval procedures – the original assessments – and the SCP opinions delivered after the adoption of the relevant member State safeguard measures – the review assessments – are risk assessments within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*.[2147] We recall in this regard that the European Communities does not suggest otherwise.[2148] In the light of this, we agree with the

[2144] The European Communities notes in its first written submission (para. 608) that "[t]he present case is, for example, very different from the circumstances of the Japan – Apples case. That case concerned a disease (fire blight) with a relatively narrow spectrum of possible consequences (compared to GMOs generally). The panel found that the disease had been known and studied for some 200 years – the GMO techniques with which this case is concerned are far more recent than that. The panel also found that there was a high quantity and quality of scientific evidence expressing strong and increasing confidence in the conclusion. In other words, the matter could fairly be described as no longer being at the frontiers of science, but rather to have passed into the realms of conventional scientific wisdom – an operational hypothesis unlikely to be disturbed other than by some revolutionary and currently totally unforeseeable new scientific discovery. That is not at all the circumstances of the present case. GMO technology is still at or close to the frontiers of science and its future consequences (compared to a case like fire blight) highly uncertain – and potentially much more far reaching."

[2145] We note that the panel in *Japan – Apples* also began its inquiry with the first requirement, an approach not faulted by the Appellate Body. Panel Report, *Japan – Apples*, para. 8.214.

[2146] Exhibits US-70; CDA-73.

[2147] We recall that the review assessments are generally in the nature of supplemental assessments and thus need to be read in conjunction with the original assessments.

[2148] It is pertinent to recall in this context that in defending the Greek safeguard measure against the Complaining Parties' claims under Article 5.1, the European Communities essentially argued that Greece acted on the basis of new scientific information which presented a view divergent from the mainstream scientific

United States and Canada that the SCP's 1999 review assessment of Topas oilseed rape, and the SCP's original assessment of Topas oilseed rape (which, as noted, was confirmed by the SCP's review assessment), serve to demonstrate that at the time of adoption of the Greek safeguard measure, the body of available scientific evidence permitted the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). We consider, therefore, that the United States and Canada have established a presumption that Greece's safeguard measure was imposed in respect of a situation where relevant scientific evidence was not insufficient. This presumption has not been effectively rebutted by the European Communities.[2149]

7.3342 As we pointed out above, the Appellate Body found that whenever one of the requirements of Article 5.7 is not met, the measure at issue is inconsistent with this provision. Thus, as it has been established that Greece's safeguard measure on Topas oilseed rape was not adopted consistently with the first requirement of Article 5.7, we conclude that that measure is inconsistent with Article 5.7.

Overall conclusions

7.3343 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that the Greek safeguard measure on Topas oilseed rape is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Greek safeguard measure on Topas oilseed rape is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel finds that the Greek safeguard

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opinion reflected in the original risk assessment. It may be that in making this argument the European Communities meant to refer to the SCP's original risk assessment. However, the fact that Greece may have disagreed with the SCP's original assessment, and possibly also with the SCP's subsequent review assessment, would not imply that the SCP's review and original assessments are not risk assessments as required under Article 5.1 and as defined in Annex A(4). The Appellate Body has made it clear that a risk assessment as required under Article 5.1 "could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view". Appellate Body Report, *EC – Hormones*, para. 184. Thus, the mere fact that the scientists taking a divergent view do not agree with the majority view does not necessarily mean that the majority view is based on a risk assessment which does not meet the standard and definition set out in Annex A(4). In any event, as noted, the European Communities does not argue that the SCP's original and review assessments of Topas oilseed rape are not risk assessments as required under Article 5.1 and as defined in Annex A(4).

[2149]In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the Greek safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

measure on Topas oilseed rape is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Greek safeguard measure on Topas oilseed rape is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(ix) Italy – T25 maize, MON810 maize, MON809 maize, Bt-11 maize (EC-163)

7.3344 We now turn to Italy's safeguard measure applied with respect to T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163). We recall the arguments of the Parties in respect of this measure.

7.3345 The **United States** argues that the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163), fails to meet any of the four requirements set out in Article 5.7. *First*, the scientific evidence is sufficient to perform a risk assessment, since the European Communities itself has conducted positive risk assessments on the products concerned. *Second*, the safeguard measure was not adopted on the basis of "available pertinent information". The SCF reviewed the safeguard measure and concluded that the information provided by Italy did not warrant any change in the earlier risk assessment. *Third*, Italy has not sought "to obtain the additional information necessary for a more objective assessment of risk", and there is no information on record that Italy has sought to perform a risk assessment that would support its measure on the products concerned. *Finally*, the United States alleges that neither Italy nor the Commission have reviewed the French safeguard measure within a reasonable period of time.

7.3346 **Canada** argues that a review of the Italian safeguard measure and the factual and scientific circumstances surrounding its adoption and maintenance reveal that the measure fails to satisfy any of the four elements of Article 5.7. *First*, the measure was not imposed in respect of a situation where relevant scientific information was insufficient. The opinion of the European Communities' own scientific experts demonstrate that there was sufficient scientific evidence to conduct a complete and objective risk assessment. In Canada's view, what was insufficient was the scientific evidence put forward by the European Communities or Italy to support the safeguard measure. *Second*, the measure was not adopted on the basis of "available pertinent information", since this would include the scientific opinions of the lead CA and of the relevant EC scientific committee, which all confirmed the safety of the product.

7.3347 With respect to the *third* element of Article 5.7, the requirement that the Member seek to obtain the additional information necessary for a more objective assessment of risk, Canada notes that this element is irrelevant in this case, given the sufficiency of the scientific evidence available from the European Communities' own sources. *Finally*, with regard to the fourth requirement, namely that the measure must be reviewed within a reasonable period of time, Canada recalls that the European Communities' own legislation requires that such a review take place. However, given the absence of "pertinent information" to support the safeguard measure, Canada draws the conclusion that the measure would have been lifted if such a review had been conducted. Furthermore, according to the Appellate Body, what constitutes a "reasonable period of time" will be influenced by the emergence of the additional information necessary to make a more objective assessment of the risk. In Canada's view, new or additional information was not necessary in the present case to conduct a risk assessment, as sufficient scientific evidence was in existence even at the time the safeguard measure was taken.

7.3348 **Argentina** argues that the Italian safeguard measure[2150] does not meet any of the four requirements of Article 5.7. *First*, the scientific evidence was not insufficient, since at least two positive scientific opinions were expressed on the products concerned, including one which specifically rejected the information provided by Italy in support of the measure. *Second*, Italy did not base its measure on the "available pertinent information", since it disregarded the positive scientific opinions of the scientific committee. *Third*, Italy has not sought to obtain further information necessary for a more objective risk assessment, because the information provided in this case is not consistent with the positive scientific opinions given by the scientific committee. *Finally*, with respect to the fourth requirement of Article 5.7, Argentina notes that Italy did not review its safeguard measure.

7.3349 The **European Communities** argues that the Italian safeguard measure meets the four requirements of Article 5.7. *First*, the European Communities asserts that relevant scientific evidence was insufficient. According to the European Communities, the concept of "insufficiency" in Article 5.7 is "relational" and must therefore refer to the matters of concern to the legislator. Specifically, "insufficient" means "insufficient" for the production of a risk assessment adequate for the purposes of the legislator who must decide whether a measure should be applied, provisionally or otherwise, for one of the reasons enumerated in Annex A(1) of the *SPS Agreement*. The European Communities defines a risk assessment which is adequate as one which has been "delivered by a reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised.

7.3350 In support of its view, the European Communities submits that the sufficiency of the evidence cannot be examined in a vacuum, but has to be examined in relation to the protection goals sought by legislators. The European Communities argues that it is artificial to suppose that there is some kind of magic moment at which the available science becomes sufficient for all purposes. In the European Communities' view, the actions of a legislator in response to available scientific evidence are a function of what that particular legislator is concerned about. Thus, in the European Communities' view, the higher the level of acceptable risk, the more likely it is that the legislator may conclude, within a relatively short period of time, that the scientific evidence is sufficient and that no provisional measure is therefore necessary. The lower the level of acceptable risk, the more likely it may be that the legislator may continue to consider, for a relatively long period of time, that the scientific evidence is insufficient, and that a measure is warranted.[2151] In other words, according to the European Communities, the sufficiency of the scientific evidence must be examined in relation to the level of acceptable risk of the legislators.

7.3351 Applying these considerations to the Italian safeguard measure on the products concerned, the European Communities submits that, having regard to the specific concerns of Italy's legislators in adopting that measure, Italy's legislators were entitled to conclude that relevant scientific evidence was insufficient for their purposes.

7.3352 *Second*, the European Communities contends that Italy has adopted and maintained its safeguard measure on the basis of "available pertinent information", which includes, *inter alia*, the information contained in the original notification, as well as the various relevant scientific discussions, papers and opinions. With respect to the *third* requirement of Article 5.7, the European

[2150] We recall that unlike the complaints by the other Complaining Parties, Argentina's complaint with regard to the Italian safeguard measure covers only three products subject to the Italian decree of August 2000, *i.e.*, T25 maize, MON810 maize and Bt-11 maize.

[2151] The European Communities considers that this analysis is confirmed by the words "reasonable period of time" in Article 5.7.

Communities argues that both Italy and the European Communities are engaged in an ongoing process by which they are seeking to obtain additional information necessary for a more objective assessment of the risk through ongoing research and the constant development of science.

7.3353 Finally, the European Communities notes that the measure is subject to a process of review within a reasonable period of time, and that such review is still ongoing both at Community and member State levels.[2152] According to the European Communities, the determination of what constitutes a "reasonable period of time" pursuant to Article 5.7 depends on all the circumstances. In the present case, for instance, assessments are being made of long-term effects, in relation to changes that may have a permanent effect, and that are being introduced at an exponential rate as compared to the past. These circumstances may justify a Member requiring a relatively long period of time to review its provisional measure.[2153] The European Communities finds support for this view in the Appellate Body's statement that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned".[2154] The European Communities differentiates the present case from *Japan-Apples*, arguing that GMO technology is still at the frontiers of science and its future consequences (compared to a case like fire blight) are highly uncertain – and potentially more far-reaching. The European Communities argues that the relevant risks are more than the mere theoretical uncertainty that always remains simply because science can never provide absolute certainty that a given substance will never have adverse effects.[2155]

"Insufficiency of relevant scientific evidence"

7.3354 The **Panel** will begin its analysis with the first requirement of Article 5.7.[2156] In other words, we will consider whether the safeguard measure in question was imposed in respect of a situation where "relevant scientific evidence [was] insufficient". Initially, we recall that we do not agree with the European Communities that in the context of Article 5.7, the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member. We also recall our view that the sufficiency of relevant scientific evidence should be assessed at the time a provisional measure was adopted, not at the time of review by this Panel. The Complaining Parties argue in this regard that in the case of Italy's safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163), relevant scientific evidence could not

[2152] We recall that the United States' argument that a requirement that measures be "constantly subject to review" does not meet the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption.

[2153] The European Communities submits that the present case is very different, for example, from that before the panel in *Japan – Apples*.

[2154] Appellate Body Report, *EC – Hormones*, para. 124.

[2155] The European Communities notes that "[t]he present case is, for example, very different from the circumstances of the Japan – Apples case. That case concerned a disease (fire blight) with a relatively narrow spectrum of possible consequences (compared to GMOs generally). The panel found that the disease had been known and studied for some 200 years – the GMO techniques with which this case is concerned are far more recent than that. The panel also found that there was a high quantity and quality of scientific evidence expressing strong and increasing confidence in the conclusion. In other words, the matter could fairly be described as no longer being at the frontiers of science, but rather to have passed into the realms of conventional scientific wisdom – an operational hypothesis unlikely to be disturbed other than by some revolutionary and currently totally unforeseeable new scientific discovery. That is not at all the circumstances of the present case. GMO technology is still at or close to the frontiers of science and its future consequences (compared to a case like fire blight) highly uncertain – and potentially much more far reaching."

[2156] We note that the panel in *Japan – Apples* also began its inquiry with the first requirement, an approach not faulted by the Appellate Body. Panel Report, *Japan – Apples*, para. 8.214.

have been insufficient to conduct a risk assessment at the time of adoption of the Italian safeguard measure, since a risk assessment was conducted by the SCF on the basis of the information provided by Italy in support of its measure.

7.3355 We recall that Italy adopted its safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) in August 2000. Following Italy's notification of the measure, the Commission requested the SCF to analyse the information provided by Italy in support of its measure in order to determine whether this information would cause the SCF to consider that the products in question constituted a risk to human health. The SCF in its opinion of September 2000 concluded that the information provided by Italy did not provide grounds for considering that the use of the products in question endangers human health. Thus, as we understand it, the SCF effectively confirmed the original risk assessments carried out by the SCP in the context of the EC approval procedures concerning the products concerned.

7.3356 We have found above that both the opinions by the EC scientific committees which were delivered in the context of relevant EC approval procedures – the original assessments – and the opinions by EC scientific committees which were delivered after the adoption of the relevant member State safeguard measures – the review assessments – are risk assessments within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*. [2157] We recall in this regard that the European Communities does not suggest otherwise.[2158] In the light of this, we agree with the Complaining Parties that the SCF's 2000 review assessment of the products concerned[2159], and the SCF's original assessment of the products concerned (which, as noted, was confirmed by the SCF's review assessment), serve to demonstrate that at the time of adoption of the Italian safeguard measure, the body of available scientific evidence permitted the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). We consider, therefore, that the Complaining Parties have established a presumption that Italy's safeguard measure was imposed in respect of a situation where relevant scientific evidence was not insufficient. This presumption has not been effectively rebutted by the European Communities.[2160]

7.3357 As we pointed out above, the Appellate Body found that whenever one of the requirements of Article 5.7 is not met, the measure at issue is inconsistent with this provision. Thus, as it has been

[2157] We recall that the review assessments are generally in the nature of supplemental assessments and thus need to be read in conjunction with the original assessments.

[2158] It is pertinent to recall in this context that in defending the Italian safeguard measure against the Complaining Parties' claims under Article 5.1, the European Communities essentially argued that Italy acted on the basis of new scientific information which presented a view divergent from the mainstream scientific opinion reflected in the original risk assessments. It may be that in making this argument the European Communities meant to refer to the SCP's original risk assessments. However, the fact that Italy may have disagreed with the SCP's original risk assessments, and possibly also with the SCF's subsequent review assessment, would not imply that these review and original assessments are not risk assessments as required under Article 5.1 and as defined in Annex A(4). The Appellate Body has made it clear that a risk assessment as required under Article 5.1 "could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view". Appellate Body Report, *EC – Hormones*, para. 184. Thus, the mere fact that the scientists taking a divergent view do not agree with the majority view does not necessarily mean that the majority view is based on a risk assessment which does not meet the standard and definition set out in Annex A(4). In any event, as noted, the European Communities does not argue that the original and review assessments of the products concerned are not risk assessments as required under Article 5.1 and as defined in Annex A(4).

[2159] Exhibits US-68; CDA-86 and ARG-47.

[2160] In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, the Italian safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure.

established that Italy's safeguard measure on the products concerned was not adopted consistently with the first requirement of Article 5.7, we conclude that that measure is inconsistent with Article 5.7.

Overall conclusions

7.3358 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel finds that the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that the Italian safeguard measure on T25 maize, MON810 maize and Bt-11 maize (EC-163) is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, the Italian safeguard measure on T25 maize, MON810 maize, MON809 maize and Bt-11 maize (EC-163) is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(x) Luxembourg – Bt-176 maize

7.3359 We now turn to Luxembourg's safeguard measure applied with respect to Bt-176 maize. We recall the arguments of the Parties in respect of this measure.

7.3360 The **United States** argues that Luxembourg's safeguard measure on Bt-176 maize fails to meet any of the four requirements set out in Article 5.7. *First*, the scientific evidence is sufficient to perform a risk assessment, since the European Communities itself has conducted positive risk assessments on Bt-176 maize. *Second*, the safeguard measure was not adopted on the basis of "available pertinent information". The SCF and the Scientific Committee for Pesticides reviewed the safeguard measure and concluded that the information provided by Luxembourg did not warrant any change in the earlier risk assessment. *Third*, Luxembourg has not sought "to obtain the additional information necessary for a more objective assessment of risk", and there is no information on record that Luxembourg has sought to perform a risk assessment that would support its measure on Bt-176 maize. *Finally*, the United States alleges that neither Luxembourg nor the Commission have reviewed Luxembourg's safeguard measure within a reasonable period of time.

7.3361 **Argentina** argues that Luxembourg's safeguard measure does not meet any of the four requirements of Article 5.7. *First*, the scientific evidence was not insufficient, since at least two positive scientific opinions were expressed on Bt-176 maize, including one which specifically rejected the information provided by Luxembourg in support of the measure. *Second*, Luxembourg did not base its measure on the "available pertinent information", since it disregarded the positive scientific opinions of the scientific committee. *Third*, Luxembourg has not sought to obtain further information necessary for a more objective risk assessment, because the information provided in this case is not consistent with the positive scientific opinions given by the scientific committee. *Finally*, with respect to the fourth requirement of Article 5.7, Argentina notes that Luxembourg did not review its safeguard measure.

7.3362 The **European Communities** argues that Luxembourg's safeguard measure meets the four requirements of Article 5.7. *First*, the European Communities asserts that relevant scientific evidence was insufficient. According to the European Communities, the concept of "insufficiency" in Article 5.7 is "relational" and must therefore refer to the matters of concern to the legislator. Specifically, "insufficient" means "insufficient" for the production of a risk assessment adequate for the purposes of the legislator who must decide whether a measure should be applied, provisionally or otherwise, for one of the reasons enumerated in Annex A(1) of the *SPS Agreement*. The European Communities defines a risk assessment which is adequate as one which has been "delivered by a reputable source, [which] unequivocally informs the legislator about what the risk is with a sufficient degree of precision, and [which] has withstood the passage of time and is unlikely to be revised.

7.3363 In support of its view, the European Communities submits that the sufficiency of the evidence cannot be examined in a vacuum, but has to be examined in relation to the protection goals sought by legislators. The European Communities argues that it is artificial to suppose that there is some kind of magic moment at which the available science becomes sufficient for all purposes. In the European Communities' view, the actions of a legislator in response to available scientific evidence are a function of what that particular legislator is concerned about. Thus, in the European Communities' view, the higher the level of acceptable risk, the more likely it is that the legislator may conclude, within a relatively short period of time, that the scientific evidence is sufficient and that no provisional measure is therefore necessary. The lower the level of acceptable risk, the more likely it may be that the legislator may continue to consider, for a relatively long period of time, that the scientific

evidence is insufficient, and that a measure is warranted.[2161] In other words, according to the European Communities, the sufficiency of the scientific evidence must be examined in relation to the level of acceptable risk of the legislators.

7.3364 Applying these considerations to the Luxembourg safeguard measure on Bt-176 maize, the European Communities submits that, having regard to the specific concerns of Luxembourg's legislators in adopting that measure, Luxembourg's legislators were entitled to conclude that relevant scientific evidence was insufficient for their purposes.

7.3365 Furthermore, the European Communities contends that Luxembourg has adopted and maintained its safeguard measure on the basis of "available pertinent information", which includes, *inter alia*, the information contained in the original notification, as well as the various relevant scientific discussions, papers and opinions. With respect to the *third* requirement of Article 5.7, the European Communities argues that both Luxembourg and the European Communities are engaged in an ongoing process by which they are seeking to obtain additional information necessary for a more objective assessment of the risk through ongoing research and the constant development of science.

7.3366 Finally, the European Communities notes that the measure is subject to a process of review within a reasonable period of time, and that such review is still ongoing both at Community and member State levels.[2162] According to the European Communities, the determination of what constitutes a "reasonable period of time" pursuant to Article 5.7 depends on all the circumstances. In the present case, for instance, assessments are being made of long-term effects, in relation to changes that may have a permanent effect, and that are being introduced at an exponential rate as compared to the past. These circumstances may justify a Member requiring a relatively long period of time to review its provisional measure.[2163] The European Communities finds support for this view in the Appellate Body's statement that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned".[2164] The European Communities differentiates the present case from *Japan-Apples*, arguing that GMO technology is still at the frontiers of science and its future consequences (compared to a case like fire blight) are highly uncertain – and potentially more far-reaching. The European Communities argues that the relevant risks are more than the mere theoretical uncertainty that always remains simply because science can never provide absolute certainty that a given substance will never have adverse effects.[2165]

[2161] The European Communities considers that this analysis is confirmed by the words "reasonable period of time" in Article 5.7.

[2162] We recall that the US arguments that a requirement that measures be "constantly subject to review" does not meet the requirement that the measures are in fact reviewed within a reasonable period of time of their adoption.

[2163] The European Communities submits that the present case is very different, for example, from that before the panel in *Japan – Apples*.

[2164] Appellate Body Report, *EC – Hormones*, para. 124.

[2165] The European Communities notes that "[t]he present case is, for example, very different from the circumstances of the *Japan – Apples* case. That case concerned a disease (fire blight) with a relatively narrow spectrum of possible consequences (compared to GMOs generally). The panel found that the disease had been known and studied for some 200 years – the GMO techniques with which this case is concerned are far more recent than that. The panel also found that there was a high quantity and quality of scientific evidence expressing strong and increasing confidence in the conclusion. In other words, the matter could fairly be described as no longer being at the frontiers of science, but rather to have passed into the realms of conventional scientific wisdom – an operational hypothesis unlikely to be disturbed other than by some revolutionary and currently totally unforeseeable new scientific discovery. That is not at all the circumstances of the present case.

"Insufficiency of relevant scientific evidence"

7.3367 The **Panel** will begin its analysis with the first requirement of Article 5.7.[2166] In other words, we will consider whether the safeguard measure in question was imposed in respect of a situation where "relevant scientific evidence [was] insufficient". Initially, we recall that we do not agree with the European Communities that in the context of Article 5.7, the insufficiency of relevant scientific evidence must be assessed by reference to the appropriate level of protection of the importing Member. We also recall our view that the sufficiency of relevant scientific evidence should be assessed at the time a provisional measure was adopted, not at the time of review by this Panel. The United States and Argentina argue in this regard that in the case of Luxembourg's safeguard measure on Bt-176 maize, relevant scientific evidence could not have been insufficient to conduct a risk assessment at the time of adoption of Luxembourg's safeguard measure, since risk assessments were apparently conducted by EC scientific committees on the basis of the information provided by Luxembourg in support of its measure.[2167]

7.3368 We recall that Luxembourg adopted its safeguard measure on Bt-176 maize in February 1997. Following Luxembourg's notification of the measure, the Commission apparently did not request the Scientific Committee for Pesticides (SCPE), the Scientific Committee for Animal Nutrition (SCAN) and the SCF to analyse the information provided by Luxembourg in support of its measure in order to determine whether this information would cause these Committees to consider that the product constituted a risk to human health or the environment. However, in response to a question from the Panel, the European Communities indicated that the Commission relied on the opinions provided by these committees in relation to Austria's safeguard measure on Bt-176 maize.[2168] To recall, the SCF in its opinion of March 1997, the SCAN in its opinion of April 1997 and the SCPE in its opinion of May 1997 concluded that the information provided by Austria did not constitute new scientific information which would change the original risk assessments which they had carried out in the context of the EC approval procedure concerning Bt-176 maize.[2169]

7.3369 We have found above that both the opinions by EC scientific committees which were delivered in the context of relevant EC approval procedures – the original assessments – and the opinions by EC scientific committees which were delivered after the adoption of the relevant member State safeguard measures – the review assessments – are risk assessments within the meaning of Annex A(4) and Article 5.1 of the *SPS Agreement*.[2170] We recall in this regard that the European Communities does not suggest otherwise. [2171] In the light of this, we consider that the 1997 SCF,

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GMO technology is still at or close to the frontiers of science and its future consequences (compared to a case like fire blight) highly uncertain – and potentially much more far reaching."

[2166] We note that the panel in *Japan – Apples* also began its inquiry with the first requirement, an approach not faulted by the Appellate Body. Panel Report, *Japan – Apples*, para. 8.214.

[2167] The United States and Argentina have provided a document indicating that EC scientific committees were consulted on Luxembourg's safeguard measure. Exhibits US-107; ARG-6. The United States has indicated, however, that it was unable to locate any opinion by an EC scientific committee on Luxembourg's safeguard measure.

[2168] EC reply to Panel question No. 106.

[2169] Exhibits US-57, -58 and -66; ARG-43.

[2170] We recall that the review assessments are generally in the nature of supplemental assessments and thus need to be read in conjunction with the original assessments.

[2171] It is pertinent to recall in this context that in defending the Austrian safeguard measure against the Complaining Parties' claims under Article 5.1, the European Communities essentially argued that Austria acted on the basis of new scientific information which presented a view divergent from the mainstream scientific opinion reflected in the original risk assessments. It may be that in making this argument the European Communities meant to refer to the original risk assessments by the SCF, the SCAN and the SCPE. However,

SCAN and SCPE review assessments of Bt-176 maize, and the SCF, SCAN and SCPE original assessments of Bt-176 maize (which, as noted, were confirmed by the review assessments), serve to demonstrate that at the time of adoption of Luxembourg's safeguard measure, the body of available scientific evidence permitted the performance of a risk assessment as required under Article 5.1 and as defined in Annex A(4). We consider, therefore, that these review assessments establish a presumption that Luxembourg's safeguard measure was imposed in respect of a situation where relevant scientific evidence was not insufficient. This presumption has not been effectively rebutted by the European Communities.[2172]

7.3370 As we pointed out above, the Appellate Body found that whenever one of the requirements of Article 5.7 is not met, the measure at issue is inconsistent with this provision. Thus, as it has been established that Luxembourg's safeguard measure on Bt-176 maize was not adopted consistently with the first requirement of Article 5.7, we conclude that that measure is inconsistent with Article 5.7.

Overall conclusions

7.3371 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel finds that Luxembourg's safeguard measure on Bt-176 maize is not consistent with Article 5.7 of the *SPS Agreement*.

In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, Luxembourg's safeguard measure on Bt-176 maize is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel finds that Luxembourg's safeguard measure on Bt-176 maize is not consistent with Article 5.7 of the *SPS Agreement*.

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the fact that Austria may have disagreed with these' original assessments, and possibly also with the subsequent review assessment by the SCP, would not imply that these committees' assessments are not risk assessments as required under Article 5.1 and as defined in Annex A(4). The Appellate Body has made it clear that a risk assessment as required under Article 5.1 "could set out both the prevailing view representing the 'mainstream' of scientific opinion, as well as the opinions of scientists taking a divergent view". Appellate Body Report, *EC – Hormones*, para. 184. Thus, the mere fact that the scientists taking a divergent view do not agree with the majority view does not necessarily mean that the majority view is based on a risk assessment which does not meet the standard and definition set out in Annex A(4). In any event, as noted, the European Communities does not argue that the original and review assessments of Bt-176 maize are not risk assessments as required under Article 5.1 and as defined in Annex A(4).

[2172]In view of this finding, it is not necessary to revisit the issue of whether, given its multiple purposes, Luxembourg's safeguard measure should be treated as constituting one or more SPS measures. Thus, like the Parties, we will continue to treat this measure as constituting one single SPS measure

> In view of this finding, as well as the Panel's previous finding that, contrary to the provisions of Article 5.1 of the *SPS Agreement*, Luxembourg's safeguard measure on Bt-176 maize is not based on a risk assessment, the Panel reaches the final conclusion that, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(e) Consistency with Article 5.6 of the *SPS Agreement*

7.3372 The Panel now turns to address Canada's and Argentina's claims of inconsistency under Article 5.6 of the *SPS Agreement*.

7.3373 We recall that Article 5.6 provides:

> "Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility."

7.3374 **Canada** argues the EC member State safeguard measures are inconsistent with Article 5.6 because they are more trade-restrictive than required to achieve the EC's appropriate level of protection. The fact that Article 2.2 includes the phrase that measures should be "applied only to the extent necessary to protect human, animal or plant life or health" highlights the relationship between Article 2.2 and Article 5.6. Given this relationship, and the fact that Article 5.6 is a more specific expression of the general obligation found in the clause in Article 2.2, a measure that is found to be in violation of Article 5.6 must also be presumed to violate Article 2.2. Therefore, these measures must also be presumed to violate Article 2.2.

7.3375 **Argentina** argues that (a) the EC member States had alternative sanitary or phytosanitary measures available, other than bans; (b) it was possible to achieve an appropriate level of protection using these alternative measures; and (c) these alternative measures would have been significantly less restrictive than a ban on biotech agricultural products already approved by the European Communities. Therefore, Argentina contends that the bans at the level of some member States violate Article 5.6 of the *SPS Agreement*. Argentina also argues, however, that in the interests of procedural economy a finding by the Panel that the relevant member State safeguard measures are inconsistent with Articles 5.1 and 2.2 will obviate the need for a further finding by the Panel that the safeguard measures are inconsistent with Article 5.6.

7.3376 The **European Communities** argues that Article 5.6 is not relevant to the specific rule provided for in Article 5.7. The appropriate level of protection referred to in Article 5.6 refers to that established pursuant to Article 5.1. Even if Article 5.6 were relevant to the application of Article 5.7, the necessity of the measure would have to be judged by reference to the insufficiency of scientific evidence, and the reasonable period of time necessary. Furthermore, because the appropriate level of protection of the Community and the member States differs, even if they agreed on the science underlying the measure, they might still disagree on the measures to be taken.

(i) Evaluation

7.3377 The **Panel** recalls that it has already reached the conclusion that the safeguard measures being challenged by Canada and Argentina, respectively, are inconsistent with Article 5.1 in that they are not based on a risk assessment. In view of our findings on Canada's and Argentina's claims under

Article 5.1, we cannot presume that the import prohibitions made effective through the relevant safeguard measures could eventually, that is after appropriate implementing action, be maintained as they are. In these circumstances, we see no need to examine, and offer additional findings on, whether the existing safeguard measures are also inconsistent with Article 5.6. Accordingly, we exercise judicial economy with regard to Canada's and Argentina's claims under Article 5.6.

(ii) Overall conclusions

7.3378 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Canada are inconsistent with Article 5.6 of the *SPS Agreement*. Accordingly, the Panel offers no findings under Article 5.6.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Argentina are inconsistent with Article 5.6 of the *SPS Agreement*. Accordingly, the Panel offers no findings under Article 5.6.

(f) Consistency with Article 5.5 of the *SPS Agreement*

7.3379 The Panel next proceeds to address Canada's and Argentina's claims of inconsistency under Article 5.5 of the *SPS Agreement*.

7.3380 We recall that Article 5.5 provides in relevant part:

> "With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade."

7.3381 **Canada** notes that its claim under Article 5.5 is presented in the alternative, that is in the event that the relevant member States' appropriate level of protection is that reflected in these member States' safeguard measures. Canada argues that the product-specific marketing bans meet all three elements that are required to establish a violation of Article 5.5. *First*, the European Communities has adopted different appropriate levels of sanitary and phytosanitary protection in "different situations" that are comparable.[2173] Canada notes that the European Communities has adopted different appropriate levels of sanitary and phytosantiary protection in at least three different situations: (i) EC-approved biotech products that are subject to the EC member State national measures; (ii) other EC-approved biotech products; and (iii) non-biotech varieties of the products in item. *Second*, those

[2173] Article 5.5 of the *SPS Agreement*. *See also*, Appellate Body Report, *EC – Hormones*, para. 214.

different appropriate levels of protection are "arbitrary or unjustifiable."[2174] *Third*, the measures embodying those differences, the product-specific marketing bans, result in "discrimination or a disguised restriction on international trade.

7.3382 **Argentina** argues that the bans on the safeguard measures by EC member States are inconsistent with Article 5.5 of the *SPS Agreement* since the three "elements" in Article 5.5 have been shown to have been violated cumulatively. Furthermore, the effect of the bans imposed by some member States on the biotechnology-producing countries is significant and adverse, inasmuch as it falls unfairly on imports. Argentina also argues, however, that in the interests of procedural economy a finding by the Panel that the relevant member State safeguard measures are inconsistent with Articles 5.1 and 2.2 will obviate the need for a further finding by the Panel that the safeguard measures are inconsistent with Article 5.5.

7.3383 The **European Communities** argues that Article 5.7 contains an express rule that effectively excludes Article 5.5. The European Communities considers that the member State measures to which Canada refers must be assessed by reference to Article 5.7 rather than Article 5.5. There is no basis for concluding that the member States have acted inconsistently with Article 5.5. Furthermore, the European Communities observes that consistency with Article 5.5 of the *SPS Agreement* should be evaluated in the context of the conduct of the European Communities. The European Communities has not behaved in an arbitrary manner or made unjustifiable distinctions such as those referred to in Article 5.5.

(i) Evaluation

7.3384 The **Panel** recalls that it has already reached the conclusion that the safeguard measures being challenged by Canada and Argentina, respectively, are inconsistent with Article 5.1 in that they are not based on a risk assessment. In view of our findings on Canada's and Argentina's claims under Article 5.1, we cannot presume that the import prohibitions made effective through the relevant safeguard measures could eventually, that is after appropriate implementing action, be maintained as they are. In these circumstances, we see no need to examine, and offer additional findings on, whether the European Communities acted inconsistently with its obligations under Article 5.5 in respect of the existing safeguard measures which embody particular levels of protection. Accordingly, we exercise judicial economy with regard to Canada's and Argentina's claims under Article 5.5.

(ii) Overall conclusions

7.3385 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Canada are inconsistent with Article 5.5 of the *SPS Agreement*. Accordingly, the Panel offers no findings under Article 5.5.

[2174] *Ibid.*

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Argentina are inconsistent with Article 5.5 of the *SPS Agreement*. Accordingly, the Panel offers no findings under Article 5.5.

(g) Consistency with Article 2.2 of the *SPS Agreement*

7.3386 The Panel now addresses the Complaining Parties' claims of inconsistency under Article 2.2 of the *SPS Agreement*.

7.3387 We recall that Article 2.2 provides:

> "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5."

7.3388 The **United States** argues that a violation of Article 5.1 can be presumed to imply a violation of the more general provision of Article 2.2. The only risk assessments put forth for the banned products are the positive scientific assessments rendered by member States to which the products were submitted, and then by the European Communities' own scientific committees. In the case of each member State ban, these favourable assessments were reaffirmed when the scientific committees considered and rejected the information provided by the member States. Thus, the member State measures do not bear a "rational relationship" to the European Communities' positive risks assessment, and are not "based on" a risk assessment, in violation of Article 5.1 and thus Article 2.2.

7.3389 **Canada** argues that a violation of Article 5.1 can be presumed to imply a violation of the more general provision of Article 2.2.[2175] Canada has already argued that the product-specific marketing bans are not "based on" risk assessments and are therefore inconsistent with Article 5.1. It can therefore be presumed that the product-specific marketing bans also violate the requirements of Article 2.2 that SPS measures be based on "scientific principles" and "not maintained without sufficient scientific evidence". Canada argues that since the product-specific marketing bans are inconsistent with Article 5.6 because they are more trade-restrictive than required to achieve the European Communities' appropriate level of protection, these measures must also be presumed to violate Article 2.2.

7.3390 **Argentina** argues that the inconsistency of the member State bans with Article 2 arises due to an inconsistency between these bans and Article 5. In addition, the lack of rational relationship between the member State safeguard measures and the scientific evidence renders these measures inconsistent with Article 2.2.[2176] The member State bans are not supported by scientific evidence. Furthermore, Article 2.2 requires that a measure be applied "only to the extent necessary," while also requires that it be based on "sufficient scientific evidence," whether it is to be implemented or to be maintained. Consequently, the member State bans also conflict with Article 2.2, and cannot be justified under the exception of Article 5.7.

[2175] Canada refers to, *e.g.*, Appellate Body Report, *Australia – Salmon*, paras. 137-138.
[2176] Argentina refers to Appellate Body Report, *Japan – Agricultural Products*, para. 73.

7.3391 The **European Communities** argues that Article 2.2 excludes from its scope of application the kinds of situations covered by Article 5.7.[2177] Article 5.7, rather than Article 2.2, is the provision to which Canada should have referred in order to properly understand the justification for the member State measures. "Necessity" can only be judged within a relevant time frame, taking into account any insufficiency in scientific evidence. Scientific principles include the principle that conclusions should be based on repeatable experiment, observation and the collection of data over time. Measures adopted on the basis of Article 5.7 are based on scientific principles, because they are based on the need to allow sufficient time for sufficient scientific evidence to be collected. There is therefore no basis for the Panel to conclude that the member State measures are inconsistent with Article 2.2 of the *SPS Agreement*.

7.3392 The **Panel** begins its examination by recalling that Article 2.2 contains three distinct requirements: (i) the requirement that SPS measures be applied only to the extent necessary to protect human, animal or plant life or health, (ii) the requirement that SPS measures be based on scientific principles, and (iii) the requirement that SPS measures not be maintained without sufficient scientific evidence. It is appropriate to analyse separately the first requirement, on the one hand, and the second and third requirements, on the other hand.

(i) First requirement of Article 2.2

7.3393 Canada and Argentina allege that the safeguard measures they are challenging are inconsistent with the first requirement of Article 2.2.

7.3394 We recall that we have already reached the conclusion that the safeguard measures being challenged by Canada and Argentina, respectively, are inconsistent with Article 5.1 in that they are not based on a risk assessment. In view of our findings on Canada's and Argentina's claims under Article 5.1, we cannot presume that the import prohibitions made effective through the relevant safeguard measures could eventually, that is after appropriate implementing action, be maintained as they are. In these circumstances, we see no need to examine, and offer additional findings on, whether the existing safeguard measures are also inconsistent with the first requirement in Article 2.2. Accordingly, we exercise judicial economy with regard to Canada's and Argentina's claims under the first requirement in Article 2.2.

(ii) Second and third requirements of Article 2.2

7.3395 All three Complaining Parties allege that the safeguard measures they are challenging are inconsistent with the second and third requirements of Article 2.2.

7.3396 Here as well, we begin by recalling that we have already reached the conclusion that the safeguard measures challenged by the Complaining Parties are inconsistent with Article 5.1 in that they are not based on a risk assessment. In *Australia – Salmon*, the Appellate Body agreed with the panel in that case that in the event an SPS measure is not based on a risk assessment as required in Article 5.1, this measure can be presumed, more generally, not to be based on scientific principles or not to be maintained without sufficient scientific evidence within the meaning of Article 2.2. The Appellate Body concluded on that basis that "by maintaining an import prohibition on fresh, chilled or frozen ocean-caught Pacific salmon, in violation of Article 5.1, Australia has, by implication, also

[2177] The European Communities refers to Appellate Body Report, *EC – Hormones*, para. 104, in respect of Articles 3.1 and 3.3 of the *SPS Agreement.* The European Communities notes that Article 3.1 contains language essentially identical to that in Article 2.2.

acted inconsistently with Article 2.2 of the *SPS Agreement*".[2178] We consider that the same logic and presumption are applicable in the present case. Accordingly, we find that by maintaining the challenged safeguard measures inconsistently with Article 5.1, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2.

(iii) Article 5.7

7.3397 We have determined above that the relevant safeguard measures are inconsistent, by implication, with the second and third requirements in Article 2.2. Before coming to a final conclusion, however, we address whether the safeguard measures are consistent with the requirements of Article 5.7 of the *SPS Agreement*.

7.3398 We have found earlier that the safeguard measures at issue are not consistent with Article 5.7. This finding applies also to our analysis under Article 2.2, and so we confirm it here. Accordingly, there can be no doubt that the second and third requirements in Article 2.2 are applicable to the safeguard measures.[2179] This in turn confirms that these measures are contrary to Article 2.2, inasmuch as they are inconsistent, by implication, with the second and third requirements in Article 2.2.

(iv) Overall conclusions

7.3399 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that by applying, inconsistently with Article 5.1 of the *SPS Agreement*, the safeguard measures which the United States is challenging, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes as follows:

(a) It is not necessary to make findings on whether the safeguard measures which are being challenged by Canada are inconsistent with the first requirement of Article 2.2 of the *SPS Agreement*. Accordingly, the Panel offers no findings with regard to the first requirement in Article 2.2 of the *SPS Agreement*.

(b) By applying, inconsistently with Article 5.1 of the *SPS Agreement*, the safeguard measures which Canada is challenging, the European Communities

[2178] Appellate Body Report, *Australia – Salmon*, paras. 137-138.

[2179] We recall that, earlier, we have left open whether Article 5.7 acts as a qualified exemption from the second requirement in Article 2.2. In view of our finding that none of the safeguard measures are consistent with Article 5.7, the issue is without practical significance for our analysis under Article 2.2, and so we do not address it further.

has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(iii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes as follows:

(a) It is not necessary to make findings on whether the safeguard measures which are being challenged by Argentina are inconsistent with the first requirement of Article 2.2 of the *SPS Agreement*. Accordingly, the Panel offers no findings with regard to the first requirement in Article 2.2 of the *SPS Agreement*.

(b) By applying, inconsistently with Article 5.1 of the *SPS Agreement*, the safeguard measures which Argentina is challenging, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(h) Consistency with Article 2.3 of the *SPS Agreement*

7.3400 The Panel finally addresses Canada's and Argentina's claims of inconsistency under Article 2.3 of the *SPS Agreement*.

7.3401 We recall that Article 2.3 provides:

> "Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade."

7.3402 **Canada** notes that in *Australia-Salmon*, the Panel stated that a violation of Article 5.5 "can be presumed to imply a violation of the more general Article 2.3".[2180] In the case at hand, Canada has demonstrated that the EC member State national measures are inconsistent with the European Communities obligations under Article 5.5. By implication, therefore, these measures also violate Article 2.3.

7.3403 **Argentina** argues that as the member State bans have been shown to be inconsistent with Article 5.5, they also violate Article 2.3. Argentina also argues, however, that in the interests of procedural economy a finding by the Panel that the relevant member State safeguard measures are inconsistent with Articles 5.1 and 2.2 will obviate the need for a further finding by the Panel that the safeguard measures are inconsistent with Article 2.3.

7.3404 The **European Communities** argues that since the member State measures are not inconsistent with Article 5.5, they are not inconsistent with Article 2.3.

[2180] Canada refers to Panel Report, *Australia – Salmon*, para. 8.109. According to Canada, the Appellate Body upheld this statement. *See* Appellate Body Report, *Australia – Salmon*, para. 178.

(i) Evaluation

7.3405 The **Panel** recalls that it has already reached the conclusion that the safeguard measures being challenged by Canada and Argentina, respectively, are inconsistent with Article 5.1 in that they are not based on a risk assessment. In view of our findings on Canada's and Argentina's claims under Article 5.1, we cannot presume that the import prohibitions made effective through the relevant safeguard measures could eventually, that is after appropriate implementing action, be maintained as they are. In these circumstances, we see no need to examine, and offer additional findings on, whether the existing safeguard measures are also inconsistent with Article 2.3. Accordingly, we exercise judicial economy with regard to Canada's and Argentina's claims under Article 2.3.

(ii) Overall conclusions

7.3406 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Canada are inconsistent with Article 2.3 of the *SPS Agreement*. Accordingly, the Panel offers no findings under Article 2.3.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Argentina are inconsistent with Article 2.3 of the *SPS Agreement*. Accordingly, the Panel offers no findings under Article 2.3.

3. Analysis of the safeguard measures in the light of the *TBT Agreement*

7.3407 The Panel now turns to address Canada's and Argentina's claims of inconsistency under the *TBT Agreement*. The United States did not present claims under the *TBT Agreement*.

7.3408 **Canada** considers that the safeguard measures it is challenging are SPS measures and that, as such, they are not subject to the requirements of the *TBT Agreement*. Canada argues, however, that if the Panel decides that the safeguard measures at issue are not SPS measures, then Canada submits, in the alternative, that these measures are "technical regulations", as that term is defined in the *TBT Agreement*, and therefore subject to the requirements of that Agreement. Furthermore, in Canada's view, these measures are inconsistent with Article 2.1, Article 2.2, and Articles 2.9.1, 2.9.2 and 2.9.3 of the *TBT Agreement.*

7.3409 Furthermore, Canada states that to the extent that the Panel determines that parts of the measure at issue are covered by the *TBT Agreement* in addition to the *SPS Agreement*, Canada's TBT claims are to be considered cumulative rather than alternative, *vis-à-vis* its SPS claims.

7.3410 **Argentina** considers that the Panel should examine the measures Argentina is challenging under the *SPS Agreement*. However, if the Panel concludes that it should not examine these measures under the *SPS Agreement*, Argentina submits, in the alternative, that the safeguard measures at issue

are "technical regulations", as that term is defined in the *TBT Agreement*, and therefore subject to the requirements of that Agreement. Furthermore, in Argentina's view, by instituting bans on specific biotech products, these measures have violated Articles 2.1, 2.2, 2.9.1, 2.9.2 and 2.9.4 of the *TBT Agreement*.

7.3411 The **European Communities** considers that, given the reasons on which the relevant safeguard measures are based, they fall in part within the scope of the *SPS Agreement* and in part outside the scope of the *SPS Agreement*. The European Communities does not agree, however, that the relevant safeguard measures are subject to the provisions of the *TBT Agreement*. In the European Communities' view, these measures are not "technical regulations" within the meaning of the *TBT Agreement*. For this and other reasons, the European Communities considers that these measures cannot be inconsistent with Article 2 of that Agreement.

(a) Evaluation

7.3412 The Panel begins its examination with Canada's claims. Canada has stated that if the Panel determines that parts of the relevant safeguard measures are covered by the *TBT Agreement* in addition to the *SPS Agreement*, Canada's claims under the *TBT Agreement* are to be considered cumulative rather than alternative. We have found, however, that each of the safeguard measures challenged by Canada constitutes in its entirety an "SPS measure" within the meaning of Annex A(1) of the *SPS Agreement* and hence falls to be assessed under that Agreement. In view of this finding and Article 1.5 of the *TBT Agreement*[2181], we do not consider that parts of the relevant safeguard measures are covered by the *TBT Agreement.* Consequently, we should treat Canada's claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement* as alternative claims. Since Canada's alternative claims are relevant only in the event that we decide that the relevant safeguard measures are not subject to the *SPS Agreement*, and since this is not what we have decided, we see no need to address Canada's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement* further.

7.3413 Argentina's claims under the *TBT Agreement* are presented in the alternative, in the event the Panel finds that the relevant safeguard measures should not be examined under the *SPS Agreement*. We have found, however, that each of the safeguard measures challenged by Argentina should be assessed in the light of the *SPS Agreement*. In these circumstances, we see no need to address Argentina's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement* further.

(b) Overall conclusions

7.3414 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Canada are inconsistent with Articles 2.1, 2.2 or 2.9 of the *TBT Agreement*. Accordingly, the Panel offers no findings under Article 2.1, 2.2 or 2.9 of the *TBT Agreement.*

[2181] We recall that Article 1.5 states that the provisions of the *TBT Agreement* do not apply to SPS measures within the meaning of Annex A(1) of the *SPS Agreement*.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Argentina are inconsistent with Articles 2.1, 2.2 or 2.9 of the *TBT Agreement*. Accordingly, the Panel offers no findings under Article 2.1, 2.2 or 2.9 of the *TBT Agreement*.

4. Analysis of the safeguard measures in the light of the GATT 1994

7.3415 The Panel now turns to address the Complaining Parties' claims of inconsistency under the GATT 1994. Canada and Argentina have presented claims under Article III:4 of the GATT 1994. The United States and Canada have presented claims under Article XI:1 of the GATT 1994. The Panel first addresses the claims under Article III:4.

(a) Consistency with Article III:4 of the GATT 1994

7.3416 Article III:4 of the GATT 1994 provides in relevant part:

> "The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use."

7.3417 **Canada** claims that Austria's safeguard measure on T25 maize, France's safeguard measures on Topas oilseed rape and MS1/RF1 oilseed rape (EC-161), and Italy's safeguard measure on MON810 maize, MON809 maize, Bt-11 (EC-163) and T25 maize fall within the scope of the GATT 1994 and are inconsistent with the European Communities' obligations under Article III:4.[2182]

7.3418 According to Canada, these four safeguard measures all are "laws, regulations or requirements laws, regulations or requirements affecting the internal sale, offering for sale, purchase, and distribution" of the biotech products concerned; the biotech products subject to these safeguard measures are "like" domestically produced non-biotech products in the light of four criteria put forth by the Appellate Body; and the imported biotech products concerned are accorded treatment less favourable than that accorded like non-biotech products of national origin. Therefore, Canada argues that the four safeguard measures constitute a violation of the European Communities' national treatment obligations under Article III:4.

7.3419 **Argentina** claims that Austria's safeguard measures on T25 maize, Bt-176 and MON810 maize, Germany's safeguard measure on Bt-176 maize, Italy's safeguard measure on MON810 maize, Bt-11 (EC-163) and T25 maize, and Luxembourg's safeguard measure on Bt-176 maize fall within the scope of the GATT 1994 and are inconsistent with the European Communities' obligations under Article III:4.

7.3420 According to Argentina, the biotech products subject to the safeguard measures and non-biotech agricultural products are "like" within the meaning of Article III:4 of the GATT 1994; the

[2182] Austria's measure on T25 maize, France's measures on Topas and MS1/RF1 oilseed rape, and Italy's measure on MON810, MON809, Bt-11 and T25 maize.

safeguard measures at issue are a "law, regulation or requirement" affecting "their [the products'] internal sale, offering for sale, purchase, transportation, distribution, or use"; and the treatment accorded to the imported (biotech) product is "less favourable" than accorded to the ("non-biotech") domestic product.

(i) Evaluation

7.3421 The **Panel** notes that Canada's claim under Article III:4 concerns four of the five safeguard measures challenged by Canada, namely, (i) Austria – T25 maize, (ii) France – MS1/RF1 oilseed rape (EC 161), (iii) France – Topas oilseed rape, and (iv) Italy – Bt-11 maize (EC-163), MON809 maize, MON810 maize and T25 maize. Argentina's claim under Article III:4 concerns all six safeguard measures challenged by Argentina.

7.3422 We recall that we have already reached the conclusion that the aforementioned safeguard measures being challenged by Canada and Argentina, respectively, are inconsistent with Article 5.1 and, by implication, the second and third requirements in Article 2.2 of the *SPS Agreement*. In these circumstances, we see no need to examine, and offer additional findings on, whether the relevant safeguard measures are also inconsistent with Article III:4. Accordingly, as did previous panels in similar situations[2183], we exercise judicial economy with regard to Canada's and Argentina's claims under Article III:4.

(ii) Overall conclusions

7.3423 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Canada are inconsistent with Article III:4 of the GATT 1994. Accordingly, the Panel offers no findings under Article III:4.

(ii) DS293 (Argentina)

With reference to DS293, and having regard to the arguments and evidence presented by Argentina and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Argentina are inconsistent with Article III:4 of the GATT 1994. Accordingly, the Panel offers no findings under Article III:4.

(b) Consistency with Article XI:1 of the GATT 1994

7.3424 The Panel now turns to address the United States' and Canada's claim under Article XI:1 of the GATT 1994.

[2183] Panel Reports, *EC – Hormones (US)*, para. 8.272; *EC – Hormones (Canada)*, para. 8.275.

7.3425 Article XI:1 of the GATT 1994 provides:

> "No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation or sale for export of any product destined for the territory of any other contracting party."

7.3426 The **United States** claims that the Greek safeguard measure on Topas oilseed rape violates Article XI:1 of the GATT 1994. According to the United States, the terms of the Greek measure make it unambiguously clear that the measure is an "import ban": "We prohibit the importing into the territory of Greece of seeds of the genetically modified rape-plant line bearing reference number C/UK/95/M5/1", and therefore, as an import ban, the Greek measure is a prima facie violation of Article XI:1.

7.3427 **Canada** claims that Greece's safeguard measure violates Article XI:1. According to Canada, as an import ban, the Greek ministerial decision constitutes an "other measure" provided for by Article XI of the GATT 1994, and, by the terms of that measure, Greece has both instituted and is maintaining a complete import prohibition on Topas oilseed rape seeds, contrary to Article XI:1.

(i) Evaluation

7.3428 The **Panel** notes that the United States' claim under Article XI:1 concerns one of the nine safeguard measures challenged by it, namely, Greece – Topas oilseed rape. Canada's claim under Article XI:1 is in respect of the same Greek safeguard measure.

7.3429 We recall that we have already reached the conclusion that the aforementioned safeguard measures being challenged by the United States and Canada, respectively, are inconsistent with Article 5.1 and, by implication, the second and third requirements in Article 2.2 of the *SPS Agreement*. In these circumstances, we see no need to examine, and offer additional findings on, whether the relevant safeguard measures are also inconsistent with Article XI:1. Accordingly, as did previous panels in similar situations[2184], we exercise judicial economy with regard to the United States' and Canada's claims under Article XI:1.

(ii) Overall conclusions

7.3430 In the light of the above, the Panel reaches the following overall conclusions:

(i) DS291 (United States)

With reference to DS291, and having regard to the arguments and evidence presented by the United States and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by the United States are inconsistent with Article XI:1 of the GATT 1994. Accordingly, the Panel offers no findings under Article XI:1.

[2184] Panel Reports, *EC – Hormones (Canada)*, para. 8.275; *Australia – Salmon*, para. 8.185; *Japan – Apples*, paras. 8.328-8.329.

(ii) DS292 (Canada)

With reference to DS292, and having regard to the arguments and evidence presented by Canada and the European Communities, the Panel concludes that it is not necessary to make findings on whether the safeguard measures which are being challenged by Canada are inconsistent with Article XI:1 of the GATT 1994. Accordingly, the Panel offers no findings under Article XI:1.

VIII. CONCLUSIONS AND RECOMMENDATIONS

8.1 Before concluding, the Panel wishes to make clear the issues on which it made a decision, and those which it did not address.

A. OVERVIEW OF THE ISSUES ADDRESSED AND DECIDED BY THE PANEL

8.2 The issues before the Panel concerned the alleged failure of the European Communities to reach final decisions regarding the approval of biotech products from October 1998 to the time of establishment of the Panel on 29 August 2003, and the WTO-consistency of prohibitions imposed by certain EC member States with regard to specific biotech products after these products had been approved by the European Communities for Community-wide marketing.

8.3 In light of this, the Panel did *not* examine:

- whether biotech products in general are safe or not.

- whether the biotech products at issue in this dispute are "like" their conventional counterparts. Although this claim was made by the Complaining Parties (*i.e.*, the United States, Canada and Argentina) in relation to some aspects of their complaints, the Panel did not find it necessary to address those aspects of the complaints.

- whether the European Communities has a right to require the pre-marketing approval of biotech products. This was not raised by the Complaining Parties.

- whether the European Communities' approval procedures as established by Directive 90/220, Directive 2001/18 and Regulation 258/97, which provide for a product-by-product assessment requiring scientific consideration of various potential risks, are consistent with the European Communities' obligations under the WTO agreements. This was not raised by the Complaining Parties.

- the conclusions of the relevant EC scientific committees regarding the safety evaluation of specific biotech products. These were not challenged by the Complaining Parties, although they did challenge the scientific basis for some of the questions and objections made by various EC member States. In light of this, the Panel, in consultation with the Parties, sought advice from a number of scientific experts.

8.4 Turning to the issues the Panel *did* examine, the Panel first considered whether the EC approval legislation under which the European Communities allegedly did not reach final decisions is properly assessed under the *SPS Agreement*. The Panel has found that the European Communities' procedures for the approval of GMOs set out in Directives 90/220 and 2001/18 are SPS measures

within the meaning of the *SPS Agreement*. The potential risks to be examined in the context of these directives, particularly as described in the annexes to Directive 2001/18, are the types of risk covered by the *SPS Agreement*. Regarding the European Communities' procedures for the approval of novel foods and food ingredients set out in Regulation 258/97, the Panel has found that these are, in part, SPS measures within the scope of the *SPS Agreement*.

8.5 The Panel notes, however, that both the evidence provided by the European Communities and the advice provided to the Panel by the experts advising it indicate that many of the identified concerns are highly unlikely to occur in practice (*e.g.*, the transfer of antibiotic resistance from marker genes used in the production of some biotech plants to bacteria in the human gut). On the other hand, other identified concerns, such as those relating to the development of pesticide-resistance in target insects through exposure to pesticides (including those incorporated into biotech plants) have indeed been documented to occur, including with respect to non-biotech crops. We reiterate, however, that the right of the European Communities to consider these possible risks prior to giving approval for the consumption or planting of biotech plants has not been questioned by any of the Complaining Parties.

8.6 The Complaining Parties asserted that a moratorium on approvals was in effect in the European Communities between October 1998 and August 2003. Based on the evidence before it, the Panel has found that the European Communities applied a general *de facto* moratorium on approvals of biotech products between June 1999 and 29 August 2003, the date of establishment of this Panel. The Panel determined that the moratorium was not itself an SPS measure within the meaning of the *SPS Agreement*, but rather affected the operation and application of the EC approval procedures, which are set out in the relevant EC approval legislation and which we had found to be SPS measures. With respect to Directives 90/220 and 2001/18, the Panel has concluded that the general *de facto* moratorium resulted in a failure to complete individual approval procedures without undue delay, and hence gave rise to an inconsistency with Article 8 and Annex C of the *SPS Agreement*. With respect to Regulation 258/97, the Panel found that, to the extent the approval procedure addressed safety aspects within the scope of the *SPS Agreement*, the general *de facto* moratorium resulted in a failure to complete individual approval procedures without undue delay, and hence also gave rise to an inconsistency with Article 8 and Annex C of the *SPS Agreement*.

8.7 The Complaining Parties also claimed that, contrary to its WTO obligations, the European Communities failed to consider for final approval applications concerning certain specified biotech products for which the European Communities had commenced approval procedures. We examined the record of consideration of 27 applications identified by the Complaining Parties. We have found that there was undue delay in the completion of the approval procedure with respect to 24 of the 27 relevant products. We therefore concluded that, in relation to the approval procedures concerning these 24 products, the European Communities has breached its obligations under Article 8 and Annex C of the *SPS Agreement*.

8.8 The Complaining Parties furthermore brought complaints against nine safeguard measures taken by certain EC member States. These safeguard measures are in the form of prohibitions imposed by an individual EC member State on a particular biotech product that has been formally approved for use within the European Communities. The safeguard measures challenged by the Complaining Parties have been taken by Austria, Belgium, France, Germany, Italy and Luxembourg. The Complaining Parties did not challenge the EC approval legislation, which provides for the conditional right of individual EC member States to impose SPS measures which differ from those of the European Communities as a whole. Instead, what the Complaining Parties challenged were the prohibitions imposed by the relevant member States on the basis of the aforementioned EC approval legislation. According to the Complaining Parties, the safeguard measures imposed by the relevant member States were inconsistent with the European Communities' WTO obligations.

8.9 We determined that the objectives identified by each member State for its safeguard measure(s) fall within the scope of the *SPS Agreement*. For each of the products at issue, the European Communities' relevant scientific committee had evaluated the potential risks to human health and/or the environment prior to the granting of Community-wide approval, and had provided a positive opinion. The relevant EC scientific committee subsequently also reviewed the arguments and the evidence submitted by the member State to justify the prohibition, and did not consider that such information called into question its earlier conclusions. The Panel thus considered that sufficient scientific evidence was available to permit a risk assessment as required by the *SPS Agreement*. Hence, in no case was the situation one in which the Panel had been persuaded that the relevant scientific evidence was insufficient to perform a risk assessment, such that the member State might have had recourse to a provisional measure under Article 5.7 of the *SPS Agreement*.

8.10 The Panel also considered whether any risk assessment had been provided by the relevant member States which would reasonably support the prohibition of the biotech products at issue. Although some of the member States did provide scientific studies, in no case did they provide an assessment of the risks to human health and/or the environment meeting the requirements of the *SPS Agreement*. The Panel likewise examined whether the risk assessments undertaken by the EC scientific committees could provide reasonable support for a prohibition of the biotech products at issue, but considered that this was not the case. In the light of this, the Panel has concluded that each of the safeguard measures taken by the relevant member States fails to meet the obligations of the European Communities under the *SPS Agreement*.

B. STRUCTURE OF THE PANEL'S CONCLUSIONS AND RECOMMENDATIONS

8.11 As we have indicated at the beginning of the Findings section, consistent with the fact that we examined three legally distinct complaints, we have particularized for each of the three Complaining Parties (*i.e.*, the United States, Canada and Argentina) the conclusions we have reached and the recommendations we make, if any, in respect of their respective complaints. Accordingly, we provide three separate sets of conclusions and recommendations.

8.12 We further recall that the Complaining Parties are each challenging three identical categories of EC measures. The categories in question are:

(a) the alleged general EC moratorium on approvals of biotech products (hereafter the "general EC moratorium");

(b) various product-specific EC measures affecting the approval of specific biotech products (hereafter the "product-specific EC measures"); and

(c) various EC member State safeguard measures prohibiting the import and/or marketing of specific biotech products (hereafter the "EC member State safeguard measures").

C. COMPLAINT BY THE UNITED STATES (DS291): CONCLUSIONS AND RECOMMENDATIONS OF THE PANEL

1. General EC moratorium

8.13 For the reasons set forth in this Report, the Panel concludes, as a factual matter, that:

(a) The European Communities applied a general *de facto* moratorium on the approval of biotech products between June 1999 and August 2003, which is when this Panel was established.

8.14 For the reasons set forth in this Report, the Panel further concludes, as a legal matter, that:

(a) The European Communities has acted inconsistently with its obligations under Annex C(1)(a), first clause, of the *SPS Agreement* and, consequently, with its obligations under Article 8 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(b) The United States has not established that the European Communities has acted inconsistently with its obligations under Annex C(1)(b) of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(c) The European Communities has not acted inconsistently with its obligations under Annex B(1) and Article 7 of the *SPS Agreement* in respect of the general *de facto* moratorium on approvals.

(d) The European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(e) The European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(f) The United States has not established that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(g) The United States has not established that the European Communities has acted inconsistently with its obligations under Article 2.3 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

8.15 Article 3.8 of the DSU provides that "[i]n cases where there is an infringement of the obligations assumed under a covered agreement, the action is considered prima facie to constitute a case of nullification or impairment". The European Communities failed to rebut this presumption. Therefore, to the extent the European Communities has acted inconsistently with its obligations under the *SPS Agreement*, it must be presumed to have nullified or impaired benefits accruing to the United States under that Agreement.

8.16 In the light of these conclusions, the Panel recommends that the Dispute Settlement Body request the European Communities to bring the general *de facto* moratorium on approvals into conformity with its obligations under the *SPS Agreement*, if, and to the extent that, that measure has not already ceased to exist.

2. Product-specific EC measures

8.17 The Panel made findings in relation to twenty-five product-specific EC measures challenged by the United States (hereafter "the relevant product-specific measures").

8.18 For the reasons set forth in this Report, the Panel concludes that:

(a) The European Communities has breached its obligations under Annex C(1)(a), first clause, of the *SPS Agreement* and, consequently, its obligations under Article 8 of the *SPS Agreement* in respect of the approval procedures concerning:[2185]

(i) Falcon oilseed rape;

(ii) MS8/RF3 oilseed rape;

(iii) RR fodder beet;

(iv) Bt-531 cotton;

(v) RR-1445 cotton;

(vi) Liberator oilseed rape;

(vii) Bt-11 maize (EC-69);

(viii) RR oilseed rape (EC-70);

(ix) BXN cotton;

(x) Bt-1507 maize (EC-74);

(xi) Bt-1507 maize (EC-75);

(xii) NK603 maize;

(xiii) GA21 maize (EC-78);

(xiv) MON810 x GA21 maize;

(xv) RR sugar beet;

(xvi) GA21 maize (food);

[2185] In respect of the approval procedures conducted under Regulation 258/97 – the procedures concerning those biotech products which are identified as "food" – the Panel's conclusions apply to the extent the relevant approval procedure is an SPS measure.

(xvii) Bt-11 sweet maize (food);

(xviii) MON810 x GA21 maize (food);

(xix) Bt-1507 maize (food);

(xx) NK603 maize (food); and

(xxi) RR sugar beet (food).

(b) The United States has not established that the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement* in respect of the approval procedures concerning:

(i) the Transgenic potato;

(ii) LL soybeans (EC-71);

(iii) LL oilseed rape; and

(iv) LL soybeans (food).

(c) The United States has not established that the relevant product-specific measures have resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(b) and Article 8 of the *SPS Agreement*.

(d) The European Communities has not acted inconsistently with its obligations under Annex B(1) and Article 7 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

(e) The European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

(f) The European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

(g) The United States has not established that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

8.19 Article 3.8 of the DSU provides that "[i]n cases where there is an infringement of the obligations assumed under a covered agreement, the action is considered prima facie to constitute a case of nullification or impairment". The European Communities failed to rebut this presumption. Therefore, to the extent the European Communities has acted inconsistently with its obligations under the *SPS Agreement* in respect of the relevant product-specific measures, it must be presumed to have nullified or impaired benefits accruing to the United States under that Agreement.

8.20 In the light of these conclusions, the Panel recommends that the Dispute Settlement Body request the European Communities to bring the relevant product-specific measures into conformity

with its obligations under the *SPS Agreement*. These recommendations do not apply to those relevant product-specific measures that were withdrawn after the Panel was established or the product-specific measure affecting the approval of Bt-11 sweet maize (food), since the application concerning Bt-11 sweet maize (food) was definitively approved during the course of the Panel proceedings.

3. EC member State safeguard measures

8.21 The Panel made findings in relation to all nine member State safeguard measures challenged by the United States (hereafter "the relevant member State safeguard measures").

(a) Austria – T25 maize

8.22 In relation to the Austrian safeguard measure on T25 maize, and for the reasons set forth in this Report, the Panel concludes that:

(a) The Austrian safeguard measure on T25 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on T25 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(b) Austria - Bt-176 maize

8.23 In relation to the Austrian safeguard measure on Bt-176 maize, and for the reasons set forth in this Report, the Panel concludes that:

(a) The Austrian safeguard measure on Bt-176 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on Bt-176 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(c) Austria - MON810 maize

8.24 In relation to the Austrian safeguard measure on MON810 maize, and for the reasons set forth in this Report, the Panel concludes that:

(a) The Austrian safeguard measure on MON810 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the

measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on MON810 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(d) France - MS1/RF1 oilseed rape (EC-161)

8.25 In relation to the French safeguard measure on MS1/RF1 oilseed rape (EC-161), and for the reasons set forth in this Report, the Panel concludes that:

(a) The French safeguard measure on MS1/RF1 oilseed rape (EC-161) is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the French safeguard measure on MS1/RF1 oilseed rape (EC-161), the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(e) France - Topas oilseed rape

8.26 In relation to the French safeguard measure on Topas oilseed rape, and for the reasons set forth in this Report, the Panel concludes that:

(a) The French safeguard measure on Topas oilseed rape is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the French safeguard measure on Topas oilseed rape, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(f) Germany – Bt-176 maize

8.27 In relation to the German safeguard measure on Bt-176 maize, and for the reasons set forth in this Report, the Panel concludes that:

(a) The German safeguard measure on Bt-176 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the German safeguard measure on Bt-176 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(g) Greece - Topas oilseed rape

8.28 In relation to the Greek safeguard measure on Topas oilseed rape, and for the reasons set forth in this Report, the Panel concludes that:

(a) The Greek safeguard measure on Topas oilseed rape is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Greek safeguard measure on Topas oilseed rape, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(c) There is no need to rule on the United States' claim under Article XI:1 of the GATT 1994.

(h) Italy - Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25 maize

8.29 In relation to the Italian safeguard measure on Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25 maize, and for the reasons set forth in this Report, the Panel concludes that:

(a) The Italian safeguard measure on Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Italian safeguard measure on Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(i) Luxembourg – Bt-176 maize

8.30 In relation to Luxembourg's safeguard measure on Bt-176 maize, and for the reasons set forth in this Report, the Panel concludes that:

(a) Luxembourg's safeguard measure on Bt-176 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, Luxembourg's safeguard measure on Bt-176 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(j) Nullification or impairment of benefits and recommendations

8.31 Article 3.8 of the DSU provides that "[i]n cases where there is an infringement of the obligations assumed under a covered agreement, the action is considered prima facie to constitute a case of nullification or impairment". The European Communities failed to rebut this presumption. Therefore, to the extent the European Communities has acted inconsistently with its obligations under the *SPS Agreement* in respect of the relevant member State safeguard measures, it must be presumed to have nullified or impaired benefits accruing to the United States under that Agreement.

8.32 In the light of these conclusions, the Panel recommends that the Dispute Settlement Body request the European Communities to bring the relevant member State safeguard measures into conformity with its obligations under the *SPS Agreement*.

D. COMPLAINT BY CANADA (DS292): CONCLUSIONS AND RECOMMENDATIONS OF THE PANEL

1. General EC moratorium

8.33 For the reasons set forth in this Report, the Panel concludes, as a factual matter, that:

(a) The European Communities applied a general *de facto* moratorium on the approval of biotech products between June 1999 and August 2003, which is when this Panel was established.

8.34 The Panel further concludes, as a legal matter, that:

(a) The European Communities has acted inconsistently with its obligations under Annex C(1)(a), first clause, of the *SPS Agreement* and, consequently, with its obligations under Article 8 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(b) The European Communities has not acted inconsistently with its obligations under Annex B(1) and Article 7 of the *SPS Agreement* in respect of the general *de facto* moratorium on approvals.

(c) The European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(d) The European Communities has not acted inconsistently with its obligations under Article 5.6 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(e) The European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(f) Canada has not established that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(g) Canada has not established that the European Communities acted inconsistently with its obligations under Article 2.3 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

8.35 Article 3.8 of the DSU provides that "[i]n cases where there is an infringement of the obligations assumed under a covered agreement, the action is considered prima facie to constitute a case of nullification or impairment". The European Communities failed to rebut this presumption. Therefore, to the extent the European Communities has acted inconsistently with its obligations under the *SPS Agreement*, it must be presumed to have nullified or impaired benefits accruing to Canada under that Agreement.

8.36 In the light of these conclusions, the Panel recommends that the Dispute Settlement Body request the European Communities to bring the general *de facto* moratorium on approvals into conformity with its obligations under the *SPS Agreement*, if, and to the extent that, that measure has not already ceased to exist.

2. Product-specific EC measures

8.37 The Panel made findings in relation to four product-specific EC measures challenged by Canada (hereafter "the relevant product-specific measures").

8.38 For the reasons set forth in this Report, the Panel concludes that:

(a) The European Communities has breached its obligations under Annex C(1)(a), first clause, of the *SPS Agreement* and, consequently, its obligations under Article 8 of the *SPS Agreement* in respect of the approval procedures concerning:

(i) MS8/RF3 oilseed rape;

(ii) RR oilseed rape (EC-70);

(iii) MS1/RF1 oilseed rape (EC-89); and

(iv) MS1/RF2 oilseed rape.

(b) The European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

(c) The European Communities has not acted inconsistently with its obligations under Article 5.6 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

(d) The European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

(e) Canada has not established that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

(f) Canada has not established that the European Communities has acted inconsistently with its obligations under Article 2.3 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

(g) There is no need to rule on Canada's claim under Article III:4 of the GATT 1994 in respect of any of the relevant product-specific measures.

(h) There is no need to rule on Canada's claims under Articles 5.1.2, 5.2.1, first part, 2.1 and 2.2 of the *TBT Agreement* in respect of any of the relevant product-specific measures.

8.39 Article 3.8 of the DSU provides that "[i]n cases where there is an infringement of the obligations assumed under a covered agreement, the action is considered prima facie to constitute a case of nullification or impairment". The European Communities failed to rebut this presumption. Therefore, to the extent the European Communities has acted inconsistently with its obligations under the *SPS Agreement* in respect of the relevant product-specific measures, it must be presumed to have nullified or impaired benefits accruing to Canada under that Agreement.

8.40 In the light of these conclusions, the Panel recommends that the Dispute Settlement Body request the European Communities to bring the relevant product-specific measures into conformity with its obligations under the *SPS Agreement*.

3. EC member State safeguard measures

8.41 The Panel made findings in relation to all five member State safeguard measures challenged by Canada (hereafter "the relevant member State safeguard measures").

(a) Austria – T25 maize

8.42 In relation to the Austrian safeguard measure on T25 maize, and for the reasons set forth in this Report, the Panel concludes that:

(a) The Austrian safeguard measure on T25 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on T25 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(c) There is no need to rule on Canada's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement*.

(d) There is no need to rule on Canada's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.

(e) There is no need to rule on Canada's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.

(f) There is no need to rule on Canada's claim under Article III:4 of the GATT 1994.

(b) France - MS1/RF1 oilseed rape (EC-161)

8.43 In relation to the French safeguard measure on MS1/RF1 oilseed rape (EC-161), and for the reasons set forth in this Report, the Panel concludes that:

(a) The French safeguard measure on MS1/RF1 oilseed rape is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the French safeguard measure on MS1/RF1 oilseed rape, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(c) There is no need to rule on Canada's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement*.

(d) There is no need to rule on Canada's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.

(e) There is no need to rule on Canada's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.

(f) There is no need to rule on Canada's claim under Article III:4 of the GATT 1994.

(c) France - Topas oilseed rape

8.44 In relation to the French safeguard measure on Topas oilseed rape, and for the reasons set forth in this Report, the Panel concludes that:

(a) The French safeguard measure on Topas oilseed rape is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the French safeguard measure on Topas oilseed rape, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(c) There is no need to rule on Canada's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement*.

(d) There is no need to rule on Canada's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.

(e) There is no need to rule on Canada's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.

(f) There is no need to rule on Canada's' claim under Article III:4 of the GATT 1994.

(d) Greece - Topas oilseed rape

8.45 In relation to the Greek safeguard measure on Topas oilseed rape, and for the reasons set forth in this Report, the Panel concludes that:

(a) The Greek safeguard measure on Topas oilseed rape is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Greek safeguard measure on Topas oilseed rape, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(c) There is no need to rule on Canada's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement*.

(d) There is no need to rule on Canada's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.

(e) There is no need to rule on Canada's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.

(f) There is no need to rule on Canada's claim under Article XI:1 of the GATT 1994.

(e) Italy - Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25 maize

8.46 In relation to the Italian safeguard measure on Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25 maize, and for the reasons set forth in this Report, the Panel concludes that:

(a) The Italian safeguard measure on Bt-11 maize (EC-163), MON810 maize, MON809 maize and T25 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Italian safeguard measure on Bt-11 maize (EC-163), MON810 maize, MON809 maize and

T25 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(c) There is no need to rule on Canada's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement*.

(d) There is no need to rule on Canada's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.

(e) There is no need to rule on Canada's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.

(f) There is no need to rule on Canada's claim under Article III:4 of the GATT 1994.

(f) Nullification or impairment of benefits and recommendations

8.47 Article 3.8 of the DSU provides that "[i]n cases where there is an infringement of the obligations assumed under a covered agreement, the action is considered prima facie to constitute a case of nullification or impairment". The European Communities failed to rebut this presumption. Therefore, to the extent the European Communities has acted inconsistently with its obligations under the *SPS Agreement* in respect of the relevant member State safeguard measures, it must be presumed to have nullified or impaired benefits accruing to Canada under that Agreement.

8.48 In the light of these conclusions, the Panel recommends that the Dispute Settlement Body request the European Communities to bring the relevant member State safeguard measures into conformity with its obligations under the *SPS Agreement*.

E. COMPLAINT BY ARGENTINA (DS293): CONCLUSIONS AND RECOMMENDATIONS OF THE PANEL

1. General EC moratorium

8.49 For the reasons set forth in this Report, the Panel concludes, as a factual matter, that:

(a) The European Communities applied a general *de facto* moratorium on the approval of biotech products between June 1999 and August 2003, which is when this Panel was established.

8.50 The Panel further concludes, as a legal matter, that:

(a) The European Communities has not acted inconsistently with its obligations under Annex B(1) and Article 7 of the *SPS Agreement* in respect of the general *de facto* moratorium on approvals.

(b) The European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(c) The European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(d) Argentina has not established that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(e) Argentina has not established that the European Communities has acted inconsistently with its obligations under Article 2.3 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

(f) Argentina has not established that the European Communities has acted inconsistently with its obligations under Article 10.1 of the *SPS Agreement* by applying a general *de facto* moratorium on approvals between June 1999 and August 2003.

8.51 In view of the above conclusions, the Panel makes no recommendations pursuant to Article 19.1 of the DSU.

2. Product-specific EC measures

8.52 The Panel made findings in relation to ten product-specific EC measures challenged by Argentina (hereafter "the relevant product-specific measures"). However, Argentina made various claims under Article 8 and Annex C(1) of the *SPS Agreement* with regard to only eight of the ten "relevant product-specific measures". Therefore, for the purposes of the Panel's conclusions concerning the claims under Article 8 and Annex C(1), the term "relevant product-specific measures" refers to the eight product-specific measures in question. The two excluded measures are those affecting the approval of Bt-531 cotton and RR-1445 cotton under Regulation 258/97. In relation to these two measures, the Panel concludes that their existence has not been demonstrated by Argentina.

8.53 For the reasons set forth in this Report, the Panel concludes that:

(a) The European Communities has breached its obligations under Annex C(1)(a), first clause, of the *SPS Agreement* and, consequently, its obligations under Article 8 of the *SPS Agreement* in respect of the approval procedures concerning:[2186]

(i) Bt-531 cotton;

(ii) RR-1445 cotton;

(iii) LL soybeans (EC-71);

(iv) NK603 maize;

(v) GA21 maize (EC-78);

(vi) GA21 maize (food); and

(vii) NK603 maize (food).

[2186] In respect of the approval procedures conducted under Regulation 258/97 – the procedures concerning those biotech products which are identified as "food" – the Panel's conclusions apply to the extent the relevant approval procedure is an SPS measure.

(b) Argentina has not established that the European Communities has breached its obligations under Annex C(1)(a), first clause, and Article 8 of the *SPS Agreement* in respect of the approval procedures concerning:

(i) LL soybeans (food).

(c) Argentina has not established that the relevant product-specific measures have resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(a), second clause, and Article 8 of the *SPS Agreement.*

(d) Argentina has not established that the relevant product-specific measures have resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(b) and Article 8 of the *SPS Agreement.*

(e) Argentina has not established that the relevant product-specific measures have resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(c) and Article 8 of the *SPS Agreement.*

(f) Argentina has not established that the relevant product-specific measures have resulted in the European Communities acting inconsistently with its obligations under Annex C(1)(e) and Article 8 of the *SPS Agreement*.

(g) The European Communities has not acted inconsistently with its obligations under Article 5.1 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

(h) The European Communities has not acted inconsistently with its obligations under Article 5.6 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

(i) The European Communities has not acted inconsistently with its obligations under Article 5.5 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

(j) Argentina has not established that the European Communities has acted inconsistently with its obligations under Article 2.2 of the *SPS Agreement* in respect of any of the relevant product-specific measures.

(k) Argentina has not established that the European Communities has acted inconsistently with its obligations under Article III:4 of the GATT 1994 in respect of any of the relevant product-specific measures.

(l) There is no need to rule on Argentina's alternative claims under Articles 5.1.1, 5.1.2, 5.2.1, first part, 5.2.2, 2.1, 2.2 and 12 of the *TBT Agreement* in respect of any of the relevant product-specific measures.

8.54 Article 3.8 of the DSU provides that "[i]n cases where there is an infringement of the obligations assumed under a covered agreement, the action is considered prima facie to constitute a case of nullification or impairment". The European Communities failed to rebut this presumption. Therefore, to the extent the European Communities has acted inconsistently with its obligations under

the *SPS Agreement* in respect of the relevant product-specific measures, it must be presumed to have nullified or impaired benefits accruing to Argentina under that Agreement.

8.55 In the light of these conclusions, the Panel recommends that the Dispute Settlement Body request the European Communities to bring the relevant product-specific measures into conformity with its obligations under the *SPS Agreement*. These recommendations do not apply to those of the relevant product-specific measures which were withdrawn after the Panel was established.

3. EC member State safeguard measures

8.56 The Panel made findings in relation to all six member State safeguard measures challenged by Argentina (hereafter "the relevant member State safeguard measures").

(a) Austria – T25 maize

8.57 In relation to the Austrian safeguard measure on T25 maize, and for the reasons set forth in this Report, the Panel concludes that:

(a) The Austrian safeguard measure on T25 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on T25 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(c) There is no need to rule on Argentina's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement.*

(d) There is no need to rule on Argentina's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.

(e) There is no need to rule on Argentina's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.

(f) There is no need to rule on Argentina's claim under Article III:4 of the GATT 1994.

(b) Austria - Bt-176 maize

8.58 In relation to the Austrian safeguard measure on Bt-176 maize, and for the reasons set forth in this Report, the Panel concludes that:

(a) The Austrian safeguard measure on Bt-176 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on Bt-176 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(c) There is no need to rule on Argentina's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement.*

(d) There is no need to rule on Argentina's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.

(e) There is no need to rule on Argentina's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.

(f) There is no need to rule on Argentina's claim under Article III:4 of the GATT 1994.

(c) Austria - MON810 maize

8.59 In relation to the Austrian safeguard measure on MON810 maize, and for the reasons set forth in this Report, the Panel concludes that:

(a) The Austrian safeguard measure on MON810 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Austrian safeguard measure on MON810 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(c) There is no need to rule on Argentina's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement.*

(d) There is no need to rule on Argentina's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.

(e) There is no need to rule on Argentina's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.

(f) There is no need to rule on Argentina's claim under Article III:4 of the GATT 1994.

(d) Germany – Bt-176 maize

8.60 In relation to the German safeguard measure on Bt-176 maize, and for the reasons set forth in this Report, the Panel concludes that:

(a) The German safeguard measure on Bt-176 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the

measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the German safeguard measure on Bt-176 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(c) There is no need to rule on Argentina's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement.*

(d) There is no need to rule on Argentina's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.

(e) There is no need to rule on Argentina's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.

(f) There is no need to rule on Argentina's claim under Article III:4 of the GATT 1994.

(e) Italy - Bt-11 maize (EC-163), MON810 maize and T25 maize[2187]

8.61 In relation to the Italian safeguard measure on Bt-11 maize (EC-163), MON810 maize and T25 maize, and for the reasons set forth in this Report, the Panel concludes that:

(a) The Italian safeguard measure on Bt-11 maize (EC-163), MON810 maize and T25 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, the Italian safeguard measure on Bt-11 maize (EC-163), MON810 maize and T25 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(c) There is no need to rule on Argentina's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement.*

(d) There is no need to rule on Argentina's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.

(e) There is no need to rule on Argentina's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.

(f) There is no need to rule on Argentina's claim under Article III:4 of the GATT 1994.

[2187] Unlike the United States and Canada, Argentina did not challenge the Italian safeguard measure on MON809 maize.

(f) Luxembourg – Bt-176 maize

8.62 In relation to Luxembourg's safeguard measure on Bt-176 maize, and for the reasons set forth in this Report, the Panel concludes that:

(a) Luxembourg's safeguard measure on Bt-176 maize is not based on a risk assessment as required by Article 5.1 of the *SPS Agreement*, and it is not consistent with the requirements of Article 5.7 of the *SPS Agreement*. Therefore, by maintaining the measure in question, the European Communities has acted inconsistently with its obligations under Article 5.1.

(b) By maintaining, inconsistently with Article 5.1 of the *SPS Agreement*, Luxembourg's safeguard measure on Bt-176 maize, the European Communities has, by implication, also acted inconsistently with the second and third requirements in Article 2.2 of the *SPS Agreement*.

(c) There is no need to rule on Argentina's claim under the first requirement of Article 2.2 and under Article 2.3 of the *SPS Agreement.*

(d) There is no need to rule on Argentina's claims under Articles 5.5 and 5.6 of the *SPS Agreement*.

(e) There is no need to rule on Argentina's alternative claims under Articles 2.1, 2.2 and 2.9 of the *TBT Agreement*.

(f) There is no need to rule on Argentina's claim under Article III:4 of the GATT 1994.

(g) Nullification or impairment of benefits and recommendations

8.63 Article 3.8 of the DSU provides that "[i]n cases where there is an infringement of the obligations assumed under a covered agreement, the action is considered prima facie to constitute a case of nullification or impairment". The European Communities failed to rebut this presumption. Therefore, to the extent the European Communities has acted inconsistently with its obligations under the *SPS Agreement* in respect of the relevant member State safeguard measures, it must be presumed to have nullified or impaired benefits accruing to Argentina under that Agreement.

8.64 In the light of these conclusions, the Panel recommends that the Dispute Settlement Body request the European Communities to bring the relevant member State safeguard measures into conformity with its obligations under the *SPS Agreement*.

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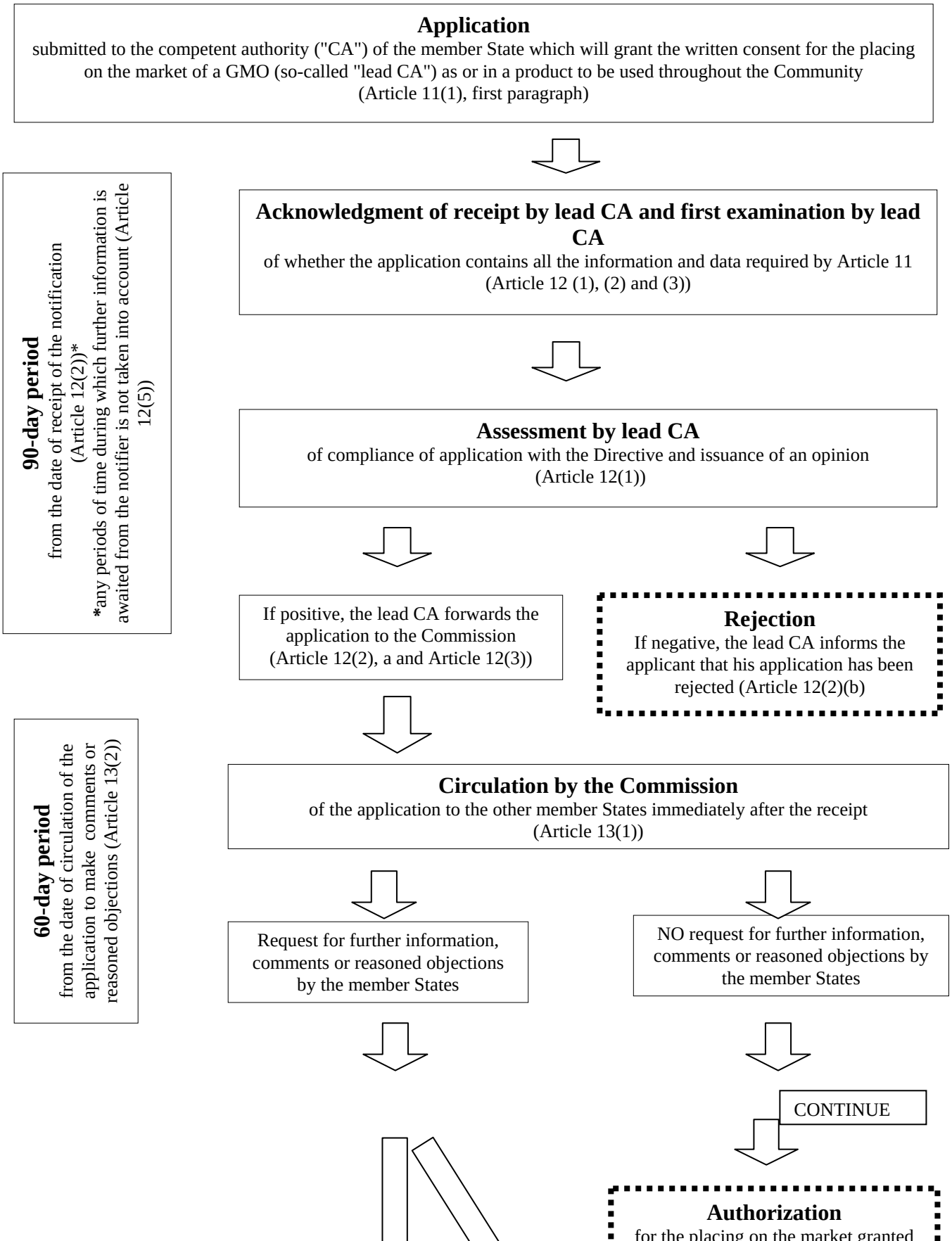
ANNEX A

EC ADMINISTRATIVE PROCEDURES FOR GRANTING CONSENTS FOR THE DELIBERATE RELEASE OF GMOS INTO THE ENVIRONMENT AND FOR NOVEL FOODS AND NOVEL FOOD INGREDIENTS

Contents		Page
Annex A-1	Directive 90/220: EC administrative procedure for granting consents for the deliberate release of GMOs into the environment	A-2
Annex A-2	Directive 2001/18: EC administrative procedure for granting consents for the deliberate release of GMOs into the environment	A-4
Annex A-3	Regulation 258/97: EC administrative procedure for granting consents for novel foods and novel food ingredients	A-6

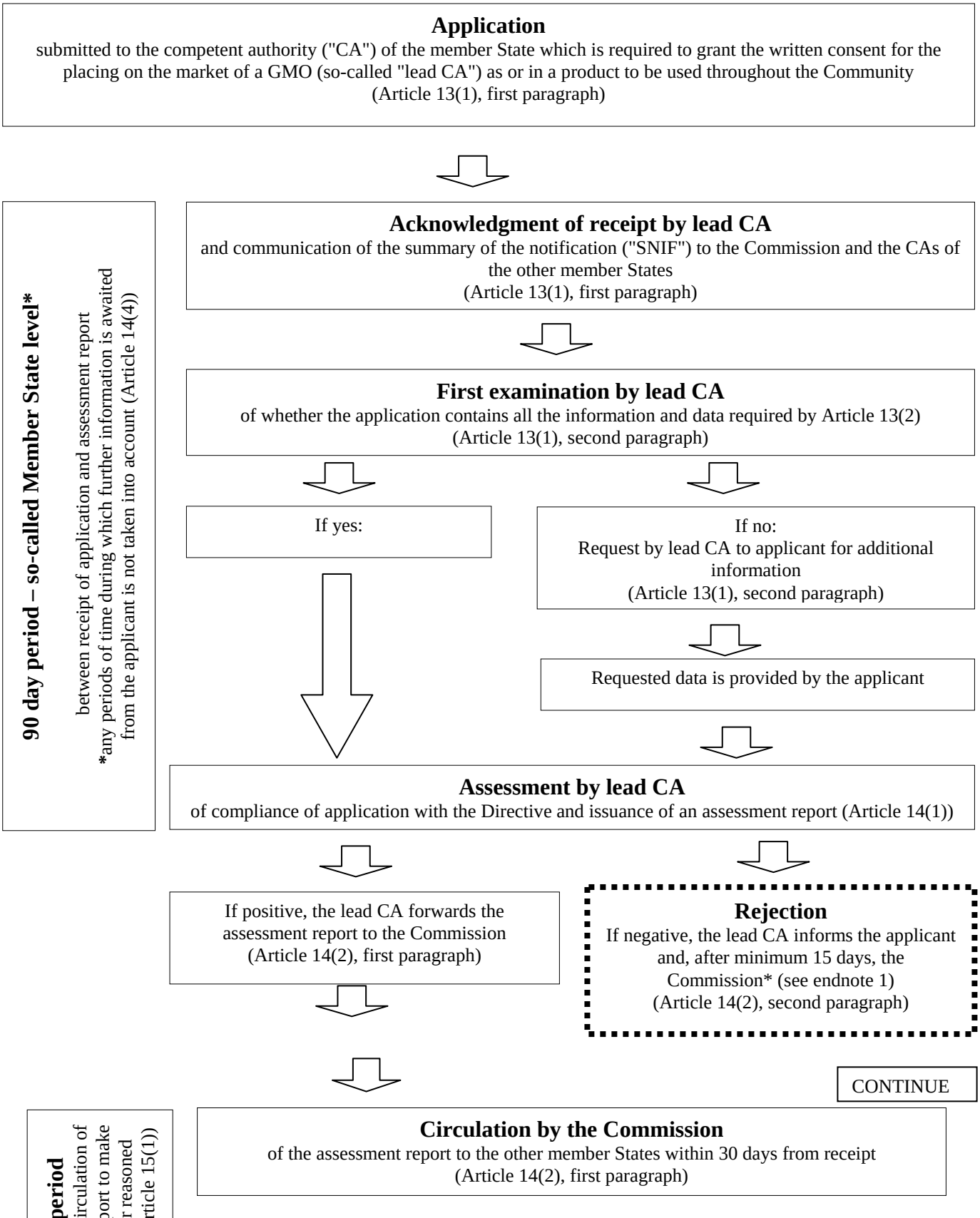
ANNEX A-1

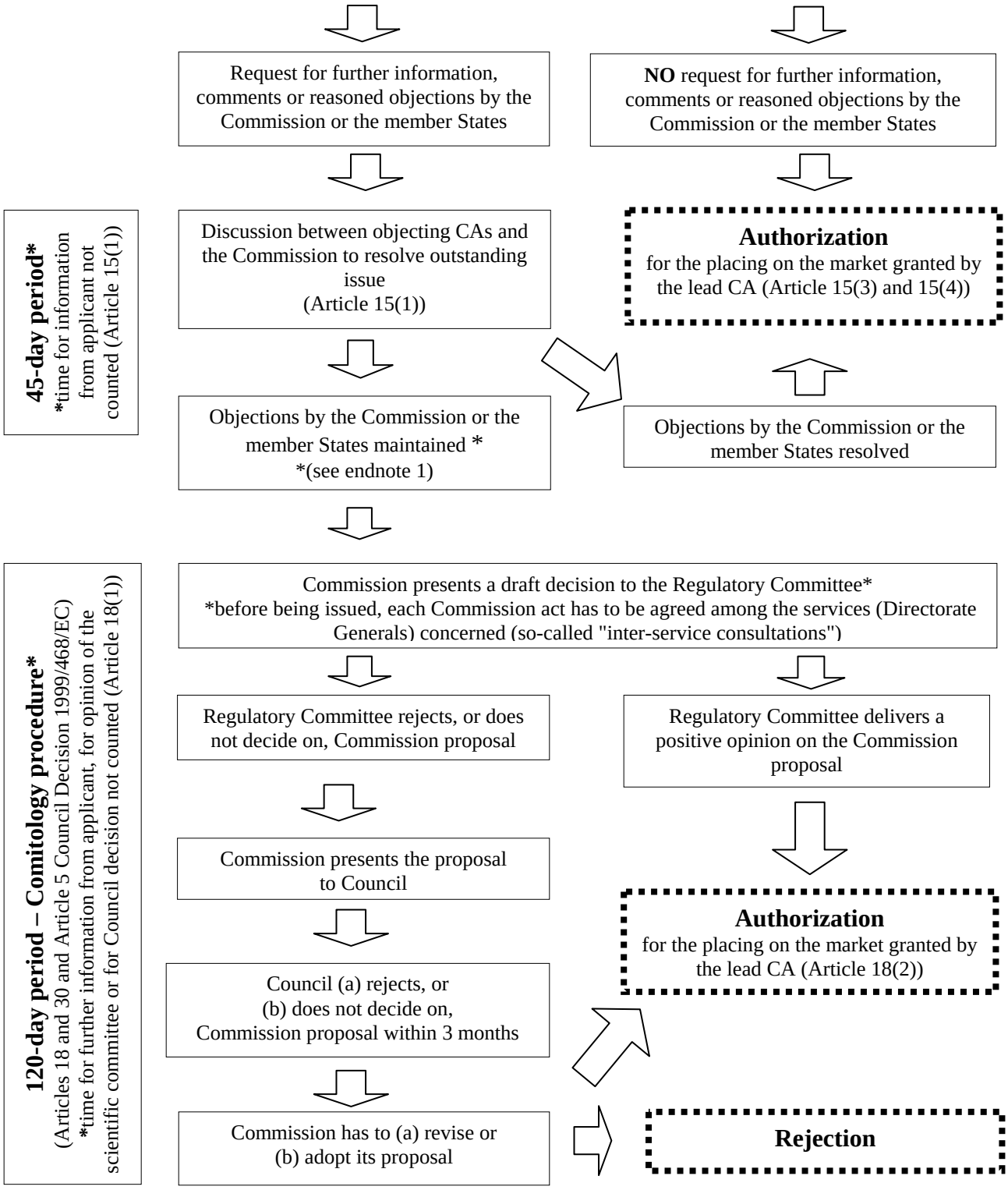
DIRECTIVE 90/220: EC ADMINISTRATIVE PROCEDURE FOR GRANTING CONSENTS FOR THE DELIBERATE RELEASE INTO THE ENVIRONMENT OF GMOs



ANNEX A-2

DIRECTIVE 2001/18: EC ADMINISTRATIVE PROCEDURE FOR GRANTING CONSENTS FOR THE DELIBERATE RELEASE INTO THE ENVIRONMENT OF GMOs

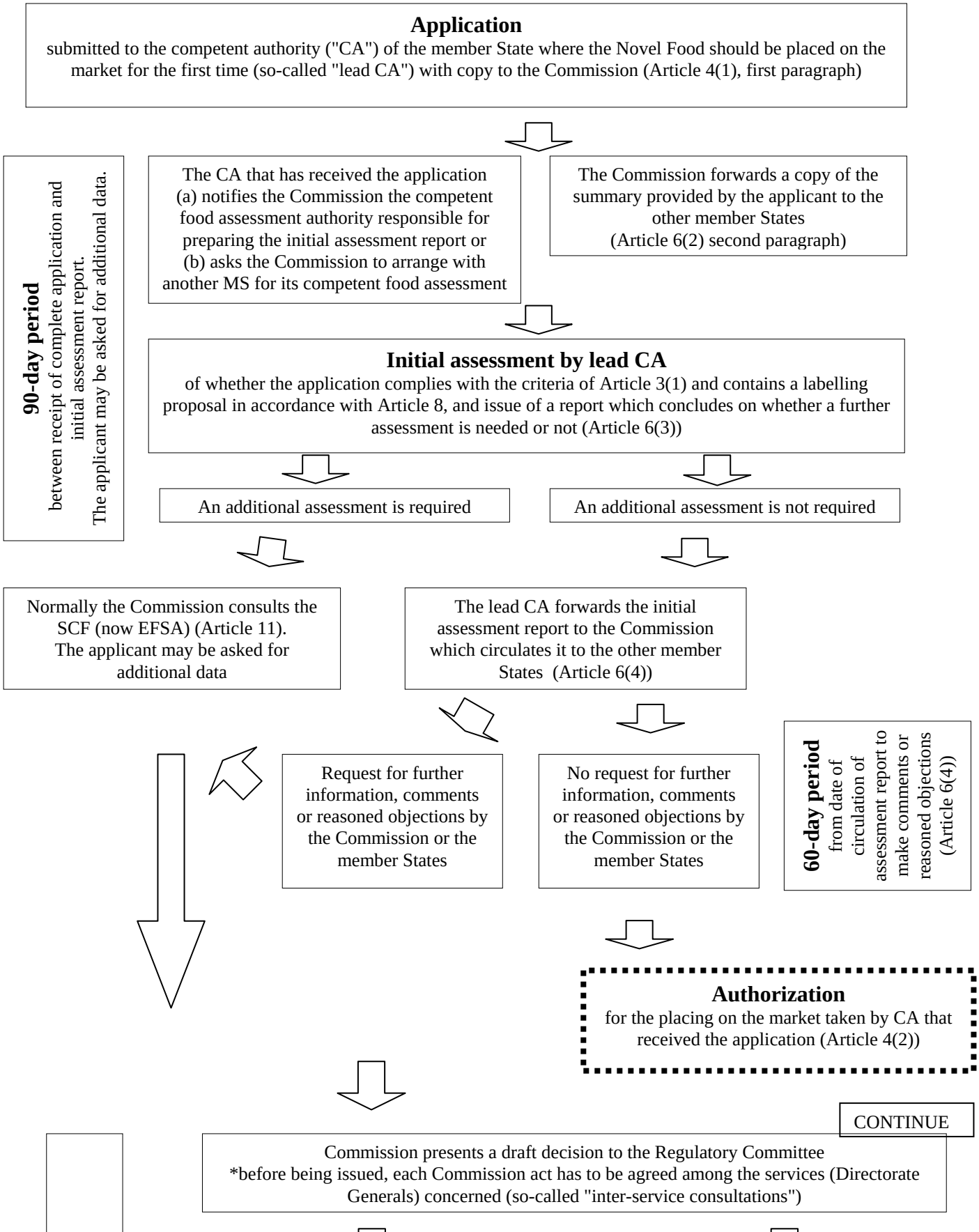




[1] In these cases, the Commission has to consult its scientific committees, on its own initiative or at the request of a member State (Article 28(1)). The Commission may also consult the scientific committees on any matter arising under Directive 2001/18 (Article 28(2))

ANNEX A-3

REGULATION 258/97: EC ADMINISTRATIVE PROCEDURE FOR GRANTING CONSENTS FOR NOVEL FOODS AND NOVEL FOOD INGREDIENTS



ANNEX B

TABLES SUMMARIZING THE HISTORY OF THE INDIVIDUAL APPROVAL PROCEDURES AT ISSUE IN THIS DISPUTE

1. The Panel has prepared a series of tables summarizing relevant aspects of the history of the individual approval procedures at issue in this dispute. The tables were prepared on the basis of information provided by the Parties, and in particular the detailed chronologies of individual approval procedures submitted by the European Communities.

2. Since the Panel's findings tend to focus on specific stages of individual approval procedures, it seemed useful to provide some background information on developments and activities at other procedural stages. Consistent with their limited purpose, the Panel's tables do not reflect any and all activities of member State authorities, EC authorities or applicants of which the Panel has been made aware. It should also be noted that the information provided in the tables is more detailed for those stages and activities which the Panel has focused on for the purposes of its analysis, and less detailed for other stages and activities.

3. In preparing the tables, the Panel has found it useful to distinguish the following procedural stages, which also reflect the main stages of the approval procedures set out in the relevant EC approval legislation for biotech products (Directives 90/220 and 2001/18 as well as Regulation 258/97):

(a) Consideration of application at member State level ("Member State Level")

  (i) Initial assessment of application by lead CA. ("Lead Member State Level").

(b) Consideration of application at Community level ("Community Level")

  (i) Circulation of lead CA assessment to other member States ("Other Member States").

  (ii) Consultation of EC scientific committee ("Scientific Committee Process").

  (iii) Preparation of draft measure to be submitted to the Regulatory Committee ("Commission").

  (iv) Consideration by the Regulatory Committee of the draft measure submitted by the Commission ("Regulatory Committee Process").

  (v) Preparation of draft measure to be submitted to the Council ("Commission").

  (vi) Consideration by the Council of the draft measure submitted by the Commission, including decision by the Council ("Council").

  (vii) Adoption by Commission of its draft measure in case the Council fails to decide (Directives 90/229 and 2001/18 as well as Regulation 258/97) and application of applicant of decision (Regulation 258/97) ("Commission").

(viii) Written consent of lead CA to placing on the market (Directives 90/220 and 2001/18) ("Lead Member State").

4. While the Panel's tables are structured according to the above-mentioned procedural stages, it is important to note that each table provides information on only those stages which have been completed or reached in the relevant approval procedure.

5. Due to constraints of space, the Panel's tables contain a number of abbreviations. They are explained below. Furthermore, the Panel has used short titles to refer to the products which are the subject of the relevant approval procedures. These short titles are explained in a list provided at the beginning of these Panel Reports.

Useful Terms	
ACRE	Advisory Committee on Release into the Environment
CA	Competent Authority
CO	Council
COGEM	Commission on Genetic Modification
COM	Community
DK	Denmark
EFSA	European Food Safety Authority
ISC	Inter Service Consultation
MS	Member States
NBC	National Biosafety Committee
RIKILT	Institute of Food Safety
SCP	Scientific Committee on Plants
SCF	Scientific Committee on Food
SNIF	Summary Application Information Format
vCVNV	Provisional Commission for Food Safety (Food Assessment Body for Novel Foods of the Netherlands)

Product	*Member State Level*	*Community Level*			
	Lead Member State Level	***Circulation to other Member States***	***Scientific Committee Process***	***Commission***	***Regulatory Committee Process***
EC-62 **Falcon oilseed rape**	**<u>Directive 90/220/EEC</u>** • 01/04/1996 Applicant submits application. • 14/05/1996–24/07/1996 Exchange of information between the applicant and the lead CA. • 25/10/1996 Statement by the lead CA.	• 25/10/1996 Full application submitted to COM. • 09/12/1996 Application circulated to all MS. • 01/1997- 10/1997 Requests for additional information by lead CA and replies by applicant. Comments/objections by MS.	• 20/02/1998 COM requests SCP opinion. • 14/07/1998 Opinion of the SCP: favourable.	• 04/09/1998 COM launches ISC on draft COM decision to be submitted to REG COM.	• 29/06/1999 COM launches vote in REG COM by written procedure. • 7/99 – 9/99 Additional information provided by the applicant. • 29/10/1999 Meeting of REG COM: vote postponed. • 10/11/1999 Applicant submits update of application, including additional information and commitments. • 09/03/2000 Meeting of REG COM: no vote held due to further requests for information. • 14/03/2000 Fax from the Italian Competent Authority requesting additional information from the applicant. • 20/04/2000 Letter of German CA to applicant about modification of the scope of application. • 11/00 Responses provided by the applicant.

Product	*Member State Level*	*Community Level*			
	Lead Member State Level	***Circulation to other Member States***	***Scientific Committee Process***	***Commission***	***Regulatory Committee Process***
	<u>Directive 2001/18/EC</u> • 16/01/2003 Statement of completeness by applicant. Applicant updates SNIF. • 14/10/2003 Request for clarification and further update of SNIF.				• 29/05/2001 Applicant submits letter, claiming that the application is already in line with Directive 2001/18. • 25/07/2001 Lead CA requests for clarification by the applicant on additional documents. • 21/11/2001 Applicant submits documents to support "working group on HT crops". • 02/04/2002 Lead CA requests further modifications and supplementary information, after applicant provided additional information. • 08/05/2002 Reply by the applicant to the request of 02/04/2002 for additional information. • 23/12/2002 Lead CA requests applicant for clarification on submitted documents.

Product	*Member State Level*	*Community Level*			
	Lead Member State Level	*Circulation to Member States*	*Scientific Committee Process*	*Commission*	*Regulatory Committee Process*
EC-63 **MS8/RF3 oilseed rape**	**<u>Directive 90/220/EEC</u>** • 30/09/1996 Applicant submits application to Belgium. • 10 and 17/12/1996 Meetings of the Belgian Biosafety Council. (Positive advice of the Scientific Committees on Transgenic Plants and on Novel feed/food).	• 07/01/1997 Submission by lead CA to COM of full application. • 29/01/1997 Application circulated to all MS. • 02/1997 – 12/1997 Statements, comments and objections by MS. Applicant provides additional information.	• 27/01/1998 COM requests for SCP opinion. • 19/05/1998 SCP opinion: favourable.	• 04/09/1998 COM launches ISC on draft COM decision to be submitted to REG COM.	• 30/06/1999 COM launches vote in REG COM by written procedure. • 22/10/1999 COM invites applicant to present additional information following interim approach to REG COM. • 10/11/1999 Applicant submits update in line with revised EC legislation. • 29/10/1999 REG COM meeting: presentation by applicant of update; no vote held. • 14/03/2000 Fax from Italian CA raising questions subsequent to the REG COM meeting. • 13/11/2000 Applicant provides answers to questions raised by Italy on 14/03/2000. • 20/12/2000 COM circulates applicants answers to all CAs. • 05/06/2001 Applicant provides clarifications to lead CA on the scope of the application, and updates to bring dossier in line with provisions of Directive 2001/18/EC.

Product	*Member State Level*	*Community Level*			
	Lead Member State Level	*Circulation to Member States*	*Scientific Committee Process*	*Commission*	*Regulatory Committee Process*
	 Directive 2001/18/EC • 14/01/2003 Applicant submits updated application.				• 19/06/2001 Meeting of CAs. • 12/07/2001 Letter of lead CA to applicant acknowledging receipt of further information and soliciting envoy of reference material. • 11/09/2001 Applicant submits reference material and information on detection methodology, in response to prior requests by the lead CA on 12/07/2001. • 13/11/2001 Meeting of Belgian Biosafety Council. • 07/02/2002 Meeting of Belgian Biosafety Council (Scientific Committee "Transgenic Plants"). • 28/03/2002 Lead CA communicates that Belgian Biosafety Council requested additional data. • 24/09/2001- 07/05/2002 Applicant provides answers to pending questions by the CA.

Product	*Member State Level*	*Community Level*			
		Circulation to Member States	***Scientific Committee Process***	***Commission***	***Regulatory Committee Process***
EC-64 **RR fodder beet**	**<u>Directive 90/220/EEC</u>** • 21/02/1997 Application received by the lead CA. • 24/03/1997 – 30/09/1997 Lead CA requests for additional information. Applicant provides the lead CA with additional data.	• 07/10/1997 Lead CA forwards the application to COM, together with positive opinion (non- confidential part). • 09/10/1997 and 15/10/1997 Non-confidential and confidential part received by COM. • 16/10/1997 Non confidential and confidential part sent to MS. • 02/12/1997 Technical meeting with CAs where comments/requests for further data were addressed. • 10/12/1997 Applicant provides additional information related to the comments raised at the CAs meeting.	• 13/03/1998 COM request for SCP opinion. • 23/06/1998 Opinion of the SCP: favourable.	• 04/09/1998 COM launches ISC on draft decision to be submitted to REG COM. • 24/09/1998 – 19/10/1999 Clarifications, additional information and commitments submitted by the applicant. - On 04/08/1999 the applicant met the Dutch CA.	• 29/10/1999 REG COM meeting: presentation by the company of the update; no vote held because of outstanding additional information. • 09/03/2000 Meeting of the REG COM: no vote held. • 14/03/2000 Fax from the Italian CA raising questions subsequent to SCP opinion. • 12/07/2000 Additional data on molecular characterisation (at the request of UK), regarding questions raised from Italy. • 04/01/2001 Clarifications by the applicant with regard to undertakings and commitments.
	<u>Directive 2001/18</u> • 16/01/2003 Updated application submitted by the applicant.	• 12/12/1997 Dutch CA requests additional information.			

Product	*Member State Level*	*Community Level*				
		Circulation to Member States	***Scientific Committee Process***	***Commission***	***Regulatory Committee Process***	***Commission***
EC-65 **Bt-531 cotton**	**<u>Directive 90/220/EEC</u>** • 02/12/1996 Applicant submits application. • 30/04/1997 Applicant expresses its intention to submit the dossier also under the Novel Food Regulation.	• 17/11/1997 Lead CA submits full application to COM. • 15/12/1997 Full application circulated to all CAs. • 20/01/1998 – 25/02/1998 Comments and objections by MS. Applicants provides answers to the questions raised.	• 06/04/1998 COM request for SCP opinion. • 14/07/1998 SCP opinion: favourable.	• 04/09/1998 COM launches ISC on draft decision to be submitted to the REG COM.	• 26/11/1998 COM launches vote in REG COM by written procedure. • 22/02/1999 REG COM vote: absence of qualified majority. Outcomes of the written procedure including written statements from Sweden, Austria and UK.	• 07/05/1999 COM launches ISC on draft measure to be submitted to the Council. • 25/07/2001 Applicant provides updated molecular characterisation and Safety Assessment. (analysis of flanking regions). • 18/02/2002 Applicant provides translations of material sent in July 2001.
	<u>Directive 2001/18</u> • 16/01/2003 Applicant submits updated application. • 01/08/2003 Lead CA requests for additional information.					

Product	*Member State Level*	*Community Level*				
		Circulation to Member States	***Scientific Committee Process***	***Commission***	***Regulatory Committee Process***	***Commission***
EC-66 **RR-1445 cotton**	**<u>Directive 90/220/EEC</u>** • 30/06/1997 Applicant submits application. **<u>Directive 2001/18</u>** • 16/01/2003 Updated application submitted by the applicant.	• 19/11/1997 Lead CA submits full application to COM. • 15/12/1997 Circulation of full application to all CAs. • 20/01/1998 - 17/02/1998 Comments, objections and questions raised by MS. Applicant provides additional information.	• 01/04/1998 COM request for SCP opinion. • 30/06/1998 Request by SCP for additional data. • 14/07/1998 SCP opinion: favourable.	• 04/09/1998 COM launches ISC on draft decision.	• 26/11/1998 COM launches vote in REG COM by written procedure. • 30/11/1998 DK requests extension of the deadline for the vote in order to revise additional information submitted by the applicant. • 04/12/1998 COM informs CAs that the deadline for the vote is extended. • 10/12/1998 Belgium requests that the vote be postponed. • 21/12/1998 UK requests that the vote be postponed, in order to meet with the applicant and discuss further information recently submitted.	• 07/05/1999 COM launches ISC on draft Council Decision.

Product	*Member State Level*	*Community Level*				
		Circulation to Member States	*Scientific Committee Process*	*Commission*	*Regulatory Committee Process*	*Commission*
					• 23/12/1998 COM informs the CAs that the deadline for the vote is extended. • 13/01/1999 Opinion of Commission du Génie Biomoléculaire. • 26/01/1999 COM informs of further extension of the deadline for the vote, at the request of the lead CA. • 22/02/1999 REG COM vote: absence of qualified majority. (Outcomes of the written procedure including statements from Sweden, Austria and UK).	

Product	*Member State Level*	*Community Level*	
		Circulation to Member States	***Scientific Committee Process***
EC-67 **Transgenic potato**	**<u>Directive 90/220/EEC</u>** • 05/08/1996 Lead CA acknowledges receipt of the application submitted by the applicant. ("not complete"). • 27/09/1996 Request for completion. • 31/01/1997 – 21/11/1997 Further requests by lead CA. Information submitted by the applicant. • 07/05/1998 Final complete application and approval by the Swedish Board of Agriculture. **<u>Directive 2001/18/EC</u>** • 16/01/2003 Applicant submits updated application.	• 08/05/1998 Lead CA sends dossier and statement to COM. • 11/06/1998 Application statement and positive opinion of lead CA circulated to all CAs. • 14/07/1998 Advice by RIKILT (Institute of Food Safety): additional information to be provided by the applicant. • 15/07/1998 – 09/09/1998 Comments and objections by MS. Information and clarifications provided by the applicant. • 14/04/2004 Lead CA forwards dossier and assessment report to COM. • 04/05/2004 Circulation of application and statement of lead CA to all CAs	• 30/09/1998 COM requests opinion of the SCP. • 09/11/1998 SCP meeting. • 04/01/1999 Amylogene provides SCP working group with the full application and additional data. • 04/02/1999- 19/04/2002 Nine requests for clarifications by the SCP. Answers given by the applicant. - Draft opinion on 12/07/1999 - SCP meeting on 28/01/2000 • 18/07/2002 Opinion of the SCP. (favourable)

Product	*Member State Level*	*Community Level*	
		Circulation to Member States	***Scientific Committee Process***
EC-68 **Liberator oilseed rape**	**<u>Directive 90/220/EEC</u>** • 13/01/1998 Applicant submits application. • 09/02/1998 – 15/06/1998 Requests for further completion and clarification of the dossier. Applicant submits further amendments and corrections. • 17/06/1998 Completeness of the dossier confirmed. **<u>Directive 2001/18/EC</u>** • 16/01/2003 Submission of update by the applicant.	• 26/10/1998 Full application and statement of lead CA submitted to COM. • 14/01/1999 Full application (confidential part) circulated to all CAs. • 15/01/1999 – 28/04/1999 Comments, objections and requests for additional information by MS. Applicant provides replies to questions.	• 18/08/1999 COM requests SCP opinion. • 27/08/1999 – 06/11/2000 Applicant forwards dossier to SCP and provides answers and additional information. • 30/11/2000 Opinion of the SCP. • 05/11/2002 Request for update.

Product	*Member State Level*	*Community Level*	
		Circulation to Member States	***Scientific Committee Process***
EC-69 **Bt-11 maize (EC-69)**	**<u>Directive 90/220/EEC</u>** • 28/05/1996 Applicant submits application. • 17/06/1996 Lead CA receives application. • 06/1996 – 01/1999 Requests for additional information. Applicant provides additional information. **<u>Directive 2001/18/EC</u>** • 15/01/2003 Applicant updates application.	• 04/04/1999 Lead CA submits application to COM with a favourable opinion. • 07/05/1999 Application sent to all CAs. • 06/1999 – 10/2000 Requests for further information and objections by CAs. Applicant provides additional information. • 16/06/2003 Applicant submits updated application (including the new SNIF, environmental risk assessment and supplementary information) to the COM, together with the statement of the lead CA and its favourable assessment report.	• 30/11/2000 SCP opinion. (favourable) • 03/05/2002 Applicant updates application by including new sequence data.

Product	*Member State Level*	*Community Level*	
		Circulation to Member States	***Scientific Committee Process***
EC-70 **RR oilseed rape (EC-70)**	**<u>Directive 90/220/EEC</u>** • 07/07/1998 Applicant submits application. • 05/08/1998 – 18/11/1999 Requests for additional information and replies provided by the applicant. • 29/02/2000 Advice on application by the scientific committees. • 22/03/2000 Update of status and completeness of dossier. • 03/2000 – 03/2001 Additional information and clarifications submitted by applicant. (We note two dates: - on 28/04/2000 applicant submitted additional information - on 17/05/2000 applicant submitted clarifications) • 12/03/2001 Request for detection method. • 10/05/2001 Request for motivation for confidentiality status of the detection method detection method.	• 16/01/2003 COM receives new SNIF. • 24/01/2003 COM circulates dossier to other CAs. • 24, 25/03/2003 Objections raised by MS. • 28/04/2003 Meeting with COM, applicant and all CAs in order to solve the outstanding issues. • 05/08/2003 – 29/09/2003 Applicant provides additional information. Evaluation of the additional information.	• 23/10/2003 COM requests scientific opinion from EFSA Scientific Panel on GMOs. • 11/02/2004 Opinion of the Scientific Panel on GMOs issues: favourable.

Product	*Member State Level*	*Community Level*	
		Circulation to Member States	*Scientific Committee Process*
	• 20/09/2001 Applicant provides lead CA with detection method after the exchange of information on the confidentiality issue. • 13/11/2001 – 29/11/2002 Exchange of information between the lead CA and applicant with regard to the confidentiality status of the primer sequences of the detection method. - On 17/01/2002 the lead CA grants confidentiality status on primer sequences and requests reference material. **Directive 2001/18/EC** • 13/12/2002 Applicant provides a full updated application.		

Product	*Member State Level*
EC-71 **LL soybeans (EC-71)**	**<u>Directive 90/220/EEC</u>** • 28/09/1998 Applicant submits application. • 30/10/1998 – 05/09/2001 Lead CA requests for additional information and answers provided by the applicant, including: - 31/03/1999: Letter from Biosafety Council requesting further data. - 01/12/2000: Applicant clarifies that the application is maintained in Belgium and provides information on when requested data will be sent. - 05/12/2000: Lead CA confirms the continuation of the evaluation process and requiring additional information. • 05/09/2001 Lead CA requests for clarifications about the status of the double application in Belgium and Portugal and explains that the maintenance of the application in Portugal will entail suspension of the evaluation process in Belgium. • 08/10/2001 Applicant asserts the maintenance of double concurrent applications. **<u>Directive 2001/18</u>** • 15/01/2003 Update of the application. • 27/01/2003 Withdrawal of the application (Portugal). • 17/03/2003 Preliminary informal answer from the applicant with some of the information requested. • 29/06/2004 Withdrawal of the application.

Product	*Member State Level*
EC-72 **LL oilseed rape**	**<u>Directive 90/220/EEC</u>** • 28/01/1999 Applicant submits application to the UK CA. • 15/02/1999 and 24/03/1999 Lead CA requests for additional information. • 30/06/1999 Lead CA acknowledges receipt ("clock restarted"). • 20/07/1999 Request for additional information. • 11/11/1999 Minutes of 62nd meeting of ACRE. • 02/12/1999 UK Scientific Committee advises the applicant that the dossier requires substantial revision and clarification. • 16/01/2003 Applicant updates application. • 27/01/2003 Lead CA requests completion of up-dated notification. • 26/03/2004 Applicant withdraws application.

Product	*Member State Level*
	Directive 2001/18/EC • 13/01/2003 Applicant submits General Surveillance Plan in accordance with Annex VII of Directive 2001/18/EC. • 16/01/2003 Applicant submits new SNIF to the UK CA. • 13/06/2003 Applicant provides clarifications on the notification. • 26/03/2004 Applicant withdraws application C/GB/99/M5/2. • 30/03/2004 SNIF re-submitted to COM under reference C/GB/04/M5/4.

Product	*Member State Level*
EC-73 **BXN cotton**	**<u>Directive 90/220/EEC</u>** • 03/05/1999 Applicant submits application. • 01/07/1999 6th Meeting of the National Biosafety Committee ("NBC") of the lead CA: several questions raised and amendments proposed. • 17/09/1999 Applicant sends fax addressing some of the issues raised. • 25/01/2000 9th Meeting of the Spanish NBC (further examination of the application). • 02/02/2000 Lead CA informs applicant about persisting doubts. ↓

Product	*Member State Level*
	<u>Directive 2001/18/EC</u> • 16/01/2003 Applicant updates application following Article 35 of Directive 2001/18. • 19/03/2003 Applicant sends SNIF summary. • 18/07/2003 SNIF circulated to COM. • 26/09/2003 Analysis of the notification by the Spanish NCB – 36th Meeting. • 02/10/2003 Lead CA sends fax to applicant requesting additional information related to labelling proposal, molecular characterization and general surveillance plan. • 07/10/2003 Fax of lead CA to the applicant requesting additional information related to substantial equivalence.

Product	*Member State Level*	*Community Level*	
		Circulation to Member States	***Scientific Committee Process***
EC-74 **Bt-1507 maize (EC-74)**	**<u>Directive 90/220/EEC</u>** • 23/11/2000 Applicant submits application. • 12/2000 – 11/2002 Lead CA requests additional information. Applicant provides additional information. - On 16/10/2001 the applicant provides first set of answers, indicating that further responses would be delivered in December 2001. - On 21/11/2001 the applicant provides additional information and replies to questions. ↓ **<u>Directive 2001/18/EC</u>** • 21/11/2002 Applicant updates application. • 02/2003 – 03/2003 Lead CA requests additional information. Applicant provides additional information. - On 10/02/2003 the lead CA requests further information on compositional data, monitoring plan, confidentiality of detection method. - On 24/03/2003 applicant provides additional information. • 28/05/2003 Applicant provides clarifications with regard to confidentiality status.	• 15/08/2003 Full application and assessment report sent to COM. • 26/08/2003 Application and assessment report circulated to all MS. • 08/2003 – 02/2004 Comments and objections by MS. Applicant provides responses.	• 26/02/2004 COM requests EFSA opinion. • 12/03/2004 Letters from COM to EFSA clarifying some MS objections.

Product	*Member State Level*	*Community Level* *Circulation to Member States*
EC-75 **Bt-1507 maize (EC-75)**	**<u>Directive 90/220/EEC</u>** • 06/07/2001 Applicant submits application. • 09/2001 – 12/2002 Lead CA requests for additional information. Applicant submits additional information. ↓ **<u>Directive 2001/18/EC</u>** • 13/02/2003 Lead CA submits updated SNIF to COM. • 02/2003 – 04/2003 Requests for additional information. Applicant provides additional information. • 28/05/2003 Applicant submits updated application.	• 08/2003 - Lead CA submits full application and assessment report to COM. - Application and assessment report circulated to all MS. • 10/2003 – 03/2004 Comments, objections and requests for additional information by MS. Applicant provides additional information. • 05/2004 – 06/2004 Comments/objections by MS.

Product	*Member State Level*	*Community Level*				
		Circulation to Member States	***Scientific Committee Process***	***Commission***	***Regulatory Committee Process***	***Council***
EC-76 **NK603 maize**	**<u>Directive 90/220/EEC</u>** • 04/08/2000 Applicant submits application. • 20/12/2000 Applicant clarifies the scope of the application and provides Spanish translation. • 02/01/2001 Lead CA acknowledges receipt.	• 14/01/2003 Lead CA submits full application and assessment report to COM. • 24/01/2003 Application and assessment report circulated to all MS. • 24/02/2003 – 28/08/2003 Comments and objections by MS. Answers and additional information given by the applicant.	• 04/09/2003 COM requests EFSA opinion. • 25/11/2003 EFSA opinion adopted: favourable.	• 08/12/2003 COM launches ISC on draft COM Decision.	• 18/02/2004 Absence of qualified majority in REG COM.	• 26/03/2004 Transmission of the proposal to the Council.

Product	*Member State Level*	*Community Level*				
		Circulation to Member States	*Scientific Committee Process*	*Commission*	*Regulatory Committee Process*	*Council*
	• 15/02/2001-19/06/2002 National Biosafety Committee requests additional information. Applicant provides additional information. - 27/02/2001: In the 18th Meeting of the National Biosafety Committee ("NBC"), additional information requested on molecular characterisation, nutritional analysis, environmental impact, etc. - On 05/09/2001 applicant provides additional information. - On 10/10/2001 lead CA forwards request of NBC for further information. - On 21/05/2002 lead CA forwards persisting doubts of NBC over certain information supplied. • 29/08/2002 Applicant updates application in line with the requirements of the Directive 2001/18/EC. **<u>Directive 2001/18/EC</u>** • 20/11/2002 Applicant provides updated SNIF.					

Product	*Member State Level*	*Community Level*			
		Circulation to Member States	***Commission***	***Regulatory Committee Process***	***Commission***
EC-77 **Transgenic red-hearted chicory** **(Notification C/NL/94/25)**	**<u>Directive 90/220/EEC</u>** • 15/12/1994 Applicant submits full application to lead CA. • 23/01/1995 Advice of Commission on Genetic Modification (COGEM): information insufficient. • 31/03/1995 Statement of Dutch CA with evaluation summary: favourable.	• 31/03/1995 Lead CA forwards full application to COM. • 20/04/1995 Full application forwarded to all CAs. • 30/05/1995-27/07/1995 Comments and objections by MS. Responses to questions and clarifications by the lead CA.	• 25/01/1996 COM launches ISC on draft COM decision.	• 08/03/1996 Consultation of the REG COM by written procedure. • 24/04/1996 Consultation of REG COM: Positive opinion.	• 03/05/1996 Request by written procedure for approval by COM members. • 10/05/1996 Written procedure suspended. • 14/05/1996 Written procedure re-launched subject to specific labelling requirements. • 20/05/1996 Decision 96/424/EC for placing of the product on the market. • 05/08/1996 Written consent by Dutch CA to applicant. • 01/03/2003 Letter of withdrawal. • 24/04/2003 Confirmation letter of withdrawal to applicant.

Product	*Member State Level*	*Community Level*		
		Circulation to Member States	***Scientific Committee Process***	***Commission***
EC-77 **Transgenic red-hearted chicory** **(Notification C/NL/94/25/A)**	**<u>Directive 90/220/EEC</u>** • 10/09/1996 Applicant submits the part of the application dealing with food safety aspects to lead CA.	• 13/09/1996 Lead CA forwards application to COM. • 11/07/1996-08/05/1998 Requests for additional information, comments and objections by MS. Applicant provides answers and additional information.	• 02/06/1998 COM requests SCP opinion. • 07-09/1998 Questions raised by the SCP and answers provided by the applicant. • 19/10/1998 SCP requests for further information. • 01/12/1998 Applicant provides further information. • 18/12/1998 Opinion of the SCP: favourable. • 10/09/1999 Questions by SCP raised in the context of the evaluation according to the 258/97 Regulation. • 16/11/1999 Comments by the SCP on the draft opinion of the SCF.	• 30/03/1999 Proposal to amend COM Decision 96/424/EC. Request for launching of ISC. (Same GM product had already been authorised for breeding activities at the Community level.) • 10/05/1999 ISC launched. • 26/05/1999 ISC closed.

Product	*Member State Level*	*Community Level*		
		Circulation to Member States	*Scientific Committee Process*	*Commission*
			• 10/07/2000 – 18/06/2001 SCF requests applicant to submit additional information and clarifications. - On 10/07/2000 SCF requests further information about substantial equivalence. - On 14/11/2000 the applicant submits further clarifications. - On 11/06/2001 the applicant requests further clarifications on the antibiotic resistance markers. - On 18/06/2001 SCF requests additional information (already requested on 10/07/2000). • 24/07/2001 Clarifications by COM to applicant about the phasing-out of antibiotic resistance markers.	

Product	*Member State Level*	*Community Level*		
		Circulation to Member States	***Scientific Committee Process***	***Commission***
EC-78 **GA21 maize (EC-78)**	**<u>Directive 90/220/EEC</u>** • 29/05/1998 Receipt of application. • 16/06/1998-13/07/1998 Two meetings of the Spanish scientific committee (33rd and 35th). Answers provided by the applicant to questions posed. • 31/07/1998 Request for further data. **<u>Directive 2001/18/EC</u>** • 15/01/2003 Applicant submits new SNIF and updated risk assessment to lead CA.	• 11/05/1999 Spanish lead CA forwards application to COM. • 06 and 07/1999 Application sent to MS. Comments/objections of MS circulated. • 28/07/1999 Voluntary commitments by the applicant. • 29/07/1999 Technical meeting on pending products. Applicant provides general information. • 08/1999 Comments by MS. Applicant provides answers. • 29/09/1999 11th meeting on technical aspects of product application dossiers pending under part C of Directive 90/220/EEC. • 21/10/1999 Responses to MS objections. • 15/09/2003 Applicant withdraws application.	• 29/10/1999 COM sends dossier to SCP for opinion. • 22/02/2000 SCP requests clarification. • 15/03/2000 Applicant provides answers to request for clarification. • 06 and 07/2000 Further requests for additional information and responses provided by the applicant. • 22/09/2000 SCP opinion: favourable.	• 19/01/2001 Applicant submits letter on the change of scope (import and processing only, planting now excluded). • 21/09/2001 Undertakings from applicant accordance with the requirements of Directive 2001/18/EC. • 18/03/2002 Applicant submits updates and commitments to COM.

Product	*Member State Level*	*Community Level* *Circulation to Member States*
EC-85 **GA21 maize (EC-85)**	**<u>Directive 90/220/EEC</u>** • 12/12/1997 Applicant submits application. • 23/12/1997 UK CA requests further information. • 01 and 02/1998 Applicant submits further information. • 27/02/1998 Amended dossier requested. • 30/03/1998 Applicant submits amended dossier. • 04 – 12/1998 Requests for further information. Applicant submits additional information. • 16/02/1999 UK CA requests amended dossier. • 03/03/1999 Applicant submits further information. • 16/09/1999 Meeting of ACRE.	• 15/10/1999 Lead CA sends full application to COM. • 01/12/1999 COM circulates application to all CAs. • 12/1999 – 02/2000 Comments and objections by MS. Applicant provides answers and clarifications. • 27/06/2001 Applicant withdraws application.

Product	*Member State Level*	*Community Level* *Circulation to Member States*
EC-79 **RR oilseed rape (EC-79)**	**<u>Directive 90/220/EEC</u>** • 21/05/1995 Applicant forwards application to the lead CA. • 05/1995 – 10/1996 Requests for additional information. Applicant submits additional information. - On 06/02/1996 the Commission du Génie Biomoléculaire requests applicant to submit studies on rats (28 days). • 02/12/1996 Applicant submits update to initial dossier.	• 02/12/1996 Lead CA forwards application to COM. • 30/06/1997 Applicant submits proposal for labelling and appropriate information. • 15/01/2003 Official withdrawal.

Product	*Member State Level*	*Community Level* *Circulation to Member States*
EC-80 **Bt-11 maize (EC-80)**	**<u>Directive 90/220/EEC</u>** • 29/05/1998 Applicant submits application. • 16/06/1998 Meeting of the Spanish Scientific Comité. • 31/07/1998 Lead CA requests additional information by the applicant. • 03/09/1998 Applicant submits additional information. • 09/1998 and 01/1999 Meetings of the Spanish Scientific Comité. • 26/04/1999 Lead CA forwards positive risk assessment report to COM.	• 30/04/1999 Lead CA forwards application to COM. • 20/05/1999 Applicant notifies withdrawal of application from Spain. • 27/05/1999 COM circulates full application to all CAs. • 28/05/1999 Official withdrawal circulated to all CAs. Review of the application closed.

Product	*Member State Level*
EC-81 **LL soybeans (EC-81)**	**<u>Directive 90/220/EEC</u>** • 24/09/1999 Applicant submits application. • 07/12/1999 Opinion of the Portuguese Ministry of Agriculture: not favourable. Request for additional information to be submitted by the applicant. • 07/01/2000 Portuguese Ministry of Health requests further information. • 17/01/2000 Request for additional information. • 11/05/2000 Additional request for information. • 28/09/2001 Applicant provides responses. • 18/10/2001 Acknowledgment of additional information and transmission of the additional information to the Portuguese Ministry of Health. **<u>Directive 2001/18/EC</u>** • 20/11/2001 Portuguese CA requests applicant to bring application into line with the new requirements of Directive 2001/18/EC. • 28/01/2002 Portuguese Ministry of Health requests applicant to provide further clarification. • 27/01/2003 Applicant submits letter of withdrawal.

Product	*Member State Level*
EC-82 **MON810 x GA21 maize**	**<u>Directive 90/220/EEC</u>** • 04/08/1999 Applicant submits application to lead CA. • 31/08/1999 Applicant submits new SNIF and translated documents. • 11/11/1999 7th session of Spanish National Commission on Biosafety. • 30/11/1999 Lead CA requests further information. • 08/2001 Applicant submits additional information. • 17/01/2002 Applicant provides translated documents. • 04/04/2002 Meeting of the Spanish National Commission on Biosafety. • 17/01/2003 Applicant submits updates to the lead CA. (Lead CA did not receive updates.) • 15/09/2003 Applicant withdraws application.

Product	*Member State Level*	*Community Level*				
		Circulation to Member States	***Scientific Committee Process***	***Commission***	***Regulatory Committee Process***	***Commission***
EC-83 **MON809 maize**	**<u>Directive 90/220/EEC</u>** • 18/12/1995 Applicant submits full application to lead CA concerning the two events (MON 801 and MON809). • 06/02/1996 National scientific committee (CGB) delivers an opinion and requests additional information as well as separate applications for the two events. • 06/03/1996 New application concerning MON809 and further data provided. • 04/04/1996 Opinion of the National scientific committee (CGB).	• 06/08/1996 Lead CA forwards application to COM. • 29/08/1996 COM forwards full application to all CAs. • 25/09/1996-14/07/1997 Comments, requests for further clarifications and objections my MS.	• 27/01/1998 COM submits application to SCP for opinion. • 11/03/1998 Meeting of the GMO working group of the SCP. • 03-04/1998 Applicant provides responses to SCP's questions. • 19/05/1998 SCP opinion: favourable	• 12/06/1998 COM launches ISC on draft COM decision to be submitted to REG COM. • 09/07/1998 ISC concluded.	• 04/09/1998 COM launches consultation of REG COM. • 23/10/1998 Consultation of REG COM ends with no opinion.	• 22/04/1999 COM launches vote in REG COM by written procedure. • 29/04/1999 Written procedure suspended because of Bt resistance management program. • 08/06/1999 Additional questions sent to SCP: consultation done in the context of the safeguard measures invoked by Austria about MON810 maize (because laboratory results showed harm to butterflies treated with pollen from Bt maize) • 24/09/1999 SCP opinion: favourable. • 04/10/2002 Applicant withdraws application.

Product	*Member State Level*	*Community Level*				
		Circulation to Member States	***Scientific Committee Process***	***Commission***	***Regulatory Committee Process***	***Commission***
EC-84 **Transgenic tomato**	**<u>Directive 90/220/EEC</u>** • 15/11/1996 Lead CA receives dossier from the applicant. • 12/1996, 01 and 02/1997 Three meetings of the Spanish Commission on Biosafety. • 19/02/1997 Lead CA requests additional information. • 02, 03 and 04/1997 Exchange of information among Spanish Ministry of Health, Spanish Ministry of Environment and lead CA. • 24/04/1997 Meeting of the Spanish Commission on Biosafety. • 23/10/1997 Fax from the applicant to the Spanish Ministry of Health: submission on genetically modified tomatoes to be assessed under the Novel Food Regulation.	• 17/11/1997 Lead CA forwards dossier to COM together with a favourable opinion. • 15/12/1997 Lead CA circulates full dossier to all MS. • 01/1998 Requests for further information by MS. • 27/01/1998 Meeting held by the COM on technical aspects of Part C dossiers. Request for further info. • 04/02/1998 Applicant provides CA with additional data. • 02 and 03/1998 Comments and some objections by MS. Applicant provides additional information.	• 23/06/1998 SCP opinion: favourable.	• 05/10/1998 Outcomes of ISC.	• 26/11/1998 COM launches consultation of the REG COM by written procedure. • 18/12/1998 Consultation of the REG COM concluded: No opinion.	• 16/02/1999 COM sends proposal for CO decision to Cabinet Bjereggard for approval. • 09/03/1999 COM sends proposal for CO decision to Legal Service for approval. • 20/08/1999 COM launches written procedure on draft CO decision. • 23/09/1999 SCF opinion: favourable. • 24/11/1999 Consultation of other DGs on draft Commission Decision under the Standing Committee on Foodstuffs. • 04/02/2002 Applicant withdraws application.

Product	*Member State Level*	*Community Level*		
		Circulation to Member States	***Scientific Committee Process***	***Commission***
EC-86 **T25 x MON810 maize**	**<u>Directive 90/220/EEC</u>** • 26/06/1998 Applicant submits full application to lead CA. • 10/08/1998 Advice of COGEM: - No risks for human health or the environment. - Need for further testing. • 08 and 09/1998 Requests for additional information. Applicant provides additional information. • 01/12/1998 RIKILT (advisory body for feed aspects) states that there are no reasons to conclude that the GMO is unsafe. • 21/01/1999 Lead CA sends draft evaluation summary to the applicant. • 22/04/1999 Applicant's response to draft evaluation summary.	• 26/04/1999 Dutch CA sends evaluation summary and application to COM. • 17/05/1999 COM circulates full application to all CAs. • 06 and 07/1999 Requests for further information, comments and objections by MS. Applicant provides additional information. • 01/09/1999 Applicant proposes for alternatives with respect to the scope of the dossier.	• 21/09/1999 COM requests SCP opinion. • 26/10/1999 Comments by SCP and draft opinion. • 17/11/1999 SCP requests further information by the applicant. • 01 and 02/2000 Applicant submits additional information. • 06/06/2000 SCP opinion: favourable.	• 18/12/2002 Applicant withdraws application.

Product	*Member State Level*
EC-87 **High-oleic soybeans**	**<u>Directive 90/220/EEC</u>** • 19/06/1998 Applicant submits full application to lead CA. • 07/1998 – 09/1998 Lead CA requests additional information. Applicant provides additional information. • 28/09/1998 Advice of COGEM: - Information submitted is sufficient - No risk to human life or the environment. • 12/10/1998 Addendum to COGEM advice: - Alteration of fatty acid composition will not result in risks in food or feed safety. - Food and feed safety due to the change of protein composition can not be guaranteed based on the information supplied. - Based on the information, no toxicological effects are foreseen in case of incidental consumption. COGEM states that this basically confirms their earlier assessment. • 07/12/1998 RIKILT requests additional information. • 01/07/1999 Applicant provides additional information. • 27/10/1999 Request for additional information to applicant, concerning feed safety aspects. • 12/12/2002 Applicant withdraws application.

Product	*Member State Level*	*Member State Level (continues)*
EC-88 **RR sugar beet**	**<u>Directive 90/220/EEC</u>** • 22/12/1998 Applicant sends application to lead CA. • 23/02/1999 Lead CA requests additional information. • 11/03/1999 Applicant provides additional information. • 14/04/1999 Lead CA requests additional information. • 14/04/1999 Applicant provides additional information. • 26/04/1999 Biosafety Advisory Council Meeting. • 02/06/1999 Biosafety Advisory Council raises remaining questions on agricultural practices, molecular characterisation, toxicology, allergenicity, and food/feed equivalence. • 07/06/1999 Lead CA requests additional information. • 14/07/1999 Applicant provides additional information.	• 08/12/1999 Applicant provides additional information. • 18/01/2000 Applicant provides additional information on horizontal gene transfer. • 02/02/2000 Lead CA requests additional information. • 02 and 03/2000 Applicant provides additional information. • 04/04/2000 Meeting with the applicant (regarding identity preservation, GAP, post market monitoring, traceability, public information, line-specific detection methods and primers). • 26/07/2000 Applicant submits additional information. • 16/11/2000 CA requests additional information on further characterisation of a protein and detection protocols. • 04/01/2001 Lead CA requests additional information on labelling and traceability. • 13/06/2001 Lead CA requests applicant to adapt the application with one of the expert's comments.

Product	*Member State Level*	*Member State Level (continues)*
	• 01/10/1999 Lead CA requests additional information (allergenicity, molecular characterisation, gene transfer in digestive tracts).	**<u>Directive 2001/18/EC</u>** • 16/01/2003 Applicant updates application. • 25/02/2003 Lead CA requests additional information. • 16/04/2004 Applicant withdraws application.

Product	*Member State Level*	*Community Level*		
		Circulation to Member States	***Scientific Committee Process***	***Commission***
EC-91 **GA21 maize (food)**	**<u>Directive 90/220/EEC</u>** • 24/07/1998 Applicant submits application to Dutch CA. • 11/08/1998 COM forwards the application to MS. • 15/09/1998 Lead CA requests applicant to complete the dossier. • 09/1998 – 02/1999 Applicant submits additional information. • 24/02/1999 Advisory Committee on the Safety of Novel Foods and Foods Ingredients requests additional information. • 25/03/1999 Applicant submits additional information. • 18/06/1999 Advisory Committee on the Safety of Nove Foods requests additional data. • 26/10/1999 Applicant submits requested data. • 21/12/1999 Initial assessment by Gezondheidsraad.	• 21/01/2000 Lead CA sends initial assessment to COM. • 18/02/2000 COM circulates initial assessment to MS. • 03 – 05/2000 Requests for additional information, comments and objections by MS. Applicant provides additional information.	• 18/05/2000 COM requests SCF opinion. • 18/07/2000 Applicant provides additional labelling proposal. • 08/2000 Applicant submits additional information. • 24/04/2001 SCF requests further information by applicant. • 17/05/2001 Applicant responds to the request for additional information. • 12-13/12/2001 Discussion on draft opinion postponed to February meeting of SCP due to lack of time. • 27/02/2002 Opinion of the SCF.	• 23/04/2002 Applicant changes scope of application. • 05/06/2002 Meeting with applicant. Applicant agrees to provide additional information. • 18/09/2002 Meeting with applicant on validation method.

Product	*Member State Level*	*Community Level*					
		Circulation to Member States	***Scientific Committee Process***	***Regulatory Committee Process***	***Commission***	***Council***	***Commission***
EC-92 **Bt-11 sweet maize (food)**	**<u>Regulation (EC) N° 258/97</u>** • 11/02/1999 Applicant submits application. • 09/03/1999 COM forwards the summary of the application to MS. • 04/1999 – 05/2000 Requests for additional information. Applicant provides additional information. • 12/05/2000 Lead CA forwards the initial assessment report to COM.	• 15/06/2000 COM forwards the initial assessment report to MS for comments/objections. • 06/2000 – 11/2000 Comments and objections by MS. Applicant provides additional information and answers to comments/objections.	• 13/12/2000 COM requests SCF opinion. • 13/12/2000 Italy requests additional information. • 15/04/2001 SCF requests further data. • 10/05/2001 Italy reiterates objections raised in July 2000. • 12/11/2001 SCF reminds applicant of request for additional information. • 27/02/2002 Applicant submits data. • 17/04/2002 SCF opinion: favourable.	• 08/11/2003 Draft Commission Decision on the agenda of the Standing Committee. (No formal opinion delivered by MS). • 08/12/2003 Vote held in REG COM. (No qualified majority was reached).	• 28/01/2004 Formal COM decision to refer the matter to the Council.	• 26/04/2004 Vote held in Council. (No qualified majority reached)	• 19/05/2004 COM adopts decision.

Product	*Member State Level*	*Community Level*					
		Circulation to Member States	*Scientific Committee Process*	*Regulatory Committee Process*	*Commission*	*Council*	*Commission*
			• 04/2002 – 10/2003 Requests for additional material on validation method. Applicant submits additional material. - On 05/06/2002, applicant agrees to provide detection measures, traceability, reference material and identification - On 22/01/2003 applicant provides material for detection method validation - On 07/07/2003 applicant submits a new method.				

Product	*Member State Level*	*Community Level* *Circulation to Member States*
EC-93 **LL soybeans (food)**	**<u>Regulation (EC) N° 258/97</u>** • 30/11/1998 Applicant submits application.	• 02/02/1999 Application sent to COM. • 08/02/1999 Belgian CA sends e-mail, confirming that it will assess the dossier. • 02/03/1999 COM note to the Permanent Representations of the MS-summary of the file. • 28/04/1999 Letter from Louis Pasteur Scientific Institute for Public Health requesting additional information. • 26/05/1999 COM informs MS that the initial assessment will not be completed on time. • 06/1999 – 07/2004 Requests for additional information. - On 07/06/1999 Greece requests additional information - On 21/07/1999 Italy sends its comments - On 01/12/200 applicant sends letter to Ministère Dr W Moens (BE) concerning additional information on the application and notification - On 18/07/2001 applicant providing additional information on the application to the Ministère Féderal des Affaires Sociales, de la santé Publique et de l'Environnement. • 06/07/2004 Applicant withdraws application.

Product	*Member State Level*	*Community Level* *Circulation to Member States*
EC-94 **MON810 x GA21 maize (food)**	**<u>Regulation (EC) N° 258/97</u>** • 29/02/2000 Applicant submits application. • 29/03/2000 Note of the European Commission to the Permanent representations of the Member States – summary of the file.	• 29/02/2000 Copy of application sent to COM. • 04-05/2000 UK, Greece and Denmark request applicant to provide full dossier. • 06/2000 Comments from Austria, UK and Italy. • 17/07/2000 Gezondheidsraad requests applicant to provide additional information. • 15/02/2002 Applicant provides additional information. • 02/07/2002 Gezondheidsraad requests applicant to provide additional information.

Product	*Member State Level*	*Community Level* *Circulation to Member States*
EC-95 **Bt-1507 maize (food)**	**<u>Regulation (EC) N° 258/97</u>** • 15/02/2001 Applicant submits application. • 03/2001 – 05/2003 Requests for full dossier and additional information. Applicant provides technical dossier and additional information. - On 28/06/2001 Gezonheidsraad sends letter to applicant, requesting for additional information. - In February 2002 applicants responds to the request of 28/06/2001. - On 25/03/2003 Gezonheidsraad sends letter to applicant, requesting for further examination. - On 16/05/2003 the applicant responds to the request of 25/03/2003. - On 11/06/2003 Gezondheitsraad requests further clarification with regard to the reply of 16/05/03. - Following the request of 11/06/2003, the applicant provides additional information to Gezondheitsraad. • 03/2003 – 07/2003 Requests for additional information. Applicant provides additional information. • 04/11/2003 Initial assessment report by CA. **<u>Regulation (EC) N°1829/2003</u>** • 17/03/2004 COM note to MS: transfer of application to Regulation (EC) N° 1829/2003.	• 18/11/2003 Initial assessment sent to COM. • 10/12/2003 COM forwards initial assessment report to MS for comments/objections. • 02/2004 Comments by MS.

Product	*Member State Level*	*Community Level*			
		Circulation to Member States	***Scientific Committee Process***	***Regulatory Committee Process***	***Council***
EC-96 **NK603 maize (food)**	**<u>Regulation (EC) N° 258/97</u>** • 24/04/2001 Applicant submits application. • 06/2001 – 03/2002 MS request full dossier and additional information. Applicant provides full dossier and additional information. - On 26/06/2001 lead CA requests copies of references. - On 20/07/2001 the applicant provides copies of references in notification. - On 13/12/2001 Gezondheidsraad requests applicant to provide further information. - On 23/01/2002 Italy requests additional information. - On 28/03/2002 applicant provides requested information. • 13/08/2002 Health Council Committee finishes its assessment report. • 05/11/2002 Lead CA forwards initial assessment report to COM.	• 06/01/2003 COM forwards initial assessment report to MS for comments/objections. • 02/2003 – 07/2003 Comments/objections by MS. Applicant provides answers. - 26/02/2003: SBB: evaluation	• 18/09/2003 COM requests EFSA opinion. • 25/11/2003 EFSA opinion: favourable.	• 30/04/2004 Draft COM decision presented to REG COM.	• 13/07/2004 Transmission to CO pending.

Product	*Member State Level*	*Community Level*		
		Circulation to Member States	*Scientific Committee Process*	*Commission*
EC-97 **Transgenic red-hearted chicory (food)**	**<u>Regulation (EC) N° 258/97</u>** • 08/04/1998 Applicant submits application. • 23/04/1998 Initial assessment by lead CA.	• 13/05/1998 COM forwards request, summary and initial assessment to MS. • 15/09/1998 Confirmation of the initial assessment report. • 27/10/1998 COM circulates initial assessment to MS.	• 29/04/1999 COM requests opinion from the SCF. • 09/1999 – 07/2001 Questions from the SCF to the applicant. Applicant provides responses. - On 10/07/2000 the SCF poses additional questions to the applicant. - On 21/07/2000 the applicant responds. - On 31/07/2000 the SCF requests additional information. - On 14/11/2000 the applicant responds. - On 18/06/2001 the SCF requests additional information. - On 23/01/2001 the applicant provides additional information. - On 24/04/2001 the SCF requests additional information. • 24/09/2001 Letter from applicant to SCF suspending the dossiers for market application	• 27/05/2003 Applicant withdraws application.

Product	*Member State Level*	*Community Level*		
		Circulation to Member States	***Scientific Committee Process***	***Commission***
EC-98 **Transgenic green-hearted chicory (food)**	**<u>Regulation (EC) N° 258/97</u>** • 14/03/1996 Applicant submits application. • 23/04/1998 Lead CA provides its initial assessment.	• 13/05/1998 COM forwards request, summary and initial assessment to MS . • 15/09/1998 Confirmation of the initial assessment report. • 27/10/1998 COM circulates initial assessment report. • 12/1998-03/1999 Comments and objections by MS.	• 29/04/1999 COM requests SCF opinion. • 05/1999-07/2001 Questions and additional requests to the applicant by SCF. Applicant provides responses. - On 10/07/2000 the SCF poses additional questions to the applicant. - On 21/07/2000 the applicant responds. - On 31/07/2000 the SCF requests additional information. - On 14/11/2000 the applicant responds. - On 18/06/2001 the SCF requests additional information. - On 24/07/2001 the SCF poses further questions to the applicant. • 24/09/2001 Applicant suspends consideration of the dossier for market application.	• 27/05/2003 Applicant withdraws application.

Product	*Member State Level*	*Community Level*	
		Circulation to Member States	***Commission***
EC-99 **High-oleic soybeans (food)**	**<u>Regulation (EC) N° 258/97</u>** • 24/07/1998 Applicant submits application.	• 11/08/1998 Summary of application forwarded to MS. • 10/1998-09/1999 Netherlands, Germany and Greece request additional information and make comments. Applicant provides responses. (We note the following dates: - On 16/10/1998 the applicant provides relevant references. - On 11/03/1999 the Health Council poses questions to the applicant. - On 28/05/1999 the applicant provides additional information. - On 06/09/1999 the Health Council sends further comments to the applicant.)	• 12/12/2002 Applicant withdraws application.

Product	*Member State Level*	*Community Level*		
		Circulation to Member States	***Scientific Committee Process***	***Commission***
EC-100 **Transgenic tomato (food)**	**<u>Regulation (EC) N° 258/97</u>** • 02/03/1998 Applicant submits application.	• 22/04/1998 Summary of application forwarded to MS. • 04/06/1998 Lead CA sends initial assessment to COM. • 22/06/1998 COM circulates initial assessment to MS. • 06/1998-10/1998 Comments and objections by MS. • 22/10/1998 COM forwards comments/objections to MS. • 11/1998 Further comments by MS. Applicant provides responses. • 22/12/1998 Italy renews its objections.	• 23/12/1998 COM requests SCF opinion. • 01-02/1998 Comments, objections by France and Austria. • 04/10/1999 SCF opinion: favourable. • 07/09/2000 SCF opinion: favourable.	• 24/09/2001 Applicant withdraws application.

Product	*Member State Level*	*Community Level*	
		Circulation to Member States	***Commission***
EC-101 **T25 x MON810 maize (food)**	**<u>Regulation (EC) N° 258/97</u>** • 20/04/2000 Applicant submits application.	• 03/05/2000 Summary of application forwarded to MS. • 05/2000-11/2001 MS request additional information. Applicant provides responses. (We note the following dates: - On 17/07/2000 the Health Council of the Netherlands requests additional information. - On 22/11/2000 the applicant provides additional information. - On 23/04/2001 the Health Council of the Netherlands requests additional information. - On 21/11/2001 applicant provides additional information and clarifies the state of play.)	• 12/12/2002 Applicant withdraws application.

Product	*Member State Level*	*Community Level*	
		Circulation to Member States	***Commission***
EC-102 **RR sugar beet (food)**	**<u>Regulation (EC) N° 258/97</u>** • 03/11/1999 Applicant submits application. • 24/03/2000 The Health Council of the Netherlands requests applicant to submit additional information. • 18/04/2000 Response by the applicant. • 10/05/2000 The Health Council of the Netherlands requests applicant to submit further information.	• 29/05/2000 COM forwards application to MS. • 06-07/2000 MS request full dossier. • 12/2000 Applicant provides responses. • 19/01/2001 Denmark acknowledges receipt of the application and comments on it. • 16/05/2001 Netherlands requests additional information.	• 16/04/2004 Applicant withdraws application.

Product	*Member State Level*
EC-110 **Transgenic green-hearted chicory**	**<u>Regulation (EC) N° 258/97</u>** • 11/03/1996 Applicant submits full application to lead CA. • 24/05/1996 Applicant submits the English version of SNIF. • 13/06/1996 Advice of Commission on Genetic Modification (COGEM) concluding that based on the information no environmental risks are foreseen. • 08/07/1996 Draft evaluation summary is sent to the applicant. • 02/01/1997 Applicant requests that the dossier not be forwarded to COM until the dispute around the food safety of dossier C/NL/94/25A is settled. • 23/04/1998 Advice vCVNV (Provisional Commission for Food safety) concerning event GM2-28. • 25/03/1999 RIKILT considers the dossier incomplete and requests additional information. • 21/05/1999 Applicant provides additional information. • 15/04/2003 Applicant withdraws application.

Product	*Member State Level*
EC-156 **T14 maize**	**<u>Directive 90/220/EEC</u>** • 10/06/1996 Applicant submits full application to lead CA. • 06/1996 – 02/1997 Commission du Génie Biomoléculaire requests additional information. • 22/07/1997 Applicant submits updated application and additional information. • 23/10/1997 Commission du Génie Biomoléculaire requests modification of the application. • 29/11/1997 Commission du Génie Biomoléculaire issues opinion. • 28/01/1998 Applicant submits new information and a modified application following request from the Commission du Génie Biomoléculaire. • 15/07/1998 Applicant withdraws application.