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EUROPEAN COMMUNITIES – MEASURES AFFECTING ASBESTOS AND ASBESTOS – CONTAINING PRODUCTS

Report of the Panel

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I. INTRODUCTION

1.1 In a communication dated 28 May 1998, Canada requested consultations with the European Communities (EC) pursuant to Article XXII of the General Agreement on Tariffs and Trade (GATT), Article 11 of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and Article 14 of the Agreement on Technical Barriers to Trade (TBT Agreement), concerning certain measures taken by France for the prohibition of asbestos and products containing asbestos (WT/DS135/1 – G/SPS/GEN/72 – G/TBT/D/15). Canada's request states that these measures include, but are not limited to, Decree No. 96-1133 of 24 December 1996 (the "Decree") banning asbestos, issued pursuant to the Labour Code and the Consumer Code, as amended. On 12 June 1998, Brazil asked to take part in the consultations because of its substantial trade interest (WT/DS/135/2).

1.2 In a communication dated 8 October 1998, Canada informed the Dispute Settlement Body (DSB) that the consultations held with the EC had failed to resolve the dispute satisfactorily. Consequently, Canada requested the DSB to establish a panel to examine the French measure concerning the prohibition of asbestos and products containing asbestos. In its communication, Canada claimed that the Decree, as well as any other measure which Canada might indicate, were inconsistent with Articles 2 and 5 of the SPS Agreement, Article 2 of the TBT Agreement, Articles III and XI of the GATT 1994, and, under Article XXIII:1(b) of the GATT 1994, nullified or impaired one or several advantages accruing to Canada directly or indirectly under the WTO Agreement or impeded the attainment of an objective of the Agreement owing to the fact that the banning of asbestos by France was applied whether or not it conflicted with the Agreement (WT/DS/135/3).

1.3 At its meeting held on 25 November 1998, the DSB established a panel pursuant to Canada's request. At that meeting, the parties to the dispute agreed that the Panel should have the following terms of reference:

> "To examine, in the light of the relevant provisions of the covered agreements cited by Canada in document WT/DS135/3, the matter referred to the DSB by Canada in that document and to make such findings as will assist the DSB in making the recommendations or in giving the rulings provided for in those agreements".

1.4 On 29 March 1999, the parties to the dispute agreed that the Panel would be constituted as follows (WT/DS135/4):

Chairman: Mr. Adrian Macey;
Members: Mr. William Ehlers;
Mr. Åke Lindén.

1.5 Brazil, the United States and Zimbabwe reserved their rights as third parties to the dispute, in accordance with Article 10 of the Dispute Settlement Understanding.

1.6 The Panel met with the parties on 1 and 2 June 1999 and with third parties on 2 June 1999. A meeting with scientific experts was held on 17 January 2000. The second substantive meeting with the parties was held on 20 January 2000.

1.7 In a communication dated 27 September 1999, the Chairman of the Panel informed the DSB that the Panel was unable to present its report within the six-month period provided in Article 12.8 of the Memorandum of Understanding. The reasons for the delay are set out in document WT/DS/135/5. In two subsequent communications dated 7 March 2000 and 28 June 2000 respectively, the Chairman of the Panel informed the DSB that the Panel would require more time to complete its report (WT/DS135/6 and WT/DS135/7).

1.8 The Panel transmitted its interim report to the parties on 13 June 2000. Its final report was submitted to the parties on 25 July 2000.

II. FACTUAL ASPECTS

A. BASIC DATA CONCERNING ASBESTOS

2.1 Asbestos is a "fibrous mineral of hydrated silicates"[1] which can be divided into two groups: amphiboles and serpentine. There are five varieties of asbestos within the amphibole group: anthophyllite, amosite (or brown asbestos), crocidolite (or blue asbestos), actinolite, and tremolite. The serpentine group comprises only chrysotile (or white asbestos). These varieties of asbestos have different physical and chemical properties.

2.2 It is mainly amosite, crocidolite and chrysolite which are exploited for industrial and commercial purposes. The special qualities of asbestos fibres (for example, resistance to very high temperatures and to different types of chemical attack) due to their particular physical and chemical properties have meant that they have been put to many uses, for example, for the manufacture of industrial and consumer products and in the building industry.

B. DECREE NO. 96-1133 OF 24 DECEMBER 1996 BANNING ASBESTOS

2.3 On 24 December 1996, the French Government adopted Decree No. 96-1133 banning asbestos, issued pursuant to the Labour Code and the Consumer Code (*décret no. 96-1133 relatif à l'interdiction de l'amiante, pris en application du code de travail et du code de la consommation*) (hereinafter "the Decree")[2]. The Decree entered into force on 1 January 1997. The following are its principal provisions:

2.4 Article 1 provides for a ban on asbestos in the following terms:

> "I. – For the purpose of protecting workers, […] the manufacture, processing, sale, import, placing on the domestic market and transfer under any title whatsoever of all varieties of asbestos fibres shall be prohibited, regardless of whether these substances have been incorporated into materials, products or devices.
>
> II. – For the purpose of protecting consumers, […] the manufacture, import, domestic marketing, exportation, possession for sale, offer, sale and transfer under any title whatsoever of all varieties of asbestos fibres or product containing asbestos fibres shall be prohibited […]."

2.5 Article 2 of the Decree allows some exceptions to the ban in Article 1.

> "I. – On an exceptional and temporary basis, the bans instituted under Article 1 shall not apply to certain existing materials, products or devices containing chrysotile fibre when, to perform an equivalent function, no substitute for that fibre is available which:
>
> - On the one hand, in the present state of scientific knowledge, poses a lesser occupational health risk than chrysotile fibre to workers handling those materials, products or devices;
>
> - on the other, provides all technical guarantees of safety corresponding to the ultimate purpose of the use […]."

2.6 The exceptions allowed are the subject of an exhaustive list prescribed by the French authorities and reviewed annually (Article 2.II). Any exception under Article 2 must be the subject of a declaration by the head of the business establishment, the importer or the party responsible for domestic marketing of a product covered by Article 2; the purpose of the declaration is to be able to

[1] *Petit Robert 1*, Dictionary of the French language.
[2] *Journal officiel* of 26 December 1996. See Annex I to this report.

determine that the activity to which it refers meets the criteria set out in the first paragraph of the Article, taking into account scientific and technological progress (Article 3).

2.7 Article 4 contains requirements on the levels of exposure to be respected when manufacturing or processing products covered by Article 2[3], as well as their labelling and marking.[4] Article 5 lays down penalties (fines) for breaches of the Decree's provisions.

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[3] In connection with this aspect, Article 4 refers back to Decree No. 96-98 of 7 February 1996 on the protection of workers against risks linked to inhaling asbestos dust (*Journal officiel* of 8 February 1996).

[4] In connection with this aspect, Article 4 refers back to Decree No. 88-146 of 28 April 1988 on products containing asbestos (*Journal officiel* of 30 April 1988).

III. ARGUMENTS OF THE PARTIES

A. CLAIMS BY THE PARTIES

3.1 In view of the facts and arguments put forward, **Canada** requests the Panel to find that:

(a) Decree No. 96-1133 of 24 December 1996 banning asbestos is incompatible with the Agreement on Technical Barriers to Trade insofar as it is a technical regulation that:

(i) Creates an unnecessary obstacle to international trade contrary to the provisions of Article 2.2;

(ii) is not based on effective and appropriate international standards – nor is it in compliance with them – contrary to the provisions of Article 2.4;

(iii) is not based on orders relating to chrysotile and chrysotile-containing products with respect to the product performance of chrysotile, contrary to the provisions of Article 2.8; and

(iv) violates the national treatment disciplines and the most-favoured-nation clause of Article 2.1.

(b) In addition, the Decree is incompatible with the GATT 1994 in that it:

(i) Creates a prohibition or a restriction on the import of chrysotile and chrysotile-containing products, contrary to the provisions of Article XI.1; and

(ii) favours the national industry of products like chrysotile fibre and chrysotile-cement products, contrary to the national treatment disciplines of Article III:4.

3.2 In the event that the Panel is unable to find a violation of Article XXIII.1(a) of the GATT 1994, Canada requests that the Panel find a violation of Article XXIII.1(b) of the GATT 1994.

3.3 In view of the foregoing, Canada requests that the Panel recommend to France that it make the Decree compatible with its obligations under the Agreement on Technical Barriers to Trade and the GATT 1994.

3.4 In view of the facts and legal arguments, the **European Communities** (hereinafter the "EC") ask the Panel to confirm that, in light of the rules of the GATT 1994, Decree No. 96-1133 of 24 December 1996 banning asbestos:

(i) Should not be examined in relation to the scope of Article XI of the GATT 1994;

(ii) does not establish less favourable treatment for similar imported products than for domestic products, within the meaning of Article III:4 of the GATT 1994;

(iii) is necessary in any event, to protect human health, within the meaning of Article XX(b) of the GATT 1994.

3.5 The EC also ask the Panel to find that:

(i) The Decree is not covered by the Agreement on Technical Barriers to Trade and that, in any case, it complies with the relevant provisions of that Agreement.

3.6 Finally, the EC further ask the Panel to find that:

(i) Article XXIII.1(b) of the GATT 1994 does not apply.

3.7 Consequently, the EC ask the Panel to reject all the arguments put forward by Canada.

B. FACTUAL ARGUMENTS

1. Introductory remarks

3.8 **Canada** recalls that, since 1 January 1997, France has prohibited the manufacture, processing, sale, importation, exportation, domestic marketing, possession for sale, offer and transfer of all varieties of asbestos fibres, regardless of whether these substances have been incorporated into materials, products or devices. There are four temporary exceptions to this general ban. The ban will become total on 1 January 2002. Canada is challenging the ban on chrysotile fibre and products containing it. Before the ban, France imported 20,000 to 40,000 tonnes of chrysotile fibre from Canada each year, equivalent to over two thirds of the total quantity imported into France. After the French Government announced its intention to ban asbestos in July 1996, imports of Canadian chrysotile dropped to under 15,000 tonnes. In 1997, the year the ban took effect, just 18 tonnes were imported. At present, for all practical purposes, they have disappeared.

3.9 Canada asserts that, unlike amphibole fibres – the asbestos most hazardous to health, which was previously used widely in France – chrysotile fibres can be used without incurring any detectable risk. Chrysotile fibres are found today in a limited number of products, where they are encapsulated in an inert matrix. These products do not pose any risk to businesses, the general public, or the environment. Exclusive use of chrysotile fibre and the adoption of effective methods for reducing dust creation are sufficient health-protection guarantees. Before banning asbestos, France had been applying controlled use practices. It is past uses, especially the spraying of brittle asbestos in fireproofing, which are the main causes of asbestos-related health problems in France. Given the long latency period between exposure to asbestos and the onset of any related diseases, workers who were victims of heavy exposure with virtually no protection 30 years ago are experiencing serious health problems today. People are currently being exposed to asbestos dust released by fireproofing that is disintegrating. The use of materials containing brittle asbestos was prohibited when the Decree that is being challenged by Canada was adopted.

3.10 According to Canada, the ban on asbestos does nothing to correct the problems resulting from past asbestos use. The ban was adopted at a time of heavy media coverage of diseases caused by uncontrolled use of asbestos in France. Alarmist campaigns condemned all forms of asbestos use and there was pressure on public officials to take action. Spurred by courts that were concurrently examining the liability of political leaders in the "tainted blood" affair, the French Government chose to prohibit chrysotile and all its uses in the hopes of assuaging public opinion, which had been badly shaken. The ban on asbestos is nothing but a political reaction on the part of the French Government to anti-asbestos propaganda. In many respects, the French reaction is identical to the reaction of the United States Environmental Protection Agency (EPA) in 1989, when it prohibited asbestos under pressure from panicked United States public opinion. Unable to justify its ban scientifically, the EPA had to reverse its decision in 1992 and acknowledge that modern products containing chrysotile enclosed in a matrix of cement or resin do not pose any detectable risk to public health. Today, although amphiboles are prohibited in the United States, a number of products containing non-brittle chrysotile are permitted.

3.11 Canada notes that France claims that its measure is based on a report from the *Institut National de la Science et de la Recherche Médicale* (INSERM).[1] Yet several experts who have analysed the report have sharply criticized the methods of the INSERM researchers. They have also very severely criticized the findings of their report. Those experts are of the opinion that the INSERM report is not a credible basis for justifying a total ban on all varieties and all uses of asbestos for public health purposes. In the justification of the measure given by Directorate General III (Industry) of the European Commission, it was admitted that application of a practice of controlled use of asbestos in industry enabled true control of the risk of diseases attributable to occupational exposure, in the case of workers involved in the mining and processing of chrysotile.[2] The practice of controlled use also applies to other possible situations of exposure to asbestos. The ban on chrysotile involves using substitute products whose effects on human health are, by INSERM's own admission, unknown. The use of substitute products is not covered by clearly-established standards, yet the INSERM researchers state how important it is to evaluate the potential risks involved. Permitting the use of these products without taking the requisite precautions may cause a repeat of the mistakes that were made at the time when the risks associated with asbestos use were unknown or poorly controlled. The undetectable risk from chrysotile is thus replaced by the unknown risk from substitutes. This results in inconsistencies in the regulation of potentially hazardous products in France.

3.12 Canada is not challenging the right of the Members of the WTO to take whatever measures are necessary to protect the health and safety of their populations. That right, however, must be exercised in compliance with the obligations that a Member has under the WTO Agreements. In that respect, France was not entitled to adopt a total ban on asbestos, with no distinctions concerning fibres and products, in the absence of scientific proof of the health risks posed by modern products containing chrysotile. Yet, one thing needs to be said: the total ban is both irrational and disproportionate considering the fact that the manufacture and use of modern chrysotile asbestos products do not pose any detectable health risks. In Canada's view, the scientific data on which France has based its case do not justify such a radical measure as the ban on chrysotile fibres and the prohibition of all uses that can be made of them. Moreover, Canada affirms that the ban does nothing to correct the problem of past exposure to asbestos, nor does it solve the problem of managing the asbestos already in use in France. Ultimately, the total ban on chrysotile fibre and chrysotile-containing products is an excessive measure. Other measures that are less restrictive on international trade and thus compatible with France's international obligations were available and would have enabled France to achieve its aim just as well as a ban. Accepting France's approach would give each Member the option of completely banning potentially hazardous natural products rather than adopting a reasonable approach of risk management based on their use. In terms of international trade, the total ban on asbestos creates a barrier to importation of chrysotile fibre and chrysotile-containing products into the French market. It is also an internal measure that upsets the competitive relationship between chrysotile fibre and chrysotile-containing products and like products of French or foreign origin: it is therefore a discriminatory measure.

3.13 The **European Communities** respond that the Canadian statement that amphiboles are "the asbestos most hazardous to health" is only recognized for the risk of mesothelioma (as explained in the INSERM report); it is accepted, however, that chrysotile has a carcinogenic potential at least comparable to amphiboles for lung cancer, as claimed below by the EC. This confusion is systematic in the Canadian arguments, as though it was less serious and less dangerous for health to suffer lung cancer than mesothelioma. It is also inaccurate to state, as Canada does, that amphibole fibres "were used widely in France". Between 1945 and 1988, some 97 per cent of the asbestos consumed by

[1] INSERM, *Rapport sur les effets sur la santé des principaux types d'exposition à l'amiante* (Report on the health effects of the main types of exposure to asbestos), INSERM joint report, Paris, INSERM publications, 1997 (hereinafter the "INSERM report").

[2] European Commission (G. Lohan, DG III), European Justification of Decree No. 96-1133 to the Canadian authorities (15 April 1997) following the French Notification (G/TBT/Notif.97.55).

France was chrysotile asbestos and since 1988 it has represented the totality. Regarding the methods which Canada deems "effective for reducing dust creation", the EC note that the dust levels created through the use of some materials that comply with the standard ISO 7337 are very much higher than the limit values allowed in France and even than the limit values recommended by the WHO group mentioned by Canada. Canada confines its analysis to the processing of raw asbestos and deliberately disregards users of material containing asbestos working on building sites or carrying out servicing or maintenance work. The dust elimination techniques cited in the standard ISO 7337 have shown their ineffectiveness for this type of changeable and mobile work; the dust levels regularly measured greatly exceed the thresholds adopted by France and many countries for which it has been proved that there is an excessive risk.

3.14 According to the EC, it is incorrect to state, as Canada does, that the use of materials containing brittle asbestos was banned in France prior to 1996. Before 1996, France authorized the use of all types of brittle asbestos, except for certain specifically prohibited uses such as fireproofing. It cannot be asserted either that "The main causes of asbestos-related health problems in France are past uses, especially the spraying of brittle asbestos in fireproofing". In fact, the increase in asbestos-related diseases precedes the practice of fireproofing: it started in the 1950s, whereas fireproofing only really started to be practised from the 1960s onwards; the very long latency period for cancer caused by asbestos means that cancer cases can only be attributed to fireproofing since the 1990s, whereas the mesothelioma mortality rate in France has for a long time shown a rapidly ascending curve. Furthermore, this increase in disease concerns workers in very different industrial sectors.

3.15 The EC point out that, when Canada claims that the prohibition imposed by France in summer 1996 was "a political reaction … to anti-asbestos propaganda", its interpretation of the decisions by a country's Government is wrong; the EC explain below all the restrictive measures taken by France for a long time and gradually. The statement does not take into account the fact that seven other European countries took an identical measure some years ago, without Canada accusing them of having taken their decisions for "political" reasons or attacking them, as far as the EC know.

3.16 The EC note that it also subjective to state that several experts who analysed the INSERM report "sharply criticized" the methods used and "very severely criticized" its findings. The report by the Expert Panel of the Royal Society of Canada[3] appointed by the Canadian Government contains praise for the work of the INSERM experts, even if certain points are raised, as is the rule for complex scientific problems. Some pages of the report of the Royal Society of Canada formally contradict Canada's statement: for example, pp. 4-7 of the English text of the report, which list the important points on which the Panel agrees with INSERM's findings, and the comments on pp. 9-18. It seems that, on the major points of INSERM's conclusions, the Canadian experts agree or make comments which are a matter of scientific discussion without questioning INSERM's findings. The EC also note that the Panel of the Royal Society of Canada worked too quickly, as is recognized in several instances (see, for example, page 15 of the English text), that it was unable to reach a consensus (page 15 of the English text), and that it worked on the basis of an incomplete document whose translation had not been reviewed (page 1), which clearly accounts for certain incorrect interpretations due to misunderstandings. This last aspect calls for a comment: Canada in fact obtained a copy of the pre-publication text of the INSERM report, without making a request to INSERM or to the French Government; it translated this into English without having the translation revised by the authors, who were not informed of the existence of the Panel and still less of its composition. At no time (neither during the examination of the INSERM report nor afterwards) did the Government of Canada or the Royal Society of Canada request explanations or comments from the French experts who participated in the INSERM report, which would no doubt have helped to remove certain ambiguities. It is absolutely alien to the tradition of scientific discussion to proceed in this way: scientific debate is

[3] Royal Society of Canada, *A Review of the INSERM Report on the Health Effects of Exposure to Asbestos*, Ottawa, 1996.

obviously necessary, but it is usually based on contradictory discussions to which each may contribute arguments and not on procedures from which one of the parties is excluded.[4]

3.17 The EC reject several of Canada's statements concerning substitute products. It is incorrect to state that "the use of substitute products is not covered under clearly established standards". The products used as substitutes for asbestos differ according to the use to which they are to be put. They are all chemical products. As such, they are subject to the regulations applicable to chemical substances for the purposes of risk prevention, and where appropriate to the regulations on carcinogenic substances if there is an established or suspected risk of carcinogenicity. Regarding the Canadian statement that "The undetectable risk from chrysotile is thus replaced by the unknown risk from substitutes", the EC point out that undetectable risk is not the same as absence of risk, contrary to what Canada seeks to claim. On this point, the INSERM report showed clearly and in detail that the low risks associated with low levels of exposure (either due to chrysotile or any other substance) are indeed undetectable for methodological reasons that are explained in detail.[5] It is therefore quite unacceptable to try to "absolve" chrysotile on the pretext that if it is inhaled in very low doses there will be an undetectable risk: if one followed this reasoning, it could be concluded that no substance is carcinogenic on the pretext that the corresponding risks are undetectable at very low levels of exposure (for example, it is clear that the risk of cancer from tobacco is undetectable if one inhales tiny quantities of cigarette smoke). The truth is that the risks from chrysotile are not only detectable, but have been detected for a long time because they are so great if there is a high level of exposure; the EC assert that this is still the case today, even with "modern" products.

3.18 The EC also emphasize that the majority of substitute products for asbestos are substances which have been used regularly for other purposes for decades without any risk associated with their use being detected, unlike the scientifically proven risk associated with the use of asbestos. No substitute product for chrysotile in fibro-cement is recognized as carcinogenic at the international level. Some fibrous substitute products used in a number of very limited cases may be suspected of being carcinogenic, but in any case their carcinogenicity for humans has not been proven scientifically at the international level. This scale of risk has been known since June 1996, the date of the French decision. It cannot be asserted that there is an "absence of scientific proof of the health risks posed by modern products containing chrysotile". The EC reject this statement, based on international authorities such as the WHO and the ILO. To France's knowledge, the methods of manufacturing asbestos-cement have not developed to any significant degree for several years. Furthermore, the fibre emissions are much higher than the limit values allowed for the servicing and maintenance of buildings, which Canada does not mention. Consequently, the concept of "modern" products does not have any meaning. The aim of the French regulation contested by Canada is to prevent the extension of the existing risk by halting the dissemination of this product, which is scientifically recognized as dangerous. Other measures have been taken by the Government in order to deal with problems due to past exposure and the management of asbestos already in place.

3.19 The EC reject the Canadian statement that "Accepting France's approach would give each Member the option of completely banning potentially hazardous natural products rather than adopting a reasonable approach of risk management based on their use". Contrary to Canada's assertion, the risks of chrysotile are not potential but proven, as the WHO declared in 1998. Moreover, the WTO Agreements give each Member the sovereign right to choose the level of protection it wishes to adopt. Confronted with such a diffuse risk that is impossible to control in such divergent exposed populations, no country can state that it has been able to establish a responsible approach to the management of a carcinogenic risk other than by replacing the incriminated substance. Contrary to Canada's claim, the effect of the French measure is not to favour products like asbestos of French origin. France does not manufacture the substitute products mainly used to replace asbestos in

[4] B. Terracini, *Review of Technical and Scientific Documents annexed by Canada to its Submission of April 26*, 19 May 1999 (document transmitted to the Panel by the EC).

[5] See pp.24-230 of the INSERM report.

asbestos-cement, but imports them from other countries. For example, PVA, an asbestos-cement substitute, is produced in only two plants worldwide, one in China and one in Japan. Moreover, substitute products are not like products because they are less dangerous and their chemical composition differs.

2. Economic and trade data

3.20 **Canada** indicates that, in 1997, global production of chrysotile was about 2 million tonnes. The Commonwealth of Independent States is the number one producer, followed by Canada. Then come China, Brazil and Zimbabwe. International trade in chrysotile is of special importance to Canada, which is the world's number one exporter. Canadian exports to the five continents totalled 430,000 tonnes in 1997.[6] Before the Decree took effect, more than two thirds of French imports of chrysotile came from Canada. The effect of the Decree was felt as of 1996 due to the announcement of the intention to ban asbestos: French imports of chrysotile from Canada dropped by more than half compared to 1995, from approximately 32,000 tonnes to about 14,000 tonnes. Once the ban took effect in early 1997, imports, for all practical purposes, disappeared. For 1997, imports were just 18 tonnes of Canadian chrysotile fibres. The Decree has eliminated the French market for chrysotile. All Canadian mines are located in Quebec Province. With annual production valued at Can$ 225 million, the chrysotile mining industry currently provides about 1,300 direct jobs and as many indirect jobs in Quebec. Moreover, the chrysotile processing industry provides about 1,500 jobs in friction product, composite material and asbestos textile companies, mainly located in Quebec. More than 4,000 Canadian jobs depend directly or indirectly on the chrysotile industry.

3.21 Canada explains that there are up to 3,000 commercial applications for asbestos, the most important of which are the following: (i) as a reinforcement material for cement, plastic or rubber; (ii) as part of brake linings or clutches; (iii) in the form of spun fibres for the protection of insulating woven fabrics or cords; (iv) in the past, it was applied by spraying in order to give boats, structural beams, pipes and boilers fire-resistant finishes; (v) in the past, it was used as a thermal insulation on pipes and boilers. Throughout the world, the most important current application is the manufacture of chrysotile products.[7] The worldwide production and use of amphiboles (amosite and crocidolite) comprise less than 3 per cent of the total amount of asbestos produced and continue to decline. Therefore, chrysotile is now the only type of asbestos used. Furthermore, modern asbestos products are not brittle and fibre emissions during their transportation, installation[8] and use (including subsequent losses due to alteration and abrasion) have been reduced to an absolute minimum, unlike earlier products which released much larger amounts of fibres into the environment.

3.22 The **European Communities** explain that, in 1973, world production of asbestos reached a peak of 5.2 million tonnes.[9] Since then, production has steadily declined, falling to 1.92 million tonnes in 1997[10], some 60 per cent of which is produced by Canada and Russia. Canada is a major producer of chrysotile asbestos. It consumes little asbestos and thus exports the bulk of its

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[6] Natural Resources Canada, *Chrysotile 1997*, chapter taken from the *Canadian Minerals Yearbook*, minerals and metals sector, Natural Resources Canada, 1998.

[7] Canada notes that, until the adoption of the Decree, 90 per cent or more of French imports of chrysotile fibres were used to produce chrysotile cement (see Le Déaut, J.-Y. and Revol, H., *L'amiante dans l'environnement de l'homme: ses conséquences et son avenir*, Office parlementaire d'évaluation des choix scientifiques et technologiques, National Assembly no. 329/Senate no. 41, 1997). According to the INSERM report, in 1984, for example, French production of chrysotile cement was 600,000 tonnes. In 1991, eight French factories produced 540,000 tonnes (see INSERM, *Rapport sur les effets sur la santé des principaux types d'exposition à l'amiante*, INSERM joint report, Paris, INSERM publications, 1997, p.21).

[8] See in particular Baujon and Authier, *Détermination des concentrations de fibres d'amiante dans l'atmosphère lors de la pose sur chantier de plaques ondulées et d'ardoises en amiante-ciment*, Laboratoire d'hygiène et de contrôle des fibres minérales, Paris, July 1993.

[9] Source: Association Française de l'Amiante (A.F.A.).

[10] Canadian Ministry of Natural Resources.

production. It should be noted that Canada produces and exports only chrysotile asbestos. Canada is thus exporting to other countries the "public health risk" associated with chrysotile. The EC emphasize that, since asbestos was first used for industrial purposes, some 95 per cent of the asbestos consumed worldwide has been chrysotile asbestos. Between 1945 and 1980, some 97 per cent of the asbestos consumed by France was chrysotile asbestos. From 1988, onwards, all the asbestos consumed in France has been chrysotile asbestos.

3.23 The EC indicate that, given the many uses of asbestos, the range of asbestos-containing products is extremely wide. Depending on their physical appearance, there are five main categories: (i) bulk asbestos: asbestos wadding for the thermal insulation of ovens, boilers, fire-doors, refrigerating equipment, flocked asbestos for the underside of concrete slabs and for steel frames for the fireproofing and soundproofing of buildings; (ii) asbestos sheets or boards: asbestos paper and board for thermal insulation, for the protection of welded joints (plumbing) and for the protection of work surfaces (glass industry), boards for the fitting of false ceilings, fireproof surfaces, partitions, etc.; (iii) textile asbestos: asbestos cord (sealing of oven doors, laboratory applications), buffer strips (to protect against heat), fireproof coverings and curtains, air, gas and liquid filters, insulation of electrical equipment; (iv) asbestos incorporated in cement products (asbestos-cement): roof tiles, roof cladding, window sills, facing of buildings, interior partitions and false ceilings, other forms of panelling, flues, ventilation shafts, rainwater pipes, plant tubs and gardening equipment; (v) asbestos in binding or bonding agents (resins, bitumens): friction linings (brake linings, clutch linings, linings for presses, winches, gantries, lifts, engines), road surfaces, flooring, decorative shingles, sealants, plaster-based finishes and coatings, glues and gums and asbestos-based paints. Asbestos-cement accounts for 90 per cent of all asbestos used.

3.24 As far as the EC know, the production methods for asbestos-cement have not developed significantly in recent years. Canada cannot therefore claim that "modern asbestos products are not brittle and fibre emissions during their transportation, installation and use … have been reduced to an absolute minimum, unlike earlier products". Furthermore, fibre emissions greatly exceed the limit values permitted for all building servicing and maintenance activities, which Canada does not mention.

3.25 **Canada** states that, since the pathogenic potential of amphiboles is greater than that of chrysotile – this is true both for mesotheliomas and for lung cancer – a review of how amphibole asbestos has been used in France in the past is necessary. Here again, the data advanced by the EC must be corrected. According to Canada, it is incorrect to state, as the EC claim, that from 1945 to 1988 only 3 per cent of asbestos used came from the amphibole family; this is in complete contradiction with the studies reviewed by INSERM, which reveal that of the samples taken after 1990 in buildings containing asbestos in France, 18 per cent of the samples contained amphibole fibres, including 13 per cent which contained only amphibole fibres.[11] It is also incorrect to claim that the use of amphiboles in France ceased in 1988; the INSERM data contradict these claims by the EC, clearly stating that the use of amphiboles continued well beyond 1988, i.e. at least until 1992.[12] Given the much higher pathogenic potential of amphiboles compared to chrysotile and the fact that amphiboles are present in nearly 20 per cent of more than 1,000 exposures to asbestos recorded and measured in France, it is quite plausible to attribute the problem of asbestos in France to past situations. While amphiboles have been banned in France since 1994, along with the use of friable materials, the significant risks associated with their presence remain. For instance, according to the WHO, building maintenance personnel are today exposed to high risks, not because of the current uses of chrysotile, but particularly because of the large quantities of "mixed in-place friable asbestos fibres".[13] Similarly, Canada seeks to refute the French argument that, since 95 per cent of the asbestos used in the world today is chrysotile asbestos, the proportion of diseases that is attributable to it is

[11] INSERM report, p.387.
[12] *Id*. Table *Importations d'amiante entre 1938 et 1992*, p.189.
[13] *Chrysotile asbestos evaluated by health experts*, Press communique (51), WHO, 26 July 1996.

"quite indisputably" of the same magnitude.[14] This reasoning, dubious at best, denies the entire heritage of past uses of amphibole fibres, the existence of a latency period, as well as the greater pathogenicity of amphibole asbestos.

3. French legislation in its context

3.26 **Canada** considers that special attention should be paid to social and political climate in which the French ban was adopted. This climate is very revealing as concerns the factors that motivated France's action and, in large part, explains the severity of that action: the political need to assuage an alarmed French population – what France's Minister for Education, Mr. Claude Allègre, then called "*un phénomène de psychose collective*" (mass psychosis). Alarmed political leaders were evidently afraid of being held criminally liable if they were not seen to be doing something about the problem. In recent years in France, media coverage of several cases of diseases linked to occupational exposure to asbestos has inflamed public opinion. That, obviously, contributed to the adoption of the Decree.[15] Indeed, since the spring of 1995, the media in France have presented alarmist articles and reports on the risks of asbestos to a public that was already shaken by two other public health cases: the "mad cow" and "tainted blood" crises. Those controversies led to the examination of the liability of political leaders in criminal courts. In the summer of 1995, with public outcry centred on Jussieu University as backdrop, the French Government commissioned a report from INSERM. INSERM was asked to study the health effects of the main types of exposure to asbestos. In late 1995, France presented an oversight programme to reduce the risks associated with asbestos. A ban did not seem to be under consideration at that time. On 21 June 1996, INSERM submitted an executive summary of its report to the French Government. On 25 June 1996, the filing of a complaint by the *Association nationale de défense des victimes de l'amiante* (ANDEVA) (National Association for the Protection of Asbestos Victims), specifically accusing the Government of inaction, reportedly helped to move France towards the ban. Seven days later, on 2 July 1996, INSERM published the summary of its report on the health effects of the main types of exposure to asbestos. The next day, 3 July 1996, France announced its intent to declare a ban on asbestos.

3.27 Canada asks why the great haste? Why was the ban announced less than two weeks after the French Government first obtained the summary of the INSERM report? Is it credible that in only two weeks the French Government could review and analyse the scientific, social and economic considerations related to such an important decision? And all this some 16 months before the final report – as opposed to the executive summary – saw the light of day! And why was the ban announced only one week after a legal action for poisoning was filed? The timing suggests that the ban was politically motivated and that the INSERM report merely provided the *ex post facto* scientific rationale. On 31 July 1996, yet another complaint for asbestos poisoning was filed, this time against eight former French ministers. All this took place during the contemporaneous examination of French political leaders' criminal liability in the tainted blood scandal. According to Canada, French political leaders were evidently under tremendous pressure to take action, any action, to be seen to be remedying a situation blown out of all proportion by the media. French parliamentarians have themselves acknowledged the pressure from public opinion and the media. In a joint report on asbestos, the Senate and the National Assembly stated: "It is because a definitive

[14] See paragraph 3.78 below.

[15] For a chronology of facts (from June to September 1996), see Info-Science <http//www.infoscience.fr/travaux/amiante/chrono.html> (access date: 4 April 1999). According to Canada, the controversy over asbestos in France results, in large part, from the situation at the University of Jussieu, where a group has led a very active fight against asbestos use for several years. On the topic of the situation in Jussieu, Claude Allègre, who was Minister for Education, Research and Technology in the Jospin Government, said: "The psychosis of those demanding that asbestos be cleared from all buildings is irrational and hazardous. The radical solution that has been chosen is going to shut down, for four years, France's foremost research centre (the University of Jussieu). That university is being wrecked for a figment of the imagination … I do not know whether asbestos at low doses causes cancer. It is not impossible, but no one has proven it scientifically." (*Le Point*, 12 October 1996. See also *Le Figaro*, 26 December 1996.)

response was so late in coming that the asbestos issue is today drawing so much media attention and political opinion is being diverted."[16]

3.28 Canada notes that, in July 1996, thus at the same time as it was preparing to prohibit asbestos, the French Government called for research proposals aimed specifically at developing fibres to replace asbestos. This specific effort on the part of the French Government was designed to accelerate the conversion of industrial groups to substitute fibres and to enable France to become a leader in substitute fibres in the global market. According to Canada, it was in that climate, when a panic had overtaken public opinion and commercial interests in French industry were moving toward the development of substitute products and fibres, that the Decree banning asbestos was adopted.

3.29 The **European Communities** note that Canada criticizes the rapidity with which the French Government announced that it was going to ban asbestos after the publication of the executive summary of the INSERM report, as well as the time taken by the French authorities to publish the final report. According to the EC, these arguments show that, on the one hand, Canada appears to ignore what constitutes a risk assessment and, on the other, how much time it takes to produce a formal publication of the results of a risk assessment. It is not uncommon practice for governments to act on the basis of unpublished results of a risk assessment. It takes on average more than one, if not two, years before formal publication in the form of a book or otherwise because the documents need careful editing and all bibliographical references must be checked. This is normal procedure also for similar publications by the WHO, the IARC and other international bodies such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA) or the Joint FAO/WHO Meeting on Pesticide Residues (JNPR), whose formal publications frequently take more than a year to be published. It would be unreasonable if governments were to be prevented from taking action quickly on the basis of the substantive results which they have in the form of an executive summary as protection of health should be given priority over formalities prior to publishing results. The EC also emphasize that the interim results and the executive summary were immediately made available to Canada for comments. The only criticism which Canada was able to make against the INSERM report is the critique made in the report by the Royal Society of Canada. But by looking at the text of that report, it can be seen that the authors' criticisms were not all unanimous; moreover, this report, which criticizes meticulous scientific work by 11 scientists, was adopted within the space of two weeks. The EC also consider that Canada's attempt to convey the impression that the Canadian scientists who reviewed the INSERM report are "better" than the French scientists who prepared the report is unacceptable. This suggestion has no foundation in fact nor in science. Canada is of course entitled to employ the scientists it wishes to assess asbestos-related risks in Canada in the past. The EC do not criticize the quality of their report. Nevertheless, the EC expect Canada to show equal respect for the French scientists who prepared the INSERM report, bearing in mind that this report conforms to the great majority (if not all) of the views of the scientific community on the risks posed by asbestos and that its findings have even been confirmed subsequently in reports by international bodies such as the WHO report 203.[17]

3.30 The EC state that, contrary to Canada's assertions, France's ban on asbestos is not an isolated and irrational act arising out of a wave of panic. During the 1970s and early 1980s, scientific evidence showed that all types of asbestos were likely to cause asbestosis, lung cancer and mesothelioma. In response to these public health concerns, many European countries began to introduce national legislation restricting, and ultimately prohibiting, the marketing and use of asbestos. Rules designed to control the use of asbestos in the workplace and ultimately to limit the release of asbestos into the atmosphere were also introduced. It cannot be asserted, as Canada does, that in spring 1995 French public opinion was shaken by the "mad cow" crisis: the events to which Canada refers occurred in 1996. Likewise, it is incorrect to state that "In late 1995, France presented

[16] *L'amiante dans l'environnement: ses conséquences et son avenir*, Office parlementaire d'évaluation des choix scientifiques et technologiques, National Assembly no. 329/Senate no. 41, p.57.

[17] *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998.

an oversight program to reduce the risks associated with asbestos … [and that a] ban did not seem to be under consideration at that time." A total ban was one of the measures envisaged by the French Government as of 1995. A decision was finally taken not because of the filing of complaints by a victims' association but as a result of the findings in the INSERM report given to the ministers concerned in June 1996.

3.31 The EC point out that a number of countries have either introduced bans on asbestos or plan to do so. The health authorities of many more are looking in detail at the dangers which the various forms of asbestos represent. As early as 1983, Iceland introduced a ban (with some limited exceptions) on all types of asbestos (updated in 1996). In 1984, Norway introduced a ban (with some limited exceptions) on all types of asbestos (revised in 1991). Since 1989, Switzerland has in principle prohibited the use of asbestos, including chrysotile asbestos, in accordance with an amendment to the law on environmentally harmful substances. In only two types of situation may an exception be granted to this principle, subject to the express authorization of the Federal Office for the Protection of the Environment: (i) where technology has not yet identified an asbestos-free substitute and where the amount of asbestos used does not exceed what is necessary to attain the desired objective; or (ii) where the technical characteristics of the product or object are such that it is impossible to use alternative components which do not contain asbestos (Annex 3.3 to the Order of 11 January 1989 amending the Order of 9 June 1986). An exemption may also be granted "on grounds of national defence" for material used in carrying out defence-related tasks, although only with the agreement of several ministerial departments. In New Zealand, the Asbestos Regulations 1983 ban the use of asbestos in the construction of new buildings. The ban applies to all types of asbestos: chrysotile, crocidolite, tremolite, actinolite, anthophyllite and amosite. In January 1999, a new amendment to the Asbestos Regulations of 1983 was published, providing for: (i) a ban on the import of chrysotile asbestos; (ii) amendments to the law relating to the recycling of asbestos-containing products; (iii) more rigorous and more systematic health checks; and (iv) a higher level of protection for workers who handle asbestos. Since 1 January 1999, the Czech Republic no longer imports nor processes asbestos, in whatever form. Asbestos is on its list of dangerous (carcinogenic) substances. In Australia**,** asbestos legislation falls within the remit of each of the federal states. However, there is a government agency, the National Occupational Health and Safety Commission (NOHCS), which is responsible for promoting health and safety at work throughout the country. The research division of the NOHCS recently published a report on the health risks posed by the use of chrysotile asbestos.

3.32 The EC point out that, with a view to ensuring a high level of health protection in the European Community and preserving the unity of the single market, numerous legislative acts have been adopted at Community level since 1980. On 4 May 1999, it was decided to introduce a total ban on all types of asbestos with effect from 1 January 2005. As early as 1972, Denmark introduced a ban on applying asbestos by the spraying process and on using it for insulation. It would appear to have been the first such ban anywhere in the world. In 1986, Denmark placed a total ban on asbestos, allowing some limited exceptions up to 1993. In 1972, the United Kingdom banned imports of crocidolite (blue asbestos). This decision was supplemented by the setting of limit values for exposure to asbestos dust at the workplace. In 1975, Sweden banned the marketing and use of crocidolite, and in 1976 the use of asbestos-cement products. In 1986, it introduced a total ban on asbestos with a few exceptions. In 1977, France set initial limit values for asbestos dust and in 1978 it banned the spraying of asbestos fibres. In 1996, France imposed a total ban on asbestos, with some limited exceptions. In 1977, the Netherlands banned crocidolite and the use of asbestos for spraying. In 1991, it introduced a total ban on asbestos, with exceptions which applied until 1997. In 1990, Austria banned the use of chrysotile asbestos, with some limited exceptions. In 1992, Finland and Italy imposed a total ban on asbestos, with exceptions which applied until 1993. In 1993, Germany imposed a total ban on asbestos, with some limited exceptions. In 1998, Belgium imposed a total ban on asbestos, with some limited exceptions.

3.33 The EC recall that, at the beginning of the 1980s, it became clear that there was a need for harmonization at European Community level. Two key Community directives[18] were adopted: Directive 83/477/EEC[19] and Directive 83/478/EEC.[20] Under Directive 83/477/EEC, the Member States of the European Community must require employers to assess the risks to workers of exposure to asbestos; they must also take the necessary preventive measures. The Directive prohibits the application of asbestos by means of the spraying process and sets limit values for exposure. It also lays down a range of preventive measures such as medical surveillance of workers and appropriate cleaning of the place of work. Lastly, it lays down specific measures to be taken to protect workers involved in removing asbestos. Directive 83/478/EEC laid down the first Community measures in respect of the marketing of asbestos. It prohibits the marketing and use of crocidolite (with some exceptions) and introduces compulsory labelling for all asbestos-containing products. Directive 85/610/EEC extends this prohibition to all other types of asbestos for certain specific uses.[21] During the same period, Council Directives 78/319/EEC[22] and 87/217/EEC[23] were adopted, laying down measures to prevent and reduce environmental pollution, including the control of asbestos-containing waste. Both these Directives were updated by Directive 91/689/EEC.[24]

3.34 The EC also recall that, at the beginning of the 1990s, a good deal of scientific evidence concerning the risks from asbestos became available and safer substitute products were developed to replace asbestos in many applications. European legislation evolved rapidly so as to achieve tighter control of the risks. In 1991,[25] for example, all types of asbestos were classed as category I carcinogens under Directive 67/548/EEC.[26] T he Directive defines category I as comprising substances known to be carcinogenic to man. Then in 1991, Directive 91/382/EEC,[27] amending Directive 83/477/EEC on the protection of workers (see above), lowered the limit values for exposure to 0.6 fibres per cm^3 for chrysotile asbestos and 0.3 fibres per cm^3 for all other forms of asbestos. One

[18] Pursuant to Article 249 (formerly Article 189) of the Treaty establishing the European Community, a directive "is binding, as to the result to be achieved, upon each Member State to which it is addressed", while leaving to the national authorities the choice of form and methods.

[19] Council Directive 83/477/EEC of 19 September 1983 on the protection of workers from the risks related to exposure to asbestos at work (Official Journal of the European Communities (hereinafter "OJ" 1983 L 263, p.25). Directive 83/477/EEC is the second individual directive adopted on the basis of Council Directive 80/1107/EEC of 27 November 1980 on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work (OJ 1980 L 327, p. 8).

[20] Council Directive 83/478/EEC of 19 September 1983 amending for the fifth time (asbestos) Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (OJ 1983 L 263, p. 33).

[21] Council Directive 85/610/EEC of 20 December 1985 amending for the seventh time (asbestos) Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (OJ 1985 L 375, p. 1).

[22] Council Directive 78/319/EEC of 20 March 1978 on toxic and dangerous waste (OJ 1978 L 84, p. 43).

[23] Council Directive 87/217/EEC of 19 March 1987 on the prevention and reduction of environmental pollution by asbestos (OJ 1987 L 85, p. 40).

[24] Council Directive 91/689/EEC of 12 December 1991 on hazardous waste (OJ 1991 L 377, p. 20).

[25] Commission Directive 91/325/EEC of 1 March 1991 adapting to technical progress for the twelfth time Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 1991 L 180, p. 1).

[26] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ 1967 L 196, p. 1).

[27] Council Directive 91/382/EEC of 25 June 1991 amending Directive 83/477/EEC on the protection of workers from the risks related to exposure to asbestos at work (second individual Directive within the meaning of Article 8 of Directive 80/1107/EEC (OJ 1991 L 206, p. 16).

year previously, Directive 90/394/EEC[28], which deals with the protection of workers from exposure to all carcinogens, had introduced the principle of replacement. Under this principle, employers are required, where this is technically possible, to replace carcinogens used at work with substances which are not dangerous or which are less dangerous. As regards the placing of asbestos on the market, Directive 91/659/EEC[29] introduced a total ban on the marketing and use of all forms of asbestos fibre, except chrysotile asbestos, whose use was nonetheless prohibited for fourteen specific categories of product. Other chrysotile-containing products (e.g. asbestos-cement) remained outside the Directive's scope of application.

3.35 The EC point out that, as there is sufficient scientific evidence to justify a ban, the Commission of the European Communities has decided to propose a directive banning the marketing and use of chrysotile asbestos, with one exception and some transitional arrangements. On 4 May 1999, the proposed directive received a favourable vote from the Member States meeting within the Standing Committee set up by Directive 76/769/EEC.[30] It is due to be finally adopted by the Commission in the near future. Under the new directive, the ban on chrysotile asbestos is to be implemented throughout the European Union by 1 January 2005 at the latest. Each Member State may choose the pace at which it wishes to move towards this harmonized position. Decisions will have to be adopted in the light of the situation within the domestic industry and in accordance with the legal procedures applicable in each country. The new directive would extend the current ban to all remaining applications of chrysotile asbestos, with one exception. Only diaphragms used for electrolysis in certain chlorine plants may be exempted from the prohibition. Diaphragms constitute a special case since they represent the only current application of chrysotile asbestos for which it is not technically possible to use a substitute product without creating a safety risk (i.e. the risk of an explosion). Diaphragms are not placed on the market. Under the directive, the exemption applied to diaphragms will be reviewed (on the basis of an independent scientific risk assessment), both as part of the general review of the directive in 2003 and specifically in 2008. The directive recognizes that scientific knowledge about asbestos and substitute products is continually developing. It therefore stipulates that the relevant scientific issues and derogations be reviewed before 2003, in order to decide whether further legislative measures are necessary in this field.

3.36 The EC note that, in France, the first preventive rules on health and safety at work go back to the beginning of the century. For about a decade, French legislation has been based on the European directives on health and safety at work. All regulatory provisions are the subject of consultations with the social partners, i.e. the representatives of employer and employee associations within the Senior Council for the Prevention of Occupational Hazards. In addition to specific legislation covering certain particularly harmful substances, France has general rules on health and safety (risk assessment, informing and protecting workers, etc.). As regards the prevention of chemical hazards, France has incorporated into its Labour Code both the EC Directive on chemical agents (Articles R231-55 *et seq*.) and EC Directive 90/394/EEC on carcinogens (Articles R231-56 *et seq*.). Since 1977, France has had specific legislation on asbestos, designed to protect workers from inhaling asbestos dust. Following the example of other European countries, this legislation was progressively tightened up as knowledge developed until, finally, it was decided to impose a ban in 1996. It should be pointed out that, in France, the number of illnesses linked to the inhalation of asbestos dust which are recognized

[28] Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ 1990 L 196, p. 1).

[29] Commission Directive 91/659/EEC of 3 December 1991 adapting to technical progress Annex I to Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (asbestos) (OJ 1991 L 363, p. 36).

[30] Commission Directive .../.../EC adapting to technical progress for the sixth time Annex I to Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (asbestos).

as being of occupational origin and for which compensation is paid has been rising constantly for several years. For example, between 1985 and 1995, the number of asbestos-linked occupational diseases for which compensation was paid (mesothelioma, lung cancer, asbestosis, pleural abnormalities) increased fourfold. The cost of such illnesses ran to F1.08 billion in 1997, or almost 40 per cent of the compensation budget for all diseases recognized as being of occupational origin in France. By way of comparison, musculoskeletal problems, which are very widespread and are at the top of the list in numerical terms, account for only 18.8 per cent of the total financial cost of occupational diseases. This increase in diseases, together with the lower life expectancy of workers formerly employed in the asbestos industry, recently prompted the French Government to introduce an early retirement plan for employees who worked in factories manufacturing asbestos products.[31]

3.37 The EC point that the situation in France until 1994 was the following: in 1997, the IARC classed all forms of asbestos (including chrysotile) as known carcinogens. It was then that the first specific regulatory provisions were adopted in France in order to limit the risk of exposure to asbestos dust. A series of texts produced by the Ministries with responsibility for health, labour, infrastructure and consumer issues followed, restricting the use of asbestos, either by prohibiting the use of the most harmful forms or by prohibiting its use in certain processes (spraying) or in the manufacture of certain products. In the field of health at work, French legislation has, since 1977, strictly regulated working conditions in the asbestos-processing industry, in particular by setting limit values for exposure. These have been lowered several times to comply with the requirements of Community Directives. In addition to having an asbestos-processing industry producing essentially asbestos-cement, France has used asbestos in numerous sectors including construction (flocking[32] and lagging[33]), the manufacture of everyday consumer goods (floor slabs, brake linings, textiles and boarding) and heavy industry (shipbuilding, metal working). Particular emphasis must be placed on the fact that many asbestos-containing products, especially semi-finished products, were accessible to the general public and sold in large retail outlets (sheets of asbestos-cement and asbestos board, asbestos yarn, heat-resistant gloves, ironing-board covers, etc.).

3.38 The EC explain that, over the years, a series of regulatory measures reduced the applications for which asbestos might be used. Two types of measure were adopted:

(a) Partial bans on processes or products: (i) in 1977, the Ministry of Housing and Planning and the Ministry of Health and Social Security prohibited asbestos flocking in residential premises; (ii) in 1978, the Ministry of Health prohibited in its turn the use of flocking in all buildings; (iii) in 1988, the Ministry of Economic Affairs restricted to a few products (notably asbestos-cement pipes and gaskets) the use of those forms of asbestos considered at the time to be the most harmful, and made labelling compulsory for all products containing other forms of asbestos; (iv) in 1994, the Ministry of Economic Affairs placed a permanent ban on the forms then considered to be the most harmful and prohibited the use of all other forms of asbestos, including chrysotile, in a wide range of products (toys, smoking accessories, paints and varnishes, filters, etc.);

(b) a regulatory framework for authorized activities: (i) in 1977, the Ministry of Labour laid down strict regulations on working conditions in the asbestos-processing industry; (ii) in 1987, the Ministry of Labour lowered the limit values for exposure; (iii) in 1990, the Ministry of Labour prohibited the recruitment of casual workers to carry out the removal of flocked asbestos or demolition work which would expose

[31] Article 41 of the Law on the financing of social security; Decree and Orders of 29 March 1999.

[32] Flocking: application of fibres onto any surface to form a coating with a fibrous, velvety or downy appearance.

[33] Lagging: thermal insulation technique used to avoid heat loss from heating installations, pipes and ventilation shafts.

them to asbestos dust; (iv) in 1992, the Ministry of Labour again lowered the limit values for exposure and issued a reminder that applying asbestos by spraying was totally prohibited. It also laid down rules on procedures for removing flocked asbestos.

3.39 The EC also indicate that 1990-1995 marked the turning point. Following the adoption of the ILO recommendation in 1986 and from the early 1990s, it became apparent that the risks in the servicing and maintenance sector needed to be better assessed. A data bank (EVALUTIL) was set up which made it possible to assess exposure to asbestos among users of asbestos-containing products.[34] This data bank highlighted the extremely high levels of exposure among certain construction workers ("exposure peaks" occurred during operations such as the cutting of flocked cladding containing 5 per cent chrysotile, the cutting of asbestos-lined fireproof doors, etc).

3.40 The EC note that, given the dangers of inhaling fibres from flocked asbestos used in the construction industry between 1950 and 1977, on 13 December 1989, the French Senior Council for Public Health called on local authorities to compile a register of all buildings, especially public buildings, in which flocked asbestos was present. The feasibility of compiling such a register was assessed by a municipal health and safety department in a pilot town between 1991 and 1994. The study came up against major difficulties linked to the fact that some companies no longer existed and in some cases records had not been kept. In the light of these disappointing results, on 15 September 1994, the Senior Council for Public Health expressed the desire to see legislation introduced on the monitoring of flocked asbestos so as to protect exposed populations.[35] The legislation was to be based on an early warning threshold expressed in terms of the erosion of flocked surfaces and corresponding to a level of atmospheric dust in the building concerned of 5 fibres per litre ("f/l") (which corresponds to the average asbestos pollution measured in the outside air) and on a 25 f/l threshold above which work would have to be carried out. In the period prior to the implementation of this legislation, the Ministries of Labour and Health sent two circulars to prefects, dated 15 September 1994 and 31 July 1995 respectively, setting out the thresholds, removal and analysis techniques and the procedures for removing flocked asbestos.

3.41 The EC point out that, at the end of 1994, the Ministry of Social Affairs (Directorate for Industrial Relations and Directorate-General for Health) convened a group of experts, whose discussions brought to light certain scientific data, on the one hand, and certain gaps in the existing legislation on the other. The experts' findings were as follows:[36] (i) an increase in the number of cases of mesothelioma in France and the worrying forecasts in a study conducted by Julian Peto[37] in the United Kingdom. The study predicted a growth in asbestos-related deaths which would total between 2,700 and 3,000 per year in the 2020s; (ii) the serious risk for workers engaged in the servicing or maintenance of asbestos-containing products or equipment. This applies in particular to workers involved in finishing work in the construction industry, such as plumbers or electricians, since their exposure at "peak" moments may be very high; (iii) the emergence of cases of mesothelioma at levels of exposure which were below limit values in force at the time under French legislation. On the other hand, it was felt that there was nevertheless a need to collect together all existing scientific knowledge on asbestos so as to shed light on the effect of low doses and on how harmful chrysotile asbestos actually was. In the light of these findings, French legislation on the

[34] For values measured during the handling of asbestos-cement materials (source EVALUTIL), see Ministry of Labour, Social Dialogue and Participation, Note setting out the main guidelines of the Senior Council for the Prevention of Occupational Hazards, 3 July 1995.

[35] French Senior Council for Public Health, Opinion on premises flocked with asbestos (Division for the assessment of environmental risks to health), session of 15 September 1994.

[36] Ministry of Labour, Employment and Vocational Training, Principal conclusions of the meeting of French asbestos experts on 20 December 1994, dated 7 February 1995.

[37] Peto, J., *et al*., *Continuing Increase in Mesothelioma Mortality in Britain*, Lancet, vol. 345, p.535, 1995, note 31.

protection of workers appeared limited. Firstly, the thresholds seemed to be too high and secondly, the provisions designed for industries and removal work where asbestos was known to be present were scarcely or not at all effective when it came to maintenance workers. This conclusion prompted the authorities to take decisive action to reinforce the existing preventive measures and to obtain more detailed information on the risks linked to asbestos.

3.42 The EC emphasize that, on 3 July 1995, the Senior Council for the Prevention of Occupational Hazards adopted the following guidelines:[38] (i) to improve scientific knowledge of risks (launching of the joint INSERM report); (ii) to enhance protection of workers, especially those engaged in servicing and maintenance work; (iii) to raise awareness among all those exposed to the dangers of asbestos; (iv) to improve compensation for asbestos-related occupational diseases; (v) to begin discussions on whether asbestos should be banned. Contrary to what is asserted in the Canadian submission, the possibility of a ban was not ruled out. In July 1995, therefore, the French Government decided to commission INSERM to carry out a detailed study of asbestos-related diseases, based on all internationally available research. In December 1995 it also adopted a general action plan comprising measures to combat asbestos-related hazards, taking account of problems in the areas of public health, the environment, the protection of workers and compensation for asbestos-related occupational diseases.

3.43 The EC point out that the implementation of the 1995 action plan presented by the Minister for Social Affairs made it possible, without waiting for the findings of the INSERM joint report, to introduce general legislation[39] in order to monitor the situation as regards buildings, limit occupational exposure and improve compensation by reorganizing and reviewing the tables of occupational diseases caused by asbestos. This action plan was intended to meet growing concerns about servicing and maintenance workers in the construction sector, a risk on the subject of which Canada remains silent. The action plan comprised the following measures: (i) owners of buildings were obliged to identify asbestos flocked surfaces and asbestos-containing insulation before 31 December 1999, or before the end of 1996 in the case of priority buildings, i.e. those housing young people or children (Decree No. 96-97 of 7 February 1996); (ii) reduction in the limit values for occupational exposure ("VLEP") to asbestos to the lowest technically possible level (0.1 fibre/cm³); the difference in the limit values for "pure" chrysotile and amphibole forms of asbestos was to be abolished on 1 January 1998, although this would apply only to a very limited number of manufacturing industries (Decree 96-98 of 7 February 1996); (iii) strict regulatory provisions on asbestos removal work; works inspectors were entitled to close asbestos removal sites if they did not consider the protective measures to be adequate (legislative provision); a prohibition was placed on hiring casual workers to carry out work involving contact with asbestos; (iv) the preparation of specific preventive rules for servicing and maintenance work (Decree No. 96-98 of 7 February 1996); (v) the creation of Table 30 bis on the recognition of occupational diseases was created specifically to cover bronchial cancer caused by asbestos; this disease could now be recognized without requiring the presence of medical "markers".[40] The necessity of these measures, taken during the first half of 1996, was confirmed by the INSERM report, which was sent to the Minister for Labour and Social Affairs at the end of June 1996. This report, which shed new light on the subject, prompted the French Government to take additional steps without delay, including banning asbestos with effect from 1 January 1997.

3.44 The EC indicate that, in the summer of 1995, contacts between the Canadian and French administrations took place. France was seeking more effective ways of managing the risk, which it already considered very serious, while Canada proposed setting up an international research centre on

[38] Ministry of Labour, Social Dialogue and Participation, Note setting out the main guidelines of the Senior Council for the Prevention of Occupational Hazards, 3 July 1995.

[39] Compendium of French legislative texts on asbestos, Edition des Journaux Officiels, Ministry of Employment and Solidarity, 1998.

[40] Table of occupational diseases produced by the *Caisse d'assurances maladies des travailleurs salariés* (CNAMTS).

the prevention of respiratory diseases. Several meetings took place with the Canadian party immediately after publication of the INSERM report and prior to the issue of the Decree on a ban; at that time, Canada asked for a derogation. Several meetings took place between the French and Canadian parties following discussions between the relevant Canadian and French ministers and on the instructions of the Prime Minister, who had received a letter from Mr. Chrétien. These meetings took place between July 1996 (announcement of the decision to impose a ban) and December 1996 (the ban entered into effect).

3.45 The EC stress that the scientific discussions took place in an atmosphere of mutual respect. On 8 October 1996, the Quebec experts met the experts from INSERM and then on 9 October 1996 they met the adviser on asbestos to the French Minister for Social Affairs (Mr. Roigt), together with the competent person from the Industrial Relations Directorate. Moreover, on 29 October 1996, France arranged an entire day's technical meeting between the Canadian-Quebec delegation and the French experts. During the day, the questions of the harmfulness of asbestos, the question of substitute fibres, the criteria on which France would allow exceptions to the ban, and the "safe" use of asbestos-cement were discussed. On that occasion, the experts from Canada and Quebec acknowledged the high quality of INSERM's work and showed an interest in discussing a number of scientific points, as is customary among researchers. The EC point out that this oral recognition is in contrast with the criticism of the INSERM report expressed by Canada.[41]

(a) As regards the harmfulness of asbestos, the Quebec delegation reported on the recently published study by Mr. Siemiatycki on women living in close proximity to asbestos mines (the study by Camus *et al*. had not yet been published when the INSERM report was produced). The French experts from INSERM pointed out that they were aware of the study and had examined it in the context of their joint report. In their view, it showed that the risk of bronchial cancer was practically nil at that level of exposure, but that there was a risk of contracting mesothelioma from the asbestos contained in the dust from the chrysolite mines, at levels of exposure accumulated over a lifetime of a few fibres per cm^3 per year. The French experts pointed out that this level was easily reached during the cutting of asbestos-cement and that no country had succeeded in containing this risk.

(b) As regards substitute fibres, the French party felt that further epidemiological data should be obtained, although no victims of the use of substitute products had so far been reported. Decisions were taken "on the basis of the knowledge available". The Canada-Quebec delegation informed the Ministry of Labour and Social Affairs of its desire to be involved in INSERM's work on the fibres used as substitutes for asbestos. Since the purpose of the report was to summarize all international studies on the subject, there was no objection to consulting Quebec scientists as part of the research. At the beginning of 1997, however, when INSERM looked for specialists in the field, its bibliographical search did not identify any Canadian experts (whether English or French speaking) with sufficient publications on the subject. In the end, two experts were proposed by Canada's Health and Safety Research Institute, and both Dr. Gibbs and J. Siematycki attended the hearing organized by INSERM.

(c) As regards exceptions to the ban, the French administration presented the draft decree and explained the circumstances in which an exemption might be granted: there had to be no substitute products performing an equivalent function to asbestos which were less harmful to workers and which offered equivalent technical guarantees of safety for users.

[41] See Section III.B.7 of this report.

(d) Lastly, the issue of the "safe" use of asbestos-cement was discussed. The main argument put forward by Canada and by Quebec in favour of extending the list of exemptions was that asbestos can be used in a "safe" way. The French experts from the INRS (National Safety Research Institute) and the *Caisse Nationale d'Assurance Maladie* (National Sickness Insurance Scheme) presented findings based on measurements which were significantly different from those presented by Canada.

3.46 The EC point out that, for reasons of substance, the request that an exemption be granted for asbestos-cement piping was not admissible. The general ban laid down by the Decree allows for exemptions only when there is no substitute product which can perform an equivalent function and which: (i) presents less of a risk to workers; and (ii) offers all technical guarantees of safety for users. In the case in point, it was very easy to replace asbestos by a less dangerous product. All alternatives to asbestos-cement are less dangerous than chrysotile. In fact, all asbestos-cement can be replaced by products which show no sign of being carcinogenic, whether they are non-fibrous products (ductile iron, plastic) or fibrous products (cellulose, polyvinyl alcohol).

3.47 The EC recall that the ban on asbestos or any material or product containing it has been in force since 1 January 1997. It applies to both industrial and commercial use, i.e. manufacture, processing, possession with a view to selling, offering for sale, import, export or any form of transfer. However, there are a very limited number of strictly monitored exceptions to the general ban. If a temporary and limited exemption is to be granted, there must be no substitute product which could perform an equivalent function and which: (i) on the basis of current scientific knowledge, presents less of a risk to workers; and (ii) provides equivalent guarantees in terms of safety of use (braking performance, for example). Firms which manufacture asbestos-based products or import asbestos must make a declaration to the Ministry justifying the use of asbestos and reporting on the progress made as regards substitution. The administration then registers the declarations which it considers to be in compliance with the legislation. The exceptions are included in a list drawn up by ministerial order.

3.48 The EC indicate that asbestos was used in numerous industrial applications because of its physico-chemical properties: good mechanical resistance (especially to pressure), resistance to high temperatures and to chemical attacks (especially corrosion). Replacing it with a substitute material requires a strict approach applied on the basis of specifications setting out what is required of the substitute product in very specific conditions of use. Once the substitute product has been identified, it must not only be tested, but its reliability over time must also be checked. This can be done by an external body (national or international) on the basis of qualification and approval procedures which, in sectors such as the aeronautical, nuclear or chemical industries, are very long and complex. The sectors most affected by residual use of asbestos are the nuclear, chemical, petrochemical and aeronautical industries.

3.49 The EC emphasize that the Decree provides for an updating procedure designed to eliminate the remaining exceptions as rapidly as possible. The list of categories of exception laid down by ministerial order is therefore reviewed each year by the Senior Council for the Prevention of Occupational Hazards, which shortens the list in the light of technical developments.

(a) The companies registered as a result of the annual declarations made in order to qualify for exemptions from the ban on asbestos are questioned on the progress they have made towards the replacement of asbestos. The findings are compared with the data held by the experts from the INRS[42] and the *Caisse Nationale d'Assurance Maladie.* Experts from co-signatory ministries are consulted (Directorate-General for Competition, Consumer Affairs and Fraud Prevention, Ministries of Industry, Infrastructure, Environment, and Agriculture, and the Directorate-General of

[42] Institut National de Recherche en Sécurité (National Safety Research Institute).

Customs). On this basis, proposals for changes are sent for an opinion to the Senior Council for the Prevention of Occupational Hazards, which comprises employer and employee representatives as well as experts.

(b) For example, the following proposals were made at the end of 1997.

(i) As regards brake linings, substitute products have been developed for heavy industrial installations and equipment, ships and special vehicles including heavy land vehicles and vehicles weighing more than 3.5 tonnes, except for certain military vehicles for which the approval procedures are not yet complete. However, it seems that the brake linings used in aircraft braking systems can be replaced only in certain cases. Where asbestos performs the function of braking agent, tests seem to have been conclusive. However, if asbestos is used as a binder between the brake support and the braking component (generally a fibreglass compound or Teflon), no substitute product has yet been found. Likewise, brake linings for compressors and sliding-vane rotary vacuum pumps have to endure extreme pressures (over 300 bars) and temperatures (over 350°C). The substitute products tested to date have not proved satisfactory; often made of graphite, they are deformed by the combined action of pressure and temperature. Finally, it was proposed that only those exceptions be withdrawn which applied to heavy industrial installations and equipment, ships and floating structures and special non-military land vehicles weighing over 3.5 tonnes.

(ii) As regards gaskets, in sectors such as the aeronautical, nuclear and chemical industries or in specific applications, less progress has been made, given the multiplicity and complexity of technical constraints. Substitute products do not offer sufficient guarantees in terms of their resistance over time to corrosive fluids. Accordingly, it was proposed that the exemption, as set out in the relevant paragraph, be maintained in its entirety.

(c) Monitoring is organized as follows: the list of firms which have made a declaration in accordance with the legislation and the list of their customers are forwarded to the other ministerial departments concerned and to the inspection units so as to facilitate checks by customs authorities, by the Directorate-General for Competition, Consumer Affairs and Fraud Prevention, and by the Labour Inspectorate.

4. Circumstances of exposure to asbestos and asbestos-related pathologies

3.50 **Canada** states that, today, science generally recognizes few or no demonstrable effects of environmental asbestos on health, and concludes that, at worst, the risk is undetectable.[43] Asbestos is used in a vast array of products, because of its very useful and often unique characteristics. During extraction and handling of the mineral, manufacturing and use of its products, as well as their final disposal, however, a certain number of asbestos fibres are released into the environment. Because the hazards resulting from high levels of exposure to asbestos fibres in certain work environments of the past are known, there is concern over the possible effects of any exposure to concentrations of asbestos. Today, chrysotile fibres are bonded to cement or other particulate or encapsulated materials in a plastic, cement, asphalt, or resin matrix. Brittle products and, to a negligible extent, non-brittle products, however, release a certain number of fibres. Canada considers that, in spite of an ever-

[43] Canada notes that, according to the World Health Organization, "risk of mesothelioma and bronchial cancer attributable to asbestos in the general population is undetectably low; the risk of asbestosis is practically nil". (World Health Organization, *Environmental Health Criteria 53: Asbestos and Other Natural Mineral* Fibres, Geneva, p.135).

increasing understanding of the importance and impact of the sources and characteristics of asbestos fibres on human health, much confusion and many misunderstandings exist regarding the various aspects of asbestos production, such as product manufacturing, the types of fibres used, their presence in the environment, and, especially, the health effects of exposure. Canada contends that, as far as the health effects of exposure to asbestos in the workplace are concerned, it is now recognized that in the past several lung diseases were caused by high levels of exposure to asbestos dust inhaled under various working conditions. In the early 1950s, there were many concerns about the link between exposure to asbestos dust in the workplace and certain diseases (asbestosis, lung cancer, and mesothelioma). In spite of the great contrasts between industrial exposure in the past, which obviously had certain effects on health, and exposure in the general environment today, fears of health risks remain excessive; and yet, the risk is undetectable for the public at large.[44] In order to evaluate the health effects of exposure to asbestos, a considerable number of toxicological tests have been performed on animals. Canada asserts that currently most of the results indicate that only fibres of more than 5 micrometers are pathogenic, and that considerable amounts must be inhaled (or implanted in animals) to cause reactions, including cancer. The length of most fibres in the ambient air, however, is less than 5 micrometers.[45]

3.51 According to Canada, it is inevitable that some asbestos fibres are released into the air, water, and soil due to the use of asbestos and asbestos products on a worldwide scale, but concentrations of asbestos in the environment were higher in the past, because of inadequate control measures. In addition to artificial sources, some natural sources (rock alteration) are a significant source of fibres in the ambient air; even water contains natural asbestos fibres. According to the WHO, the total amount of asbestos released by natural sources probably exceeds emissions from industrial sources.[46] A large number of artificial asbestos sources have been studied but, in most cases, there did not seem to be significant fibre emissions. Some of these sources, however, have raised the most fears, for example, brake linings, factory emissions, mines, shipyards, and asbestos in buildings. Although there were some major industrial emissions in the past, a good share of current atmospheric emissions are not respirable, because of the relatively large size of most dust particles and other substances to which the fibres are normally linked. Canada considers that the strong bond between chrysotile and cement in chrysotile-cement products reduces the release of fibres into the air to a minimum.[47] Furthermore, some asbestos products are coated, which makes it very difficult for the fibres to be released. Regarding brake linings, because of the high temperatures caused by friction, up to 99 per cent of the asbestos is physically and chemically transformed into inert and non-hazardous material. Moreover, the fibre remaining after this transformation is less than 5 micrometers in length, and, therefore, has no biological effects.[48] One of the major problems that remain is the elimination of brittle asbestos products that were once used in buildings, especially if they contain amphiboles, as well as the demolition of buildings that may contain significant amounts of these products.

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[44] *Id.*

[45] *Id.*, p.134; Dunnigan, J. and Seymour, N., *L'amiante et la santé: une mise à jour scientifique*, rev. ed., 1991, p. 24.

[46] World Health Organization *Environmental Health Criteria 53: Asbestos and Other Natural Mineral Fibres*, WHO, Geneva, 1986, p. 34.

[47] Commins, B. T., *Estimations of Risk from Environmental Asbestos* in *Non-Occupational Exposure to Mineral Fibres,* IARC Scientific Publication no. 90, Lyon, 1989, pp. 476 and 477.

[48] See, in particular, Commins, B.T., *The Significance of Asbestos and Other Mineral Fibres in Environmental Ambient Air,* Cummins Associates, Berkshire, U.K., 1990, p. 17. See also Commins, B.T., *Estimations of Risk from Environmental Asbestos* in *Non-Occupational Exposure to Mineral Fibres,* IARC Scientific Publication no. 90, Lyon, 1989, pp. 476 and 477. Canada notes that the data obtained in the United Kingdom under situations of very heavy vehicular traffic indicate that the use of asbestos in brake linings does not measurably contribute to atmospheric asbestos concentrations in the urban environment. Even at two heavily-used intersections in the London metropolitan area, concentrations varied from 0.0002 to 0.0004 f/ml (Jaffrey, S., *Environmental Asbestos Fibre Release from Brake and Clutch Linings in Vehicular Traffic* (1990) 34 Ann. Occup. Hyg., Vol.34, p.529.)

3.52 Concerning the concentrations of fibres in the environment, Canada notes that asbestos fibres are present in outdoor as well as indoor air. The average long-term concentration calculated for several years of exposure, taking into account indoor and outdoor air conditions, appears to be between 0.0002 and 0.001 f/ml of more than 5 micrometers, with an average concentration of approximately 0.0005 f/ml of air.[49] Some of this asbestos comes from natural erosion. In urban areas, however, atmospheric asbestos comes mainly from the extensive use of this product. It seems that ambient air concentrations are currently lower than those observed a few years ago. Regarding exposure to asbestos from drinking water, whether or not it is routed through asbestos- cement pipes, drinking water contains 200,000 to 2,000,000 fibres per litre.[50] Canada considers that, in order to evaluate the health effects of asbestos in the environment, it is important to determine the consequences of human exposure, as well as possible inhalation or ingestion of these fibres. There is a lot of confusion regarding the inhalation of all types of particles that penetrate the airways. In Canada's view, it must be recognized that only extremely fine particles can penetrate the deep areas of the lungs. Many inhaled particles are immediately exhaled, because they do not succeed in depositing themselves. Large particles that penetrate through the upper parts of the airways are handled by an extremely effective biological elimination system; the mucociliary mechanism traps the fibres and pushes them out of the airways. Canada considers that the health effects of ingested asbestos are practically nil.[51] The results of animal studies on ingestion by feeding have been absolutely negative, as have the vast majority of human epidemiological studies conducted in areas where asbestos concentrations in water are naturally high due to the presence of asbestos in the rock over which the water flows.[52]

3.53 Canada notes that the WHO clearly reaffirmed, particularly in a 1989 follow-up, that the use of chrysotile-cement pipes is completely safe for transporting drinking water.[53] It is essential to distinguish clearly between the obvious health effects associated with very high exposure to asbestos in the workplace and the absence of demonstrable health effects linked to current environmental asbestos concentrations. Therefore, the WHO considers the risk of mesothelioma and lung cancer attributable to mass exposure to asbestos is so low as to be undetectable.[54] According to Canada, long-term exposure at rates of around 0.0005 fibres of more than 5 micrometers per ml of air corresponds to a possible cancer risk equal, at the most, to the extremely low risks of "rare events," for example, the risk of being killed by lightning or getting cancer from consuming meat grilled over charcoal, or by an increase in the exposure to cosmic rays caused by one transatlantic airline flight each year. Consequently, the risk of cancer due to the exposure to an environmental concentration of 0.0005 f/ml of more than 5 micrometers would be only about one in 100,000 (estimated lifetime risk).

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[49] Spengler, J. *et al.*, *Summary of Symposium on Health Aspects of Exposure to Asbestos in Buildings*, Energy and Environmental Policy Center, Harvard University, 14-16 December, 1988, p. 16; Doll, R., and Peto, J., *Asbestos; Effects on Health of Exposure to Asbestos*, Her Majesty's Stationery Office, U.K., 1985, p. 53.

[50] Dunnigan, J. and Seymour, N., *L'amiante et la santé: une mise à jour scientifique*, rev. ed., 1991, p. 24.

[51] According to Canada, the studies concluded that there is no health risk linked to the ingestion of asbestos. See, in particular, Commins, B. T., *Estimations of Risk from Environmental Asbestos* in *Non-Occupational Exposure to Mineral Fibres*, IARC Scientific Publication no. 90, Lyon, 1989, pp. 476-478.

[52] Dunnigan, J. and Seymour, N., *L'amiante et la santé: une mise à jour scientifique*, rev. ed., 1991, p. 53.

[53] Canada notes that natural concentrations of asbestos fibres are found in spring water, whether or not asbestos-cement pipes are used. The possible contribution to asbestos concentration in water after the use of asbestos-cement pipes was studied in several countries. For example, in the State of Illinois, in the United States, in 15 public water supply networks, some of which were 50 years old, there was no difference in fibre concentrations between samples of drinking water before and after they passed through asbestos-cement pipes. (Hallenbeck, J. *et al.*, *Is Chrysotile Asbestos Released from Asbestos-Cement Pipes into Drinking Water?* (1978) Amer. Water Works Ass., Vol. 70, no. 2, p.97). See also World Health Organization, Letter to T.A. Jafri, *Asbestos in Drinking Water/Amiante dans l'eau de boisson*, Helmer, D.R., WHO, Geneva, 5 April 1989.

[54] World Health Organization, *Environmental Health Criteria for Asbestos and Other Natural Mineral Fibres*, Geneva, 1986, p. 135.

In other words, it is a rate that does not justify any additional measures.[55] According to the French *Académie nationale de médecine*, "this figure, which equals zero based on the degree of biological uncertainty […] indicates that there is no demonstrable risk."[56] These estimated environmental risk values are based on workplace health data and on the use of a linear lung cancer model, as well as on an exponential model for mesothelioma. The estimated values are conservative for various reasons, particularly because of the fact that a large number of previous workplace exposure values underestimated the actual exposure conditions for different types and mixtures of asbestos, and because the model used assumed they would apply even to extremely low exposure values, which means that they do not consider the possibility of a "threshold" effect under which there would be no detectable effect. In reality, Canada concludes that the risk could be even lower because, now, the public is exposed mainly to chrysotile, which is less hazardous than amphiboles.

3.54 Canada points out that environmental risks have to be put into perspective. Generally, it is acknowledged that, of the risks to which our society is exposed, some are less serious than others. Often, however, many people have a poor appreciation of the relative value of these risks, even though they have been published for several years. The following table provides an overview of the risks of exposure to environmental asbestos concentrations in comparison with other risks. It shows that the estimated risk attributed to this exposure is equal to or lower than that of very rare events.

[55] Commins, B.T., *The Significance of Asbestos and Other Mineral Fibres in Environmental Ambient Air*, Cummins Associates, Berkshire, U.K., 1990, p. 62. According to Commins, "[A]ny risk for future exposures to asbestos are of course likely to be lower still because of improving control measures." (p. 64.)

[56] Académie nationale de Médecine (Étienne Fournier), *Amiante et protection de la population exposée à l'inhalation de fibres d'amiante dans les bâtiments publics et privés*, Bulletin de l'Académie nationale de médecine, Vol. 180, no. 4, p. 5.

EVALUATION OF LIFETIME RISKS (SELECTED CASES)[57] (according to data mainly from the United States)	
Lifetime risk per 100,000 inhabitants	
Extremely high risk	
Smoking (all causes of mortality)	21,000
Smoking (cancer only)	8,800
Very high risk	
Driving an automobile	1,600
High risk	
Frequent air travel (deaths)	730
Cirrhosis of the liver, moderate alcohol consumption (deaths)	290
Pedestrians hit by automobiles (deaths)	290
Moderate risk	
Low alcohol consumption (one beer per day) (cancer)	150
Death by drowning (all recreational activities)	140
Atmospheric pollution, U.S., benzopyrene (cancer)	110
Natural radiation at sea level (cancer)	110
Cosmic rays, frequent airline travel (cancer)	110
Low risk	
Household accidents (deaths)	88
Secondhand smoke (cancer)	75
Diagnostic X-rays (cancer)	75
(Rate of risk which few people are willing to use their own resources to reduce, Royal Society, London.)	70
Very low risk	
Natural radiation, people living in brick houses (cancer)	35
Smallpox vaccinations, by vaccination (deaths)	22
One transcontinental flight per year (deaths)	22
Saccharine, average consumption in the U.S. (cancer)	15
Consumption of Miami or New Orleans water (cancer)	7
(Rate of risk at which few people feel measures are necessary, in the absence of clear links to consumer products, Royal Society, London.)	7
Extremely low risk ("rare events")	
One transcontinental flight per year, natural radiation (cancer)	4
Lightning (deaths)	3
Hurricane (deaths)	3
Consumption of one charcoal cooked steak per week (cancer)	3
RISK DUE TO ENVIRONMENTAL ASBESTOS CONCENTRATIONS (cancer) (approximately 1 per 100 000 or less[58])	1
("Acceptable" risk, WHO, drinking water (cancer))	1
(Additional restrictive measures are certainly not justified, Royal Society, London, United Kingdom)	0.7

3.55 Canada emphasizes that, because of the extremely low risks linked to the current use of asbestos products, there is no reason to have to reduce the use of chrysotile or tighten restrictive measures if adequate restrictive measures have been taken. Such was the case in France in 1997, according to the French Senate and National Assembly.[59] Despite the importance of applying general restrictive measures, there are currently three specific cases that require particular vigilance: (i) the presence and elimination of old asbestos products in buildings; (ii) the demolition of buildings

[57] Commins, B. T., *Estimations of Risk from Environmental Asbestos* in *Non-Occupational Exposure to Mineral Fibres*, IARC Scientific Publication no. 90, Lyon, 1989, pp. 476-483.

[58] Results of exposure in buildings containing sprayed asbestos over a period of 20 years (See Doll, R., and Peto, J., *Asbestos; Effects on Health of Exposure to Asbestos*, Her Majesty's Stationery Office, U.K., 1985, p. 53.

[59] Le Déaut, J.-Y. and Revol, H., *L'amiante dans l'environnement de l'homme: ses conséquences et son avenir*, Office parlementaire d'évaluation des choix scientifiques et technologiques, National Assembly no. 329/Sénat no. 41, 1997, p. 133.

containing significant amounts of asbestos; and (iii) the elimination of asbestos waste. In addition, particular attention must be paid to the hazards caused by amphiboles. Because of the relatively high risks, compared to those of chrysotile, which are linked to exposure to various types of amphiboles in the workplace, most countries, including Canada and France, have prohibited their use. Special restrictive measures were adopted for extraction and crushing, as these activities can produce large amounts of dust. Appropriate regulation of modern crushing procedures allows asbestos to be exploited with minimal emission of fibres into the environment. For this purpose, for example, effective air purification systems such as electrostatic precipitators, cyclones, or sleeve chambers are used.[60] The uncontrolled use of certain types of asbestos and of certain work processes was responsible in the past for unacceptable emissions. Today, with the help of advanced technologies and the widespread use of wet processing, it is relatively easy to use chrysotile in such a way as to ensure the protection of workers' health while avoiding possible air contamination.[61] Controlled use has been implemented in a number of countries.[62]

3.56 Regarding the limitation of asbestos emissions during construction activities, Canada notes that the use of modern chrysotile products prefabricated in the factory for the construction industry reduces the problems of environmental contamination to a minimum.[63] In these chrysotile-cement construction materials, the asbestos fibres are strongly linked to a matrix. If it should, nonetheless, become necessary to cut them on the construction site, the use of tools that almost entirely eliminate emissions (low-speed saws, with water injection or equipped with suction units), and the wearing of a

[60] Canada indicates that, over the last 15 years, ambient air concentrations of asbestos in the institutions where chrysotile was being extracted in Quebec never exceeded 0.02 f/ml. In 1986, A. Churg (See Churg, A., *Lung Asbestos Content in Long-Term Residents of a Chrysotile Mining Town*, (1986) 134 Amer. Rev. Respirat. Diseases 125) concluded that residents of the mining region of Thetford Mines in Quebec showed no sign of disease due to asbestos and that repeated epidemiological studies did not document any abnormal incidence of respiratory diseases in persons that had never worked in this industry. Canada also draws attention to the work of Dr. Camus *et al* (Camus, M., Siemiatycki, J., Meek, B., *Nonoccupational Exposure to Chrysotile Asbestos and the Risk of Lung Cancer*, (1998) 338, New England Journal of Medicine 1565.) They published a vast study on women in chrysotile mining communities in Quebec, many of whom were exposed to very high levels of fibres between 1920 and 1975. These women were subjected to exposure of 0.0107f/ml, higher than the current exposure limits in France, and literally thousands of times higher than the levels measured in public buildings. Nonetheless, Canada notes that no excess in lung cancer was detected in this population. According to the study's authors, this is particularly important in light of the current French situation. In fact, applying the risk model adopted by France for the exposure studied results in a forecast of approximately 100 lung cancer deaths, while in reality there are none. Likewise, use of the French risk model would have resulted in estimates of approximately 250 and, at any rate, no less than 50 deaths from mesothelioma, whereas the preliminary results of the study in question show only 10 cases, some of which may be associated with exposure to amphiboles. Research continues, particularly with an analysis of the work history of each individual in order to determine the exact link, if any, between these cases of mesothelioma and on-the-job exposure, as well as exposure to amphiboles.

[61] See, in particular, Bragg, G.M., *Basics of Asbestos Dust Control*, Institut de l'amiante, Montreal, 1988.

[62] See paras. 3.120 *et seq* below.

[63] Canada points out that in Germany, for example, a study revealed the low degree of chrysotile fibre emissions in the environment from chrysotile-cement roofing materials, even when these were in a state of advanced corrosion. These chrysotile fibre concentrations, which were measured in urban areas, were well under 0.001 f/ml, i.e. the concentration found acceptable by the German health authorities. (Teichert, U. (1986) 46 Staub Reinhaltung der Luft 432, p. 7 of the English translation.) In Austria, after having compared chrysotile fibre concentrations between areas with and without chrysotile-cement roofing (< 0,0001 f/ml), it was concluded that there was no significant link between the use of chrysotile-cement based materials and the chrysotile fibre concentrations found in the areas concerned. (Felbermeyer, W. S., Ussar, M.B., *Environmental Pollution by Atmospheric Effects on Asbestos Cement Sheets*, Institute for Environmental Protection and Clean Air, Leoben Austria, 1980). Canada notes that, in Australia, the possible contribution of chrysotile-cement roofing materials on school buildings to environmental asbestos concentrations has been analysed. Most of the concentrations were found to be equal to or less than 0.0002 f/ml. (Safety and Welfare of Western Australia, *Asbestos Cement Products*, Report of the Working Party, 1990).

mask by the operator guarantee their safety. It is easy to obtain a copy of the codes of practice that employees must follow when handling modern chrysotile products.[64]

3.57 Canada considers that, in general, the extremely low risks of exposure to asbestos in buildings have been accurately demonstrated.[65] In some cases, however, the materials enclosing the sprayed asbestos in the buildings can deteriorate and pose a certain hazard to their occupants. In France, as in Canada and everywhere else, regulations provide that, beyond a certain concentration of airborne asbestos in buildings, corrective measures such as isolation, encapsulation, or even elimination must be considered. If a large amount of asbestos is present in an old building to be demolished, especially if amphiboles are involved, it may be advisable to eliminate these materials in advance, if possible. The procedures to be followed in these projects are well documented. Canada also considers that the elimination of most modern asbestos products should present only a slight difficulty if a building has to be demolished. It is important to use effective measures for handling, packaging, and transport, as well as for waste disposal. The procedures to be followed for these operations are well documented and often standardized. These measures, which are normally easy to implement, allow asbestos waste in the environment to be kept to a satisfactory minimum.[66] Industrial waste containing asbestos is normally easy to handle and confine, because it is often wet and, therefore, does not produce powder. Furthermore, many industries today recycle their waste because this measure, in addition to being more economical, allows the waste to be disposed of effectively. In most countries, industries must comply with regulations limiting emissions of asbestos into the atmosphere.

3.58 To conclude, Canada contends that, in light of the available data, there is no scientific justification for the prohibition or reduction of the manufacturing or use of modern asbestos products. This conclusion is as valid for developed countries as it is for developing countries. It is enough to continue to take adequate restrictive measures, particularly for mineral extraction and crushing, the manufacturing and use of products, and the elimination of asbestos waste.

3.59 The **European Communities** respond that Canada presents the health effects of asbestos by distinguishing on the one hand the environmental risks and, on the other, certain asbestos-related occupations: mining and crushing, manufacturing of products, building and demolition of buildings, elimination of waste. Canada simply disregards the fact that once asbestos has been used in the construction of a building and until it is demolished, any installation containing asbestos is likely, during its life cycle, to require some form of plumbing, heating or electrical work carried out by professionals or amateurs. Regular servicing and maintenance work carried out by people who are unaware of whether the material on which they are working contains asbestos or not may, if asbestos is present, lead to extremely high peaks of exposure, significantly higher than the exposure limits, and which have been proven to be carcinogenic in a perfectly "detectable" way. According to the EC, the large majority of cancers due to asbestos are the result of such work (servicing and maintenance) on materials containing chrysotile. For many years, scientific bodies and governmental authorities disregarded this type of risk. In the early 1990s, scientists started to note an increase in cases of mesothelioma affecting professionals who had never worked in the asbestos-manufacturing industry. France, following the example of several other countries, became aware of the seriousness of the risk faced by these workers and individuals, exacerbated by the number of asbestos products freely on sale and frequently used. In such situations, controlled use practices, which the EC consider do not in any case eliminate the risk, are inapplicable. Persons liable to be exposed to the risk are unaware that they are working with products containing asbestos. They are therefore unable to protect themselves.

[64] See, in particular, *Code of Practice on Safety in the Use of Asbestos*, International Labour Organization, Geneva, 1984.

[65] Commins, B.T., *The Significance of Asbestos and Other Mineral Fibres in Environmental Ambient Air*, Cummins Associates, Berkshire, U.K., 1990, p. 19.

[66] Institute of Waste Management, *Code of Practice for the Disposal of Asbestos Waste*, Northampton (UK), Institute of Waste Management, 1988.

Even if they did know, controlled use practices imply[67] the use of costly material and equipment and make even the simplest and quickest operations very complicated. Taking these elements into account, France decided, by means of the regulation contested by Canada, to halt the dissemination of such risks by banning all future uses of products containing asbestos.

3.60 The EC point out that Canada asserts that "today science generally recognizes few or no demonstrable effects of environmental asbestos on health". If the idea of ambient air is limited to the usual levels of exposure in towns or buildings that have not deteriorated, the INSERM report reaches the same conclusion unambiguously in several places. But the French regulation is not solely intended to prevent the risk due to ambient exposure, i.e. exposure caused by living in a building containing asbestos. The French regulation calls for caution in this area, but the purpose of the contested ban is to prevent the extension of risks due to exposure, usually only of an occasional nature, for professional activities (servicing and maintenance in buildings/public works, for example) or leisure activities (handymen). The EC state that these risks have been scientifically proven both by metrological data concerning the concentration of asbestos fibres and by international epidemiological data.

3.61 The EC consider that the Canadian assertion that "Today chrysotile fibers are bonded" or "encapsulated" in other materials and therefore do not present any risk is misleading because health problems are not simply due to the presence of chrysotile fibres in materials, but to the fact that very high levels of fibres are released into the atmosphere when working with these materials, for example, when sawing, cutting, etc. This idea is often repeated in Canada's arguments in order to make it appear that asbestos incorporated in various materials, including asbestos-cement, is not dangerous: the purpose of this assertion is to provide misleading reassurance, and it will not be systematically contested. Moreover, it should be noted that the manufacture of asbestos-cement has always required that the asbestos and other materials be bonded. In this connection, it cannot be stated, as Canada does, that there are "modern" manufacturing methods. To the knowledge of the EC, the production methods for asbestos-cement have not evolved to any significant degree for many years. It is also wrong to claim that "The strong bond between chrysotile and cement in chrysotile-cement products reduces the release of fibers into the air to a minimum". This claim is incorrect when the product in chrysotile-cement is the subject of servicing or maintenance which requires drilling or cutting. In such cases, the release of dust into the air is several hundred times higher than the value limit allowed in France, and the United States, or even the limit recommended by the WHO and cited by Canada. The EC note that the risks of "asbestosis" have been known since the beginning of the century and the first regulations adopted to protect the health of workers from the dangers of asbestos were drawn up in England in 1931, as is recalled in the European submission. The risks of asbestos for health have thus been recognized for a very long time.

3.62 The EC point out that Canada cites very low risks for health at very low exposures (0.0005 f/ml). It should be emphasized, however, that: (i) these are the same values as those cited in the INSERM report for such levels of exposure, which Canada appears to disregard; (ii) these values were obtained using the same model as that used by INSERM, whose validity Canada nonetheless denies. If the model can be used by Canada to show that the risks are low at low levels of exposure, why would it not be valid for higher levels of exposure? The EC note that Canada does not provide any justification for this contradiction and adds that this model does not take into account "a threshold below which there is no effect": this ignores the scientific consensus that there is no such threshold. The WHO report of 1988 on the dangers of chrysotile (cited by the EC but never by Canada, which only refers to the 1986 WHO report) recognizes that there is no threshold for chrysotile. The EC note that Canada acknowledges that it has banned the use of amphibole asbestos, like many other countries. Taking into account the equally dangerous threat of lung cancer from both chrysotile asbestos fibres and amphibole asbestos fibres and the theoretical possibility of so-called "safe" use,

[67] Aubier, M., Fournier, M., Pariente, R., *Pneumologie*, Médecine-Sciences, Flammarion, Paris, pp.453 *et seq.*

the Canadian ban on amphiboles alone appears inconsistent, unless it is justified by the fact that Canada does not produce amphibole fibres. It is difficult to understand why it should not be possible to ensure "safe" use of fibres of the amphibole variety when Canada claims that this is possible for fibres of the chrysotile variety: the production methods and the conditions of use are nonetheless strictly identical in both cases.

3.63 According to the EC, Canada's assertion that "It is relatively easy to use chrysotile in such a way as to ensure the protection of workers' health" is a euphemism that hides the real problems faced in practice. On the one hand, such protection can only exist if the worker knows he is handling asbestos products. On the other, following the ISO 7337 standard recommendations means cumbersome and costly individual measures (practically turning oneself into a cosmonaut) without being certain that no fibre can get through the protection. Furthermore, the asbestos-cement market is very diffuse. It is utopian to imagine that all the public concerned could apply the Canadian safe use programme. France recognizes that this is the only way of limiting as far as possible the risks of such operations when the asbestos is already there and it has adopted very strict regulations to this effect. The EC nevertheless contest the fact that Canada seeks to impose the adoption of such measures on very large parts of the economic sectors. In addition to their lack of effectiveness, these measures have a significant impact on the costs of French companies and are unknown to diffuse users of asbestos materials (on building sites, for example): asbestos-cement products were marketed in France as materials that did not present any particular risk, as Canada intimates when it refers to "modern asbestos-cement materials" in which asbestos fibres are "encapsulated"! The EC point out that, as shown by the occupational disease statistics, it is equally impossible to ensure the effective protection of workers in the raw asbestos processing industry, even with sophisticated dust collection and ventilation systems.

3.64 The EC consider that the Canadian claim that "the elimination of most modern asbestos products should present only a slight difficulty if a building has to be demolished" is a euphemism. Asbestos products used in the building industry are fragile and inevitably break or dissolve, releasing fibres into the atmosphere. In addition, the need to remove asbestos before demolition involves huge expenditure because any removal of asbestos requires the observance of draconian technical regulations essential for the protection of the workers. Lastly, the EC reject the Canadian argument that "in light of the available data, there is no scientific justification for the prohibition or reduction of the manufacturing or use of modern asbestos products. Chrysotile asbestos, like other types of asbestos, is dangerous for the health of workers and the population, no safe use allows the risk to be reduced. Scientifically, the French measure on a general ban is justified.

3.65 The EC state that, as the risks from exposure to asbestos were gradually identified and became the subject of preventive rules and regulations, the various types of exposure were listed and were placed in the following three categories: the first category includes occupational exposure of workers, including "primary" users and "secondary" users. "Primary" users are those working in the asbestos industry: mining of asbestos, manufacture of asbestos products (asbestos fibres, asbestos-cement, gaskets, asbestos boards for soundproofing or thermal insulation; since 1965, there has been no asbestos mining in France and less than 1,500 people were working in the asbestos-processing industry at the time the ban came into effect. "Secondary" users are in enterprises which use asbestos products (building industry, metalworking, shipbuilding, etc.); enterprises which, in the course of their work on buildings or plants, encounter materials containing asbestos (servicing and maintenance, electrical work, plumbing, etc.); enterprises engaged in the removal and/or containment of asbestos, particularly flocked asbestos; in France, the use of asbestos products involved several hundred thousand persons at the time of the ban and, at the present time, servicing, maintenance and do-it-yourself using asbestos products affect several million people; removal and containment of asbestos involve several hundred persons. The EC note that the Canadian guide on "controlled" use covers only the mining of asbestos and the processing of raw asbestos into asbestos products, i.e. it applies only to "primary" users. According to the EC, the second category includes para-occupational and domestic exposure, where people come into contact with workers in the first category. Many

members of the general population encounter similar exposure to servicing and maintenance workers when engaged in do-it-yourself activities. Such individuals even undertake the removal of asbestos on their own. They are therefore exposed without being aware of it, for asbestos is often undetectable, as the Canadian submission points out. Environmental exposures are in the third category and three types of source can be distinguished: (i) pollution from a natural source of geological origin; (ii) pollution from a particular "industrial" source; (iii) pollution from asbestos in buildings and various types of equipment. This breakdown reflects that generally found in other industrial countries, except for those countries where asbestos is mined, such as Quebec, where 1,300 persons fall into the category of "primary" users.

3.66 The EC recall that three diseases are caused by asbestos. Firstly, mesothelioma is a pleural cancer for which the only known cause is the inhalation of asbestos.[68] Asbestos in all its forms (amphiboles or chrysotile) is the only known agent which can cause mesothelioma or cancer of the pleura. In this disease, liquid forms between the lung and the thoracic cavity (pleurisy) causing pain and breathlessness. Asbestos of the amphibole type and chrysotile asbestos both cause mesothelioma, although amphiboles would seem to be somewhat more carcinogenic (but only in the case of mesothelioma).[69] This cancer occurs mostly as a result of occasional low-intensity exposure. After a long latency period (lasting for 30 years on average), this cancer enters the terminal phase, which lasts for one year on average. There is as yet no curative treatment with any effect. In 1996 alone, an estimated 750 persons died of mesothelioma in France. Secondly, cancer of the lung may be due to the inhalation of asbestos, but unlike mesothelioma there are other known triggers. The effects of lung cancer are quicker to make themselves felt than those of mesothelioma and both the symptoms and the outcome of the disease are widely known. The first symptoms include blood in the sputum, breathlessness and a general deterioration in the patient's health. Only certain forms of cancer can be treated, depending on their location and histological nature. Both chrysotile asbestos and the amphibole varieties can cause this form of cancer, their carcinogenic impact being comparable.[70] Asbestosis is a form of pulmonary fibrosis (or pneumoconiosis) arising from an accumulation of asbestos fibres, just as silicosis results from the inhalation of silica. The fibrosis takes the form of a scarring process which follows from the inflammatory reactions caused by the presence of asbestos fibres (or silica dust) in the pulmonary alveoli. The fibrous thickening of the thin alveolar wall prevents the circulation of oxygen. Once exposure has ceased, the disease either stabilizes or becomes progressively worse, with respiratory difficulties which may end in the patient's death. No curative treatment is yet available. Asbestosis results from what is considered a high level of occupational exposure. It develops over an average period of seven to eight years. Currently there are some 150 cases of asbestosis per year in France; in the United States there were on average 733 cases per year between 1982 and 1993.[71]

3.67 The EC explain that, in all, asbestos is responsible for some 2,000 deaths per year in France, including 750 deaths from mesothelioma. These figures are based on reliable and verified data. In the INSERM report (pages 172 to 180) a detailed description is given of the data in question, which are drawn from two major French studies and from cancer records. The figures have been fully borne out by the surveys conducted by the *Programme National de Surveillance du Mésothéliome* (PNSM) (National Mesothelioma Surveillance Programme), which was set up under the French Health Monitoring Authority in 1998. In France, asbestos-related occupational diseases account for almost 40 per cent of all social security expenditure in respect of occupational diseases, i.e. over F 1 billion per year.

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[68] Aubier, M., Fournier, M., Pariente, R., *Pneumologie*, Médecine-Sciences, Flammarion, Paris, pp.453 *et seq.*

[69] IPCS, *Environmental Health Criteria (203) on Chrysotile*, World Health Organization 1998, Geneva.

[70] *Id.*

[71] *Atlas of Respiratory Disease Mortality*, United States: 1982-1993, US Department of Health and Human Services, CDC-NIOSH, 1998.

3.68 The EC point out that one important point in this connection is that mesothelioma is regarded as a very reliable indicator of exposure to asbestos. Researchers plot the course of the disease against the use of asbestos since this technique yields important data for assessing the risk involved in various situations where people are exposed to asbestos. Unlike lung cancer, which is the other cancer caused by asbestos, mesothelioma has certain special characteristics: (i) apart from exposure to asbestos, no other causal factor present in the industrialized countries has been established or even seriously suspected. Interpretation of the course of the disease is not therefore impeded by the presence of other factors, such as tobacco in the case of lung cancer; (ii) the spontaneous occurrence of mesothelioma is very rare: where no asbestos is present, the frequency of the disease is estimated at one or two cases per year per million inhabitants,[72] with the same frequency being found in both men and women; whenever levels are found in excess of this frequency, they are regarded as a sure indicator of the presence of asbestos. It is for these reasons that mesothelioma is studied to ascertain the harmful effects of asbestos. But this approach, which is justified for methodological reasons, should not lead one to overlook the fact that most asbestos-related cancer deaths are attributable to lung cancer. According to the EC, it is generally recognized[73] that to obtain the total number of cancer deaths attributable to asbestos, the number of mesothelioma deaths has to be doubled at the very least.

3.69 The EC recall four important dates which mark the progress of international awareness of the health risks. In 1977, the WHO, acting through the IARC, recognized that all varieties of asbestos, including chrysotile, were carcinogenic, causing both lung cancer and mesothelioma, and classified them in group I (known carcinogens). In 1986, the ILO recommended in Convention No. 162 that legislators should make provision for the replacement of asbestos by less harmful materials or technologies, at the earliest opportunity. In 1996, the WHO recommended that asbestos, including chrysotile, should be replaced by harmless substitutes wherever possible. Lastly, in 1998, the WHO again drew attention to the carcinogenic effects of chrysotile, particularly as a cause of mesothelioma; it reiterated its call for the replacement of chrysotile and pointed out that numerous categories of worker were at risk in many areas.

3.70 The EC indicate that the diseases described above and caused by chrysotile asbestos (mesothelioma, lung cancer, asbestosis) are incurable. As it has been recognized for decades that all types of asbestos are life-threatening, measures to protect workers have been taken, and have been in place for a very long time in many countries. Since regulatory measures were first put in place in the United Kingdom in 1931, the ceilings set in many countries for exposure at work have been gradually lowered. The use of certain forms of asbestos has been banned in certain countries and that of any form of asbestos in others. In 1977, following a great many international scientific studies, the WHO listed asbestos in all its forms as a substance known to be carcinogenic to man.[74] Chrysotile asbestos and amphibole asbestos, which cause identical fatal diseases, cannot be treated separately. According to the EC, the diseases identified must be dealt with in a consistent fashion. These two varieties of asbestos cause the same cancers and the exposure conditions are identical. The EC note that, logically, just as it recommends the "safe" use of chrysotile asbestos, Canada could equally well have promoted the "safe" use of amphibole asbestos rather than approving and encouraging its prohibition. It is difficult to understand how Canada can accept the grounds for government measures banning amphibole asbestos while denying their legitimacy in the case of chrysotile.

3.71 The EC point out that asbestos is the cause of an international public health problem which affects both France and Canada. Mortality due to mesothelioma has been increasing in men in

[72] McDonald, J.C., McDonald, A.D., *Epidemiology of Mesothelioma*. In: Liddell, D.K., Miller, K., eds. Mineral Fibers and Health. Boca Raton FL: CRC Press, 1991: 143-164.

[73] Peto, Decarli, La Vecchia *et al*, *The European Mesothelioma Epidemic*, British Journal of Cancer, 1999, 79 (3/4): 666-672.

[74] IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man, *Asbestos*, Vol.14.

industrialized countries by some 5 to 10 per cent per annum since the 1950s.[75] A similar increase has also been seen in France.[76] A recent study coordinated by J. Peto[77] found that in seven European countries nearly 10,000 people had died from mesothelioma during the period 1990-1994. The most recent forecasts on mesothelioma mortality show that over the next few decades there will inevitably be hundreds of thousands of deaths caused by exposure to asbestos dust. Peto's 1999 study, mentioned above, also looks at the evolution of pleural mesothelioma mortality in six Western European countries (Great Britain, France, Germany, Italy, the Netherlands, Switzerland) over the period 1995-2029. This study estimates the total number of deaths due solely to mesothelioma in these six countries at around 200,000. According to the EC, the number of deaths will at least double between the periods 1990-1994 and 2015-2019, when it will reach 6,700 deaths per annum. If these figures are extended to all the countries of Western Europe and deaths from lung cancer are added, by 2029 around 500,000 deaths from cancer will have been caused by exposure to asbestos.

3.72 The EC indicate that, in France, the number of mesothelioma deaths in 1996 is estimated at 750. Contrary to what Canada states,[78] this figure of 750 estimated by INSERM rests on solid data. The data come from two major French studies based on actual cases of mesothelioma since 1979 in the geographical areas covered by the cancer registers in France. The frequency of mesothelioma is steadily increasing: all the French registers listing cases of mesothelioma show that the increase observed is 25 per cent every three years. According to the EC, these data are fully confirmed by the first available data provided by the *Programme National de Surveillance du Mésothéliome* (PNSM), which was set up under the authority of the *Réseau National de Santé Publique* in 1998.[79] A recently published study,[80] similar to that by Peto *et al*., predicts that the annual number of deaths from mesothelioma in France will continue increasing until 2020, in all the hypotheses studied. By that date, there could be 1,040 annual deaths from mesothelioma among men; the total number of deaths from mesothelioma over the whole period 1996-2020 could be 20,000 deaths among men and 2,900 deaths among women. INSERM has estimated that around 1,200 deaths from lung cancer were caused by asbestos in France in 1996.[81]

3.73 The EC note that, in Canada, the promoter of the so-called "safe" use of chrysotile, the health situation is no better than in other countries. It is regrettable that Canada has never provided its own health statistics on certified deaths from mesothelioma, in spite of the repeated requests made during the WTO consultations in Geneva on 8 July 1998. Unlike most other industrial countries, which are

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[75] See for example: McDonald, J.C., McDonald, A.D., *Epidemiology of Mesothelioma*. In: Liddell, D.K., Miller. K., eds. Mineral Fibers and Health. Boca Raton FL: CRC Press, 1991:143-164. See also the INSERM report, Chapter 8 (pp.154-190), which analyses in detail how the frequency of mesotheliomas has evolved internationally. INSERM report, pp.172-180.

[76] INSERM report, pp.172-180.

[77] Peto, Decarli, La Vecchia *et al*, *The European Mesothelioma Epidemic*, British Journal of Cancer, 1999, 79 (3/4): 666-672.

[78] See paragraph 3.222 below.

[79] Source: Programme National de Surveillance du Mésothéliome, *Rapport d'activité 1998*. Saint-Maurice, Réseau National de Santé Publique, February 1999.

[80] Gilg Soit Ilg, A., Bignon, J., Valleron, A-J., *Estimation of the Past and Future Burden of Mortality from Mesothelioma in France*. Occupational Environmental Medicine, 1998; 55:760-765.

[81] The EC note that Canada seems to believe that this figure is not correct, because it assumes that 5.7 per cent of cases of lung cancer are attributable to asbestos, a figure which comes from a single study carried out in Scotland (and which Canada considers too high, though it does not propose a different value based on the results of scientific studies). This criticism is not justified. The EC point out that, on page 10 of the INSERM report, there is a table summarizing the proportions of lung cancers attributable to asbestos in all the studies which provided an estimate: it shows that in certain studies this fraction is clearly higher than the 5.7 per cent given, and may considerably exceed 10 per cent. In the part of the report which explains the method of calculating the number of cases of lung cancer (page 180), the higher percentage (7 per cent) observed 10 years earlier in Great Britain has not been used since it was believed that this proportion must have declined. According to the EC, it is therefore clear that the INSERM report consistently uses relatively low estimates of the effects of asbestos on cancer mortality in France.

concerned about the deleterious effects of asbestos on the health of their population, Canada has never, as far as the EC are aware, published any data on the incidence of mesothelioma over a long period among its own population, although such data are available. The table below thus had to be reconstituted by French experts from the raw world data published regularly by the IARC.[82]

ANNUAL INCIDENCE OF MESOTHELIOMA IN CANADA AND QUEBEC

NUMBER OF CASES ANNUALLY PER MILLION PEOPLE				
1978-92				
PERIOD	Canada		Quebec	
	M	F	M	F
1978-82	6	2	9	4
1983-87	9	2	11	3
1988-92	11	2	15	3

This table shows that in Canada, each year between 1978 and 1982, six men per million were affected by mesothelioma. Ten years later, more than 11 men per million per year were affected, in other words, the figure doubled in less than 15 years, which is a particularly high rate of growth. According to the EC, the situation in Quebec, the province which produces Canada's asbestos, is even worse: the increase in the number of cases was of the same order, but the rates are consistently higher than in Canada as a whole (about 35 to 50 per cent higher, depending on the period). The fact that the rates for women have remained more or less stable (though markedly higher in Quebec) shows indisputably that the cause of these mesotheliomas is essentially work-related. Furthermore, the fact that the increase in the frequency of mesothelioma-type cancers can be seen throughout Canada, according to the EC, shows that the risk of death from chrysotile is not confined to the asbestos mining industry (which exists only in the province of Quebec), but that it affects all sectors of the economy. The EC also emphasize that Canada, which produces only chrysotile asbestos, has mainly used this type of asbestos.

3.74 The EC note that the number of mesotheliomas, and hence the number of asbestos-related cancers, correlates with the amount of asbestos imported. The more asbestos that is imported into a country, the more deaths there are from cancer caused by asbestos. Analysis of the data for ten Western countries[83] shows a very clear and strong correlation between cases of mesothelioma and consumption of asbestos per inhabitant, measured by the amount of imports. A study was conducted where the rates of cancer in the ten countries were compared with the total amount of asbestos imported per inhabitant (the study analyses the statistical correlation between these two values). This correlation is extremely strong (the very revealing correlation coefficient is 0.70). According to the EC, the number of cases of cancer thus increases proportionally with the increase of imports of asbestos into each country. It is important at this stage to bear in mind that about 95 per cent of all the asbestos used in the world is chrysotile.

3.75 The EC stress that chrysotile is a known carcinogen causing lung cancer and mesothelioma. The fact that chrysotile is carcinogenic has long been internationally recognized. Since 1977, the IARC has classified both chrysotile and amphiboles as carcinogens endangering human health (i.e. category I).[84] The IARC has recognized that chrysotile causes lung cancer and mesothelioma. Very recently - in 1998 - following an assessment conducted under the International Programme on Chemical Safety, the WHO reaffirmed that chrysotile asbestos "has been associated with an increased

[82] Source: *Cancer in Five Continents*, International Agency for Cancer Research, 1987/1992/1997.

[83] Takahashi, K., Huuskonen, M., Tossavainen, M., Higashi, T., Okubo, T., Rantanen, J., *Ecological Relationship between Mesothelioma Incidence/Mortality and Asbestos Consumption in Ten Western Countries and Japan*, Journal of Occupational Health 1999, 41: 8-11.

[84] *IARC Monograph on the Evaluation of Carcinogenic Risk of Chemicals to Man – Asbestos,* 1977, Lyon, Vol.14.

risk of pneumoconiosis, lung cancer and mesothelioma in numerous epidemiological studies of exposed workers"[85]. The WHO thus confirms the conclusions reached by the 1996 INSERM report.[86] Still more recently, INSERM's conclusions were again confirmed by the United Kingdom's Health and Safety Commission (HSC)[87], which considers all forms of asbestos dangerous as they can all cause mesothelioma, lung cancer and asbestosis. The EC note that Canada never cites these WHO and HSC reports, but on the other hand it does cite the recent publication by Camus *et al*[88] on cancer mortality among women living in the vicinity of Quebec's chrysotile asbestos mines. This study does not reveal any risk of lung cancer among these women. Canada fails to mention, however, that other studies, carried out among workers in the Quebec chrysotile mines, had already shown that the dose observed, as compared with the effect noted, was the lowest of all the estimates published in the international scientific literature on the risk of lung cancer. The number of cancers observed among workers in the Quebec asbestos mines is in fact much smaller than that found in all other situations linked to asbestos. This was pointed out in the INSERM report.[89]

3.76 The EC point out that the 1998 WHO report also explicitly noted that: "The exposure-response relationship between chrysotile and lung cancer risks appears to be 10-30 times higher in studies of textile workers than in studies of workers in mining and milling industries." It should be noted that these risks were observed in an American textile factory which had imported chrysotile asbestos from the Quebec mines. According to the EC, there is an international consensus that there is no threshold of harmlessness for chrysotile. It is important to make the distinction between setting exposure ceilings and the existence of a threshold of harmlessness beneath with there would be no health risk. These are two different problems which do not have the same rationale. The exposure ceilings are set by the authorities, taking various factors into account, such as the technical possibility of obtaining sufficiently low levels of exposure in the environment or the technical means of measuring the actual levels in the air for control purposes. The concept of the threshold of harmlessness is a biological and medical one: the aim is to establish whether biological effects are caused by chrysotile below a given level of exposure. There is thus no contradiction between the fact that it is scientifically accepted that there is no biological threshold of harmlessness and the fact that, nonetheless, an exposure limit is set at a certain level that can be achieved and easily measured for control purposes. The 1998 WHO report carried out under the International Programme on Chemical Safety states that, for chrysotile: "No threshold has been identified for carcinogenic risks".[90] This international authority thus confirms the conclusions of the INSERM report on this point.[91]

3.77 The EC point out that most malignant tumours have their origin in the transformation of a single cell, and a very low dose of a carcinogen is quite capable of inducing a transformational mutation in the genetic make-up of a cell. In epidemiology and the biological sciences it is now agreed that the most plausible model for carcinogenicity is one with no threshold value. According to the EC, the results of the most recent studies confirm this fact, while virtually all the references cited by Canada are from the 1980s. Thus, the French study by Iwatsubo *et al*.[92] shows that asbestos has

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[85] *IPCS, Environmental Health Criteria (203) on Chrysotile*, World Health Organization, 1998, Geneva, point 1.6 ("Effects on Humans").

[86] INSERM report, pp.259-266.

[87] Health and Safety Commission, United Kingdom, (1999), *Proposals for Amendments to the Asbestos (Prohibitions) Regulations 1992*.

[88] Camus, M. *et al., Non-Occupational Exposure to Chrysotile Asbestos and the Risk of Lung Cancer*, New England Journal of Medicine, 1998, 338 (22):1566-71.

[89] INSERM report, pp.193-202, particularly Table 2, p.196 and figures 1 and 2, pp.198 and 199.

[90] *IPCS, Environmental Health Criteria (203) on Chrysotile*, World Health Organization, 1998, Geneva, p.144.

[91] See Chapter 9, pp.193-241 of the INSERM report.

[92] Iwatsubo, Y. *et al, Pleural Mesothelioma: Dose-Response Relation at Low Levels of Asbestos; Exposure in a French Population – Based Case – Control Study*, American Journal of Epidemiology, 1998, 148: 133-142.

carcinogenic effects at levels well below those specified in earlier publications. Other recent studies analysed in the INSERM report show similar results (see pages 122 and 123 of the report).

3.78 In the EC's view, the model which considers that the risk of cancer is directly proportional to the dose of asbestos inhaled is that which is usually adopted. The model of simple proportionality between the dose of asbestos and the risk of cancer is that which is generally accepted nowadays. In the case of exposure to asbestos, such a model, which sees the risk of cancer as directly proportional to the dose of asbestos inhaled, fits very satisfactorily with direct epidemiological observations of high exposure (above 1 fibre/ml). As applied to low doses, this model is generally considered to be the most scientifically plausible. The EC point out that this model, which is strongly criticized by Canada, is that used by all the official committees of experts to date; it is also used in the HEI (Health Effects Institute) report so comprehensively cited by Canada.[93] It was also used to calculate the lifetime risks presented by Canada to show how insignificant the risks were at very low levels of exposure.[94] The EC stress that the values cited by Canada (0.0002 fibres/ml) in no way correspond to the cases covered by the French Decree challenged by Canada. Such excessively low values are found in the ambient air of towns and buildings: at this infinitesimal level, the risk is clearly undetectable, as the INSERM report states in several places (pages 145 and 146, and 224-230). The ban on asbestos, in France and in other countries, is not intended to eliminate the approximately 0.0002 fibres/ml which exist "naturally" in the air. The ban is intended simply to protect all the workers and users of asbestos who are often exposed to much higher values, which may reach tens of fibres per millilitre (i.e. several thousand times more) in the case of standard procedures for dealing with materials containing asbestos-cement.[95] Chrysotile represents the vast majority of the asbestos used throughout the world. About 95 per cent of all the asbestos used since the end of the Second World War has been of the chrysotile variety and more than 80 per cent of this chrysotile is incorporated into asbestos-cement products. This explains, in particular, the very high incidence of mesothelioma among building workers. It is therefore quite indisputable, in the EC's view, that it is indeed the chrysotile variety of asbestos which causes the vast majority of asbestos-related cancers. This has also been shown in recent publications.[96]

3.79 The EC point out that chrysotile and asbestos-cement pose a threat to an extremely large section of the population. Production workers are not the only section of the population affected. The EC note that, when discussing exposure to asbestos, Canada refers only to workers in the production and processing of asbestos ("primary users"). However, such workers are relatively few in number compared with the huge group of "secondary users". It is because these secondary users are very numerous and run significant risks that there is a very rapid rise worldwide in the mortality rates for cancers caused by asbestos. As the British Health and Safety Commission (HSC) points out, the risks for secondary users of asbestos have, in the past, been underestimated.[97]

3.80 The EC note that the occupations and branches of industry affected have changed and diversified. Several studies show the scale of exposure to asbestos in all countries. They also show the huge variety of occupations and sectors that are affected. In the 1960s, the main occupations affected were those in the insulation industry, in the production and processing of asbestos, in the central heating industry and in the shipyards. In the 1980s and 1990s, in contrast, the highest

[93] See, for example, paragraph 3.124 below.

[94] See, for example, paragraph 3.53 above.

[95] Blotière, C. and Huré, P., *Travaux sur des matériaux contenant de l'amiante – données métrologiques*, Chimie Info No. 60-11/1998.

[96] See for example: Stayner, L.T. *et al., Occupational Exposure to Chrysotile Asbestos and Cancer Risk: A Review of the Amphibole Hypothesis.* American Journal of Public Health. 1996, 86:179-186 and Smith Attand Wright, C.C., *Chrysotile Asbestos, the Main Cause of Pleural Mesothelioma,* American Journal of Industrial Medicine, 1996, 30: 252-266.

[97] *Proposals for Amendments to the Asbestos (Prohibitions) Regulations 1992,* Health and Safety Commission, United Kingdom, (1999).

incidence was found among those whose work involved materials containing asbestos. It was only in the 1990s that studies were published on mortality by type of occupational exposure to asbestos, raising awareness of the large-scale health problem which such exposure posed for many categories of worker. In Great Britain, the study published by Peto *et al*[98] in 1995 dealt with mesothelioma mortality in England and Wales for the years 1979-1980 and 1985-1990. The table below (taken from this study) shows the principal occupations in which deaths from mesothelioma have been observed; the percentages represent the distribution by occupation of all the deaths from mesothelioma that have occurred in England and Wales. It shows the variety and the relative importance of the various occupations exposed to asbestos to a significant degree. The types of work are classified in descending order of frequency of death from mesothelioma. The occupations shown in this table account for some 50 per cent of all the deaths from mesothelioma which occurred during the period studied.

DISTRIBUTION OF DEATHS FROM MESOTHELIOMA BY OCCUPATION[99]

Occupation	**%**
Fitter	6.8
Carpenter	5.7
Plumber	4.5
Construction - non specific	4.2
Machine operator	4.0
Electrician	3.6
Sheet metal worker/boiler-maker	2.5
Engineer - non specific	2.3
Buildings maintenance	2.2
Painter and decorator	2.2
Welder	1.6
Docker	1.5
Metal sprayer	1.1
Boiler operator	0.9
Building foreman	0.9
Electrical engineer	0.9
Industrial coach-builder	0.8
Plasterer	0.6
Industrial designer	0.6
Technician - non specific	0.5
Laboratory technician	0.5
Upholsterer	0.4
Electric power station worker	0.4
Chemical engineer	0.4

3.81 The EC point out that the figures in the table are not estimates but death rates which have actually been recorded. The occupations at high risk of mesothelioma include welders, dockers, laboratory technicians, painters and decorators, plasterers, fitters, upholsterers, power station workers, etc. Thus, the building sector alone accounts for a quarter of all the deaths from mesothelioma which have occurred in England and Wales, a proportion considered by Peto *et al*. probably to be underestimated. When the numbers of deaths from mesothelioma are compared to the number of people who work in each occupation, it can be seen that the jobs which are proportionally most affected are sheet metal workers/boiler-makers (including workers in shipyards) and industrial coach-builders. They are followed by plumbers, carpenters and electricians. In France, a recent study showed that, depending on the generation, between 18 and 25 per cent of French men, i.e. millions of people, have been exposed to asbestos at least once in the course of their working life.[100] Another

[98] Peto, J. *et al., Continuing Increase in Mesothelioma Mortality in Britain*. Lancet 1995; 345:535-539.
[99] *Id*.
[100] Goldberg, M. *et al*., *Past Occupational Exposure to Asbestos among Men in France.* Scandinavian Journal of Work and Environmental Health, 1999 (in press).

French study (currently under way), conducted in six *départements* with a sample of men who had retired between 1994 and 1996, shows the extreme variety of job periods which entailed exposure to asbestos. The EC emphasize that many sectors are exposed to asbestos, and that they are not the traditional industries of asbestos mining and processing. Thus, 45 per cent of building and public works occupations are exposed to asbestos. More than 40 per cent of industrial production jobs involve exposure to asbestos, metallurgy and the machines and tools sector being particularly affected.

3.82 The EC state that the study carried out by Y. Iwatsubo[101] on the French population confirms these data. This is one of the most important worldwide studies analysing the relationship between exposure to asbestos and the risk of mesothelioma; it covers the entire population of the country concerned. Although it had not been published at the time, this study was the subject of an analysis in the INSERM report (see pages 121 and 122). According to the EC, the very large scale of the study showed that there is a clear risk of cancer at levels of exposure that are lower than those previously recognized. This study shows that the vast majority of cases of cancer occur in workers who are "secondary users". Great numbers of people are often employed in the areas in question, which explains the large number of cases of mesothelioma which occur. The study shows, for example, that exposure to asbestos took place in 54 per cent of job periods in the construction sector.

3.83 The EC consider that the principal data which have been presented illustrate the ubiquity of asbestos in the workplace which can, at sufficiently high levels of exposure, lead to numerous cases of fatal disease. As a rule, the very many categories of workers affected handle materials containing asbestos sporadically, particularly asbestos-cement in building and public works occupations. These workers are often unaware of the risk they run. In fact, as Canada rightly and insistently notes, asbestos is undetectable when mixed with other materials, particularly cement. It is therefore not possible for the innumerable workers in all these sectors to be systematically informed of the risks they are taking when working with these materials. It is for this reason, above all, that there are also considerable risks to the general population such as do-it-yourself enthusiasts, who may often use products containing asbestos and may be exposed to significant quantities of asbestos dust when cutting, sanding, sawing and doing repairs of all kinds. It is therefore not entirely true, as Canada maintains, that there is no danger to the public from asbestos. According to the EC, Canada controversially finds that there is little difference between the undetectable risk associated with the levels of exposure in the ambient air - measured by the rate of asbestos fibres within a town or in the vicinity of a building - and the risks associated with the occasional, but sometimes high, levels of exposure which a very large section of a country's population may face.[102] Far from affecting only those working in asbestos production (mining and processing), the danger linked to inhaling asbestos at much higher levels than those cited by Canada is now particularly serious for users of products containing asbestos, whether they use such products in an occupational (textile workers, building workers etc.), para-occupational and/or domestic (do-it-yourself) context. In France, several hundred thousand or even millions of daily users of asbestos are therefore affected; they are never mentioned in Canada's submission.

3.84 **Canada** responds that, even if the EC refuse to recognize this fact, there are significant physical and chemical differences between chrysotile and amphibole asbestos, distinctions which are reflected in the pathogenic potential of the two types of asbestos. These distinctions are crucial in this case since the current problem of asbestos in France is due essentially to past uses and to the use of amphibole fibres. According to Canada, the distinction between chrysotile and amphibole asbestos is

[101] Iwatsubo, Y. *et al, Pleural Mesothelioma: Dose-Response Relation at Low Levels of Asbestos Exposure in a French Population-Based Case-Control Study*. American Journal of Epidemiology, 1998; 148:133-142.

[102] The EC emphasize that the INSERM report, so disparaged by Canada, also stressed the undetectability of the risks associated with very low exposures which are found in the ambient air of towns and buildings (see pp. 145 and 146, and 224-230).

also important by virtue of the fact that the extrapolations performed by INSERM to assess the risks associated with chrysotile asbestos are based on exposure to amphibole fibres, in proportions of up to 100 per cent and in circumstances which have nothing to do with the current uses of chrysotile asbestos.[103] Today, 97 per cent of chrysotile fibres are used in high-density and non-friable materials. Construction materials and pipes based on asbestos-cement account for nearly 90 per cent of the international market. Friction products, for their part, account for approximately 7 per cent of the market, with the remaining 3 per cent consisting of various products such as seals, textiles and membranes. The debate must therefore focus on the current uses of chrysotile, i.e. essentially chrysotile-cement.

3.85 In simple terms, according to Canada, three characteristics of fibrous materials are currently recognized as being significant parameters which determine biological activity: "durability" (or biopersistence), "dimension,"[104] and "dose."[105] In Canada's view, these characteristics are all relevant in the assessment of the health risk, as WHO, INSERM and the EC recognize.[106] It is important to highlight the lower biopersistence and pathogenicity of chrysotile fibres compared to amphibole fibres in order to demonstrate that the current health problems linked to asbestos are largely due to exposure to amphiboles. Canada emphasizes that the ban on current uses of chrysotile is not the solution to the health problems that France is experiencing today. The use of modern research techniques, in particular the mineral analysis of pulmonary tissues, sometimes called lung burden study, has made it possible to identify the "durability" factor as being a key parameter in the study of the pathogenicity of inhaled particles. This characteristic, which varies significantly from one particle to another and is probably linked to the chemical composition and crystalline configuration of the particles, will determine the extent of a basic biological phenomenon: biopersistence, i.e. the period during which the inhaled particles persist in the lungs and exert a harmful effect on the surrounding tissues before being eventually dissolved or eliminated.

3.86 Canada states that the recent studies which use both the fibre mass and the number of fibres as dose units confirm that amphiboles are more pathogenic than chrysotile.[107] The WHO declares that the use of gravimetric data "may be misleading when comparing samples of chrysotile and amphibole asbestos, because the former may contain more than ten times more fibres per unit weight".[108] Thus, the studies demonstrating that there is no distinction between chrysotile and amphiboles on a gravimetric basis mean in fact, according to the WHO, that amphiboles are more than ten times more dangerous than chrysotile, fibre per fibre. This is confirmed by INSERM, which reveals that the risk of mesothelioma is in fact ten times greater for amphiboles than for chrysotile.[109] Several studies

[103] See in particular INSERM report, p. 213.

[104] According to Canada, the pathogenicity of asbestos fibres varies depending on their dimensions. Hazardous fibres are defined as those having a length of more than 5 microns, a diameter of less than 3 microns and a length-diameter ratio of more than 3:1. See in particular *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, 1998, p. 14 . The longest and finest fibres pose the greatest health risk.

[105] According to Canada, the lack of epidemiological data demonstrating the risks associated with low-dose exposures makes it possible to state that the exposure levels associated with the current uses of asbestos do not pose any detectable health risk. See in particular *IPCS Environmental Health Criteria 203 on Chrysotile*, WHO, 1998, p. 144.

[106] *Id.*, p. 51; INSERM report, p. 90 *et seq.* See also para. 3.188 below.

[107] See *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998, pp. 69 and 81; INSERM report, Table 2, p. 196; EPA, Integrated Risk Information System, *Asbestos*, Document No. CASRN 1332-21-4 on-line: EPA, <http://www.epa.gov/ngispgm3/iris/subst/0371.htm> (access date: 10 June 1999). Canada points out that, in the large majority of the experimental protocols, the comparisons of the effects were still based on gravimetric data; i.e. the effects were produced by an equivalent mineral mass. In fact, retrospective attempts aimed at converting gravimetric doses into doses of numbers of fibres have indicated that, if based on the number of fibres, pathogenicity studies would show that, fibre for fibre, chrysotile fibres are less pathogenic than the other types of asbestos fibres, indeed even less than certain synthetic fibres.

[108] *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998, p. 69.

[109] INSERM report, Table 2, p. 196.

published in the early 1980s were conducted on samples of pulmonary tissues from workers whose deaths were thought to be linked to exposure to asbestos, compared to control subjects who had been exposed to various levels of urban pollution. The results showed that the quantities of amphiboles present in the pulmonary tissue of the experimental subjects were one hundred times higher than those found in the control subjects, but that the quantities of chrysotile were similar.[110] Thus, the workers died from exposure to amphiboles, not to chrysotile.

3.87 Canada states that, according to the WHO and studies reviewed by it, the biopersistence of chrysotile is lower than that of amphiboles:

> "The fractional deposition of chrysotile was lower than for amosite and crocidolite [...] The alveolar clearance of chrysotile was faster than that of crocidolite. [...] The retention of chrysotile, as measured a few days after the end of the 6-week exposure period, was only about one third that of amphiboles. [...] This difference in the lung clearance of chrysotile and amphibole fibres has been confirmed by several studies."[111]

3.88 Canada emphasizes that the half-life of amphibole fibres, although difficult to estimate, appears to be in the order of decades, while that of chrysotile fibres may be only a few months.[112] The research of Dr. Bernstein, on the basis of the Interim Protocol for the Inhalation Biopersistence of Mineral Fibres of the EC, confirms, in a 1998 study, the higher biopersistence of amphiboles compared to chrysotile. Chrysotile alone, according to Dr. Bernstein, "would have little if any toxicological effect."[113] Even INSERM recognizes "[Tr.] the difference in carcinogenicity between the two types of fibres for mesothelioma." According to INSERM: "[Tr.] experimental studies have shown that the biopersistence of chrysotile fibres was lower than that of amphiboles."[114] The IARC is of the opinion that the type of fibre must be duly taken into account in assessing the risks of lung cancer.[115] The IARC also recognizes that: "[I]n manufacturing and application industries mesotheliomas have been caused by exposure to crocidolite, and less frequently to amosite and chrysotile."[116] Finally, the IARC adds that when fibres are identified in the lungs, amphibole fibres are predominant.[117]

3.89 Canada also recalls that Drs. Kumar, Cotran and Robbins state, in their authoritative medical textbook on pathology:

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[110] See in particular Wagner, J.C. *et al. Correlation Between Fibre Content of the Lung and Disease in East London Asbestos Factory Workers* (1988) 45 British Journal of Industrial Medicine 305, according to which: "[W]e believe therefore that chrysotile is the least harmful form of asbestos in every respect and that more emphasis should be laid on the different biological effects of amphiboles and serpentine asbestos fibre."

[111] *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998, p. 60, citing Albin *et al., Retention Patterns of Asbestos Fibres in Lung Tissue Among Asbestos Cement Workers* (1994) 51 Journal of Occupational Environmental Medicine 205: "The present data indicate that chrysotile has a relatively rapid turnover in human lungs, whereas amphibole, tremolite and crocidolite, have a slower turnover."

[112] Mossman, B.T. and Churg, A., *Mechanisms in the Pathogenesis of Asbestosis and Silicosis* (1998) 157 American Journal of Respiratory and Critical Care Medicine 1666, p. 1669. The authors also state: "Both animal and human studies show that continuing exposure to amphiboles results in continuously increasing amphibole fiber levels recoverable from the lung, whereas continuing exposure to chrysotile is associated with a negligible increase in chrysotile fiber burden over time." (*Id., p.* 1669).

[113] Bernstein, D., *Summary of the Final Reports on the Chrysotile Biopersistence Study*, Geneva, 1998.

[114] INSERM report, pp. 395-96.

[115] IARC, Vol. 2, p. 17, para. 5.2, available on-line: IARC http://193.51.164.11/htdocs/monographs/Vol02/Asbestos.html> (access date: 10 June 1999).

[116] *Id.*

[117] IARC, Asbestos (Suppl. 7), Part A available on-line: IARC <http://193.51.164.11/htdocs/monographs/Suppl7/Asbestos.html> (access date: June 10, 1999).

> "The basis for the carcinogenicity of asbestos is still a mystery. Clearly, the physical form of the asbestos is critical; very nearly all cases are related to exposure to amphibole asbestos, which has long, straight fibers, and not to serpentine chrysotile."[118]

3.90 For his part, Prof. Sir Richard Doll states that:

> "First, there is the difference between the effects of chrysotile and amphiboles which is so great in relation to mesothelioma that it is possible to argue that chrysotile does not cause mesothelioma at all."[119]

3.91 Canada emphasizes that the French *Académie nationale de médecine* stated, in 1996, that amphibole fibres are "[Tr.] currently considered the most dangerous" and that chrysotile fibres are "[Tr.] considered to pose little danger because of their spontaneous degradation in the human organism. [...] Chrysotile asbestos is a form of asbestos which has not caused mesotheliomas, except in cases of massive and prolonged exposure. This is apparently explained by its solubility in the organism."[120] Canada recalls that, in 1997, the French Ministry of Labour, through the report of the *Groupe scientifique pour la surveillance des atmosphères de travail* (Workplace air quality scientific monitoring group) (G2SAT), cited by the EC, was of the opinion that chrysotile, once in an acidic medium – the lungs for example – ceases to exhibit "virtually any carcinogenic activity":

> "[Tr.] It has been demonstrated that chrysotile is much more easily eliminated from the human lung than the other forms. Moreover, it ceases to exhibit virtually any carcinogenic activity (by intra-cavitary injection) after acid attack, which dissolves most of the magnesium."[121]

3.92 Canada points out that chrysotile fibres are "curly" and downy whereas amphibole fibres are straight and rigid like needles.[122] A 1998 WHO study notes that "[I]nhalation of respirable straight fibres [amphiboles] is reported to be associated with greater penetration to the terminal bronchioles than in the case of 'curly' fibres [chrysotile]."[123] Once they have entered the respiratory tract, chrysotile asbestos fibres, because of their curly shape, are more easily cleared by the mucociliary process than straight and rigid amphibole fibres.[124] Canada observes that, for chrysotile fibres which nonetheless manage to become lodged in the lungs, the macrophages are able to deal more easily with chrysotile fibres than amphibole fibres. In addition, amphibole fibres are much more resistant than chrysotile fibres in an acidic medium such as the lungs; they will therefore remain there longer than chrysotile fibres. According to the WHO, the lower biopersistence of chrysotile compared to amphiboles may be due in part to the fact that chrysotile fibres dissolve in an acidic medium such as the lungs, while amphibole fibres resist dissolution in this medium.[125]

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[118] Kumar, V., Cotran, R. and Robbins, S., *Basic Pathology*, 6th Ed., London, Saunders Co., 1997, p. 435).

[119] Doll, R., *Mineral Fibres in the Non-Occupational Environment: Concluding Remarks*, in Bignon, J., Peto, J. and Saracci R., dir., *Non-Occupational Exposure to Mineral Fibres*, IARC scientific publication No. 90, 1989, pp. 511-518.

[120] See Académie nationale de médecine (Etienne Fournier), *Amiante et protection de la population exposée à l'inhalation d'amiante dans les bâtiments publics et privés*, Bulletin de l'Académie nationale de médecine, Vol. 180, no. 4, April 1996, p. 2.

[121] See INRS, *Rapport du Groupe scientifique pour la surveillance des atmosphères de travail" (G2SAT)*, 1997.

[122] *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998, p. 11.

[123] *Id.*.

[124] Kumar, V., Cotran, R. and Robbins, S., *Basic Pathology*, 6th Ed., London, Saunders Co., 1997, p. 228.

[125] *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998, p. 4. See also Kumar, V., Cotran, R. and Robbins, S., *Basic Pathology*, 6th Ed., London, Saunders Co., 1997, p. 227; INSERM report, p. 396.

3.93 Canada states that it is a basic principle in toxicology that the health risks posed by a toxic agent are directly proportional to the duration of the contacts with the target organs. Thus, since chrysotile is less biopersistent than amphiboles, it logically follows that chrysotile is less pathogenic. In a study by Coffin *et al*. cited by the WHO in 1998:

> "Large differences in the incidence of mesothelioma in intratracheal injection studies were demonstrated [...] crocidolite [was] 30-60 times more tumorigenic than chrysotile on fibre number basis."[126]

3.94 Canada points out that, contrary to what the EC and the United States claim, the United States EPA states that studies demonstrate a difference in carcinogenicity between the types of asbestos fibres.[127] The medical textbooks on pathology also indicate a clear distinction between amphiboles and chrysotile:

> "It is important to make the distinction between various forms of amphiboles and serpentines, because amphiboles, even though less prevalent, are more pathogenic than the serpentine chrysotile, particularly with respect to induction of malignant pleural tumors (mesotheliomas). Indeed, some studies have shown the link is almost invariably to amphibole exposure."[128]

This comes back to one of Canada's main criticisms of the INSERM report, i.e. that the extrapolations performed by INSERM are based on data on exposure to amphiboles or to mixtures of fibres containing amphiboles.[129] The danger of amphiboles cannot and must not be used to justify a ban on chrysotile, in light of the fundamental differences between the two types of fibres.

3.95 Canada asserts that convincing evidence of this distinction between the risk posed by chrysotile and the risk posed by amphiboles is the fact that the asbestos regulations in several industrialized countries make a clear distinction between the two types. Because of the greater risk involved, the regulations impose stricter exposure limits in the case of amphiboles than in the case of chrysotile. The following table indicates, for the sake of example, certain regulatory distinctions.

REGULATORY EXPOSURE LIMITS IN 1998[130]

Country	**Amphiboles**	**Chrysotile**
France (in 1994)	0.3 f/ml	0.6 f/ml
European Communities	0.3 f/ml	0.6 f/ml
Canada	0.2 f/ml (crocidolite) 0.5 f/ml (amosite)	1 f/ml
Spain	0.2 f/ml (amosite)	0.6 f/ml
Japan	0.5 f/ml	1 f/ml
United Kingdom	0.2 f/ml	0.5 f/ml

[126] *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998, p. 81.

[127] EPA, Integrated Risk Information System, *Asbestos*, Document No. CASRN 1332-21-4, available on-line: EPA, <http://www.epa.gov/ngispgm3/iris/subst/0371.htm> (access date: 10 June 1999).

[128] See Kumar, V., Cotran, R. and Robbins, S., *Basic Pathology*, 6th Ed., London, Saunders Co., 1997, pp. 227 and 228.

[129] See paras. 3.222 and 3.223 below. Canada draws attention to the statement by the WHO in 1998 that the use of this type of data: "contributes less to our understanding of the effects of chrysotile, due to concomitant exposure to amphiboles." *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998, p. 107.

[130] Canada notes that, in the case of bans on asbestos, the regulatory limits apply to asbestos already in place.

3.96 Canada notes that amphiboles have been banned in France since 1994, while chrysotile continued to be used there until 1997. Amphiboles have also been banned in the United Kingdom since 1992. Convention 162 and Recommendation 172 of the ILO both call for a ban on crocidolite, which they do not however impose for chrysotile.[131] A WHO Committee which met in Oxford in 1989 also made the same distinction in its recommendations: "For crocidolite and amosite asbestos, on the basis of health, it is recommended that their use be prohibited as soon as possible."[132] In the case of chrysotile, far from suggesting a ban, it suggests an exposure limit of 1 f/ml. The regulatory distinction recognizing the difference in pathogenicity is also found in the disputed Decree, which, for instance, makes an explicit distinction between amphiboles and chrysotile, permitting exceptions only for chrysotile and not for amphiboles. Canada points out that it has demonstrated that the pathogenic potential of amphiboles is much higher than that of chrysotile. Consequently, INSERM is taking the wrong approach by using exposure to amphiboles to determine the risks associated with chrysotile. It is the high pathogenicity of amphiboles – used more extensively in France than the EC would have one believe – which, with the use of friable materials, is the cause of the health problems observed today in the French population. Canada considers that serious questions must be raised as to the reasons which prompt the EC to ignore – indeed even to deny in the way they treat the available scientific data – the existence of all this evidence which establishes, beyond the shadow of a doubt, the significant difference in pathogenicity between chrysotile and amphiboles. Indeed, the latter are the basic cause of the French problem, while the former has no health effects when used in a context of controlled use.

3.97 Canada points out that the EC claim that there is no safe threshold of exposure to asbestos, whether of the amphibole or chrysotile variety.[133] INSERM came to a different conclusion, at least with respect to asbestosis:

> "[Tr.] Most of the epidemiological data gathered in exposed occupational populations suggest that clinically and/or radiologically confirmed asbestosis appears only following sufficiently high exposures […]."[134]

3.98 Canada recalls that the EC have adopted the position that human experience has not demonstrated the existence of a threshold of exposure in the case of lung cancer or mesothelioma below which exposure to asbestos dust poses no health hazard. On the contrary, human experience, via the epidemiological data, supports the idea of a threshold. According to Canada, it is wrong to claim that there is an "[Tr.] international consensus that there is no safety threshold for chrysotile."[135] An EC study cited by WHO suggests the existence of a threshold:

> "It is very likely that there is a practical level of exposure below which it will be impossible to detect any excess mortality or morbidity due to asbestos. [...] Thus, it is possible that there is a level of exposure (perhaps already achieved in the general public) where the risk is negligibly small."[136]

3.99 According to Canada, this appears also to be the position of the EC when they state that their main data "[Tr.] illustrate the ubiquitous nature of asbestos in the workplace which can, at sufficiently high exposure levels, cause numerous cases of fatal diseases."[137] On the contrary, this statement

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[131] International Labour Organization, Geneva, Convention concerning Safety in the Use of Asbestos (Convention 162, adopted on 24 June 1986), Article 11, and Recommendation concerning Safety in the Use of Asbestos (Recommendation 172, adopted on 24 June 1986), Article 18.

[132] WHO, *Occupational Exposure Limit for Asbestos*, Report prepared by a Group of Experts meeting in Oxford, April 1989.

[133] See paras. 3.76 *et seq* above.

[134] INSERM report, p. 327.

[135] See para.3.76 above.

[136] *IPCS Environmental Health Criteria 53 for Asbestos and Other Mineral Fibres*, WHO, Geneva, 1986, p. 143.

[137] See paragraph 3.83 above.

presumes that no disease appears at low exposure levels to asbestos dust in the workplace. The existence of a threshold suggests the possibility of demonstrating that the effect does not manifest itself at or under an identified dose. However, the unequivocal scientific demonstration of a zero effect is impossible, as DG XXIV acknowledges.[138]

3.100 Canada asserts that, when the available epidemiological data are insufficient to make it possible to determine the risks of cancer associated with low exposure to a toxic contaminant, a methodology called "risk analysis" is used. Quantitative risk analyses project the risks observed at high exposure (experimental or occupational studies) to low exposure possibly associated with unobservable low risks. Such projections outside the field of empirical observations must be based on mathematical models. Canada indicates that the linear model is one of the possible risk projection models. This model is simple to calculate mathematically and statistically. It implies, however, that there is no exposure value, no matter how low, which is not associated with a certain level of risk, no matter how low. The uncertain choice of the best model has a major impact on the estimated risk.[139] In the case of asbestos, the linear model is in fact used to extrapolate risks from workers heavily exposed in the past to the exposures 100,000 times lower of the general population and asbestos workers today. In statistics, any extrapolation far from the region of observations (observable values, available studies) is speculative and very risky.

3.101 According to Canada, the EC assert that the linear model is the most plausible by using the following fallacious argument: "[Tr.] This hypothesis of the linearity of the risk based on the level of exposure and the lack of a threshold are part of the currently accepted assumptions concerning carcinogens; for instance, it is included in the ILO encyclopedia. This hypothesis is therefore the most plausible." However, this does not mean that this is the most plausible model, but rather the simplest and most "conservative" model in that it projects higher risks in the region of low doses than the other mathematical models of carcinogenesis. The risk assessment agencies emphasize this distinction and this criterion.[140] The EC confuse the lack of an identified threshold with the lack of a threshold. For instance, the WHO report on chrysotile asbestos notes that: "No threshold has been identified for carcinogenic risks."[141] For Canada, this means simply that a specific threshold cannot be identified, if there is one. At no place in the WHO report or in any other risk assessment is it claimed that there is no threshold. On the contrary, this possibility is mentioned by the Health Effects Institute-Asbestos Review (HEI-AR). According to this group of international experts, which included experts in modelling of cancer risk such as J. Peto, D. G. Hoel and W. Nicholson, the linear dose-response model is not adopted for its validity but rather because it tends to over-estimate the actual risk. This model ignores the natural biological defence mechanisms against toxic invaders of

[138] *Opinion on a Study Commissioned by Directorate General III (Industry) of the European Commission on "Recent Assessments of the Hazards and Risks Posed by Asbestos and Substitute Fibres, and Recent Regulation on Fibres World-Wide"* (Environmental Resources Management, Oxford) (opinion expressed on 9 February 1998).

[139] According to Canada, the linear model predicts risks 100,000 times higher than those predicted by a "log-probit" model at doses 100,000 times lower than those for which risks have been observed. See Brown, C.C., Mantel, N., *Models for Carcinogenic Risk Assessment*, Science 1978; 202:1105.

[140] Environmental Protection Agency, *Guidelines for Carcinogen Risk Assessment*. Fed Reg 1986; 51, CFR 2984 (185/Sept.24):33,992-34,003. Health and Welfare Canada. *Carcinogen Assessment*. Ottawa, Canada: Dept. of Supply and Services Canada, 1991; 96. Health and Welfare Canada. *Carcinogen Assessment*. Ottawa, Canada: Dept. of Supply and Services Canada, 1992. National Research Council. Science and Judgment in Risk Assessment. Student Edition. Washington, D.C.: Taylor and Francis, 1996. National Research Council. Risk Assessment in the Federal Government: Managing the Process. Washington, D.C.: National Academy Press, 1983.

[141] *IPCS Environmental Health Criteria (203) on Chrysotile,* WHO, Geneva, 1998, p. 144, under a).

the body, which, as Canada has previously demonstrated, are very effective in the case of chrysotile.[142] With respect to the validity of the linear model in general, Prof. Doll wrote as follows:

> "We have no real ground for postulating that a linear relationship for lung cancer can be extrapolated back to the levels of dose with which we are concerned in non-occupational settings."[143]

3.102 Canada points out that, similarly, Ames and Gold wrote: "linear extrapolation from the maximum tolerated dose in rodents to low-level exposure in humans has led to grossly exaggerated forecasts in mortality."[144] E. Fournier and M.-L. Efthymiou are even more severe. In their view "linear extrapolation to zero is an unscientific methodology whose social consequences are so immense that it warrants unconditional elimination."[145] Canada indicates that, once a cell has been altered carcinogenically, there are natural defence mechanisms of the organ or of the organism which seek to destroy or eliminate the invaders.[146] The conventional models of carcinogenesis do not take this broader organic context into account. The EC and INSERM appear to confuse dose and exposure in their justification of the linear model. This model is applied to the ambient exposures of workers and of the general population, while it is justified in carcinogenesis on the basis of the effective dose of the target tissues. Not only is it implausible, according to Canada, that the dose-response relationship should be linear at the cellular level (level of mathematical modelling of carcinogenesis), but this is even more implausible at the level of the exposure-effects relationship. In fact, the deposition and clearance of solid particles in the lungs may be non-linear saturable processes,[147] in

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[142] HEI-AR, *Asbestos in Public and Commercial Buildings: A Literature Review and Synthesis of Current Knowledge (Executive Summary)*, Health Effects Institute – Asbestos Research, Cambridge, 1991, pp. 6-62.

[143] Doll, R., *Mineral Fibres in the Non-Occupational Environment: Concluding Remarks* in Bignon, J., Peto, J. and Saracci R., dir., *Non-Occupational Exposure to Mineral Fibres*, IARC scientific publication No. 90, 1989, pp. 516-17.

[144] Ames, B.N. and Swirsky Gold, L., *Causes and Prevention of Cancer: Gaining Perspectives on the Management of Risk*, in Risks, Costs, and Lives Saved: Getting Better Results From Regulation?, New York, OUP, 1996, p. 6.

[145] Fournier, E. and Efthymiou, M.-L., *Problems with Very Low Dose Risk Evaluation: the Case of Asbestos* in *What Risk?*, p. 49.

[146] According to Canada, simulations with stochastic mathematical models predict that as soon as "defenders" have an effectiveness greater than zero against "invaders", even a linear dose-response relationship at the cellular level will be transformed into an infra-linear relationship at the broader level of the organ or of the organism. See Holland, C.D., Sielken, R.L.J., *Quantitative Cancer Modeling and Risk Assessment*, Englewood Cliffs, New Jersey: Prentice Hall, 1993; Sielken Jr., R.L., Bretzlaff, R.S., Stevenson, D.E., *Incorporating Additional Biological Phenomena into Two-Stage Cancer Models* in Spitzer, H.L., Slaga, T.J., Greenlee, W.F., McClain, M., Eds. *Receptor-Mediated Biological Processes: Implications for Evaluating Carcinogenesis.* New York: Wiley-Liss, 1994; 237-60. Stevenson., D.E., Sielken Jr., R.L., Bretzlaff, R.S., *Challenges to Low-Dose Linearity in Carcinogenesis from Interactions among Mechanistic Components as exemplified by the Concept of "Invaders" and "Defenders"*, BELLE Newsletter 1994; 3(2):1-8. Stevenson, D.E., *Dose-Response Studies of Genotoxic Rodent Carcinogens: Thresholds, Hockey Sticks, Hormesis or Straight Lines? - Comment on the Kitchin and Brown paper*, BELLE Newsletter 1995; 3(3):14-15.

[147] Gart, J.J., Krewski, D., Lee, P.N., Tarone, R.E., Wahrendorf, J. *Statistical Methods in Cancer Research. Vol. III – The Design and Analysis of Long-term Animal Experiments*. IARC Scientific Publications. Vol. 79. Lyon: International Agency for Research on Cancer (WHO), 1986. Vincent, J.H., Donaldson, K., *A Dosimetric Approach for Relating the Biological Response of the Lung to the Accumulation of Inhaled Mineral Dust*, British Journal of Industrial Medicine 1990;47:302-7; Morrow, P.E., Muhle, H., Mermelstein, R., *Chronic Inhalation Study Findings as a Basis for Proposing a New Occupational Dust Exposure Limit*, Journal of the American College of Toxicology 1991;10(2):272-290; David, J.M.G., *The Role of Clearance and Dissolution in Determining the Durability or Biopersistence of Mineral Fibers*, Environmental Health Perspectives 1994;102 (Suppl.5):113-117; Hext, P.M. *Current Perspectives on Particulate Induced Pulmonary Tumours*, Human & Experimental Toxicology 1994;13(10):700-715; David, J.M.G., McDonald, J.C., *Low Level Exposure to Asbestos: Is there a Cancer Risk?* (Editorial). British Journal of Industrial Medicine 1988; 45:505-508; Lippmann, M., *Deposition and Retention of Inhaled Fibres: Effects on Incidence of Lung Cancer and Mesothelioma*. Occupational and Environmental Medicine 1994;51(12):793-798.

which case, even if the relationship between the dose in the tissues and the risk of cancer were linear, the relationship between dose and exposure would be infra-linear, perhaps even with a threshold, and the resulting relationship between exposure and risk would also be infra-linear, or with a threshold. And this would also depend on the type of fibres.[148]

3.103 Finally, Canada emphasizes that the available epidemiological studies which make it possible to study the relationship between lung cancer and exposure to asbestos are statistically compatible with the linear model, but when an *a priori* non-modelized method such as "adjustment by least squares weighted by distance" is applied, the form of the resulting curves is generally infra-linear, except in the case of workers exposed to 100 per cent amosite.[149] Infra-linearity and even a threshold have been noted by various researchers in the case of chrysotile-cement workers,[150] and miners exposed to vermiculite contaminated by tremolite.[151] For the reasons outlined above, in Canada's view, the linear model must be presented as a possible model yielding an upper risk limit, and not as yielding the most accurate or most probable risk estimate. Finally, the possibility of a threshold must be considered plausible and even very probable, even if it is difficult to determine this threshold quantitatively.[152]

3.104 The **European Communities** affirm that the carcinogenic character of asbestos for humans is internationally recognized. Since 1977, the WHO has recognized that all varieties of asbestos, including chrysotile, are carcinogenic, causing cancer of the lung or mesothelioma.[153] In 1986, the ILO advised lawmakers, through Convention No. 162[154], to have asbestos replaced by less harmful materials or technologies as soon as possible. In 1996, the WHO recommended that asbestos, including chrysotile asbestos, be replaced by harmless substitutes, wherever possible. In 1998, WHO reaffirmed the carcinogenic effect of chrysotile asbestos, particularly with respect to mesothelioma, continued to promote substitution and noted that the risk was very widespread among numerous categories of workers.

3.105 According to the EC, asbestos is at the root of a public health problem and chrysotile is the cause of most asbestos-related diseases. In 1998[155], the WHO reaffirmed that chrysotile "has been associated with an increased risk of pneumoconiosis, lung cancer and mesothelioma in numerous epidemiological studies of exposed workers", which confirms the conclusions of the 1996 INSERM report. Since asbestos began to be used for industrial purposes, chrysotile has accounted for about 95 per cent of world asbestos consumption. Between 1945 and 1980, about 97 per cent of the

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[148] Lippmann, M. *Deposition and Retention of Inhaled Fibres: Effects on Incidence of Lung Cancer and Mesothelioma*. Occupational and Environmental Medicine 1994;51(12):793-798.

[149] Camus, M., *Lung Cancer Mortality among Females in Quebec's Chrysotile Asbestos-Mining Areas compared to that predicted by the U.S. E.P.A. Exposure-Effect Model* [doctoral thesis]. McGill University, 1997.

[150] Hughes, J.M., Weill, H. *Asbestosis as a Precursor of Asbestos Related Lung Cancer: Results of a Prospective Mortality Study*. British Journal of Industrial Medicine 1991;48:229-233.

[151] Vacek, P.M., McDonald, J.C. *Risk Assessment using Exposure Intensity: an Application to Vermiculite Mining*. British Journal of Industrial Medicine 1991;48:543-547.

[152] Canada notes that Dr. Gibbs (*A Review of the Report: "Rapport d'expertise collective INSERM*" October 1996, in paragraph 12) cites studies demonstrating the existence of a threshold, notably: Berry, G., *Mortality and Cancer Incidence of Workers Exposed to Chrysotile Asbestos in the Friction-Products Industry* (1994) 38 Ann. Occup. Hyg. 539; Newhouse, M.L. and Sullivan, K.R., *A Mortality Study of Workers Manufacturing Friction Materials:* 1941-1986 (1989) 46 British Journal of Industrial Medicine 1.

[153] According to the EC, it is estimated that asbestos causes twice as many cancers of the lung as cancers of the pleura (mesotheliomas), see Stayner *et al. Exposure to Chrysotile Asbestos and Cancer Risk: a Review of the Amphibole Hypothesis*, American Journal of Occupational Health, 1996, 86:179-186.

[154] International Labour Organization, Geneva, Convention concerning Safety in the Use of Asbestos (Convention 162, adopted on 24 June 1986), International Labour Conference, Geneva. See, in particular, Article 10.

[155] *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998.

asbestos consumed in France was chrysotile asbestos. Since 1988, chrysotile has accounted for all the asbestos consumed in France.[156] According to the EC, these figures show that most asbestos-related diseases are caused by chrysotile and not amphiboles, as Canada would have the Panel believe. This is confirmed by recent publications. Thus, according to the study by Stayner *et al*.:

> "Our review of both the toxicologic and epidemiologic literature strongly supports the view that occupational exposure to chrysotile asbestos is associated with an increased risk of both lung cancer and mesothelioma".[157]

3.106 The EC note that the study coordinated by J. Peto[158] and published in 1999 found that in six European countries (France, Germany, Italy, Netherlands, Switzerland, United Kingdom) nearly 10,000 people died of mesothelioma between 1990 and 1994. Moreover, it estimated that during the period 1995-2029 about 200,000 people would die of mesothelioma. If these figures are extrapolated to all the countries of Western Europe and deaths due to lung cancer are included, then the results show that exposure to asbestos could lead to about 500,000 deaths by cancer between now and 2029. In France, the number of deaths due to mesothelioma is increasing steadily. A recently published study[159], similar to that made by Peto *et al*., predicts that the annual number of deaths due to mesothelioma in France will go on increasing up to 2020. It is estimated that in France over the entire period 1996-2020 a total of 20,000 men and 2,900 women will die of mesothelioma.

3.107 The EC state that chrysotile poses a threat to an extremely large section of the population. Several scientific studies show that a huge range of occupations and economic sectors is at risk.[160] For a long time, the asbestos producing and consuming countries considered that the risks of cancer were wholly restricted to "primary users"[161] (asbestos miners and workers in the asbestos-processing industry). In the early 1990s, an international scientific consensus emerged to the effect that the asbestos-related risks for secondary users (users of asbestos-based products, servicing and maintenance workers, "do-it-yourself" enthusiasts, and specialists in asbestos removal and containment) had been historically underestimated.[162] According to the EC, many sectors are exposed to asbestos and they are usually far from fitting the description of the traditional asbestos mining and processing industries.[163] Thus, 4 per cent of construction industry trades and 4 per cent of jobs in the industrial manufacturing sector are exposed to asbestos. As noted by the WHO in its report 203 on the risks of chrysotile asbestos: "Risks are likely to be greater among workers in construction and possibly other user industries".[164] The recent study by Y. Iwatsubo *et al*.[165] shows that the great majority of cancer cases occur among "secondary users". These workers are often unaware of the risk they are running, since when asbestos is mixed with other materials, particularly cement, its presence is not readily discernible.

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[156] See para. 3.22 above.

[157] Stayner, L.T. *et al*., *Occupational Exposure to Chrysotile Asbestos and Cancer Risk: a Review of the Amphibole Hypothesis*, American Journal of Public Health. 1996, 86:179-186. Smith *et al*., *Chrysotile Asbestos, the Main Cause of Pleural Mesothelioma*, American Journal of Industrial Medicine, 1996, 30:252-266.

[158] Peto *et al., The European Mesothelioma Epidemic*, British Journal of Cancer (1999), 79 (3/4), 666-672.

[159] Gilg Soit Ilg, A., Bignon, J., Valleron, A-J., *Estimation of the Past and Future Burden of Mortality from Mesothelioma in France*. Occupational Environmental Medicine, 1998; 55:760-765.

[160] See paras. 3.78 *et seq.* above.

[161] See para. 3.59 above.

[162] Health and Safety Commission, United Kingdom, (1999), *Proposals for Amendments to the Asbestos (Prohibitions) Regulations 1992*. See also para. 3.59 above.

[163] See paras. 3.78 *et seq*. above.

[164] *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998.

[165] Iwatsubo, Y. *et al*, *Pleural Mesothelioma: Dose-Response Relation at Low Levels of Asbestos; Exposure in a French Population – Based Case – Control Study*, American Journal of Epidemiology, 1998, Vol.148, no. 2.

3.108 The EC stress that the international scientific community does not recognize the existence of a threshold of harmlessness for chrysotile. It is important to note the distinction between the establishment of occupational exposure limits and the existence of a threshold of harmlessness below which there is no risk to health. The occupational exposure limits take into account various criteria, including the technical feasibility of obtaining sufficiently low exposure levels in the workplace and the technological means of measuring actual levels for monitoring purposes. Thus, the occupational exposure limit does not correspond to a threshold of harmlessness which, in the case of asbestos, has never been found. Since as long ago as 1976, the IARC has recognized that "at present it is not possible to assess whether there is a level of exposure in humans [to asbestos] below which an increased risk of cancer would not occur".[166] This position received support from the WHO in its 1998 report[167], which states that "no threshold has been identified for carcinogenic risks", thus confirming the conclusions of the 1996 INSERM report. According to the EC, all the scientific studies show the existence of a linear relation between the dose of asbestos inhaled and the risk of cancer. In 1998, the WHO[168] noted that "there was a clear dose-response relationship (...)". The results of more recent studies[169] confirm the impossibility of identifying a threshold below which asbestos would not present any risk for the populations exposed. As pointed out in the Collegium Ramazzini report, "The strictest occupational exposure limits in the world for chrysotile asbestos (0.1 f/cc) are estimated to be associated with lifetime risks of 5/1,000 for lung cancer and 2/1,000 for asbestosis (Stayner *et al*., 1997)." The EC incorporate here, by reference, the report by the Collegium Ramazzini communicated to the Panel on 7 May 1999.

3.109 The EC state that the number of cases of asbestos-related diseases correlates with the amount of asbestos imported. An analysis of the data for ten Western countries shows a very strong correlation between the incidence of mesothelioma and per capita asbestos consumption measured in terms of imports. In each country, the number of cancer cases increases in proportion to the increase in asbestos imports.[170] Accordingly, in view of the acknowledged carcinogenicity of asbestos, whatever the variety, the number of deaths recorded or predictable over 30 years, the absence of a threshold of harmlessness, the proportion of total asbestos consumption represented by chrysotile and the direct link between the amount of asbestos used and the number of cancer cases, it is essential to stop the risk from spreading by banning all future use of asbestos, whether amphibole or chrysotile.

3.110 The EC state that France has the right to establish its own level of protection against the inhalation of asbestos fibres. The scientific findings available to France when it took its decision to ban asbestos were unambiguous. It has been scientifically established that: (i) chrysotile is a toxic material which has a dramatic effect on health (mesothelioma, cancer of the lung, asbestosis) and is no less toxic than other varieties of asbestos; (ii) there is no threshold of harmlessness as far as the carcinogenicity of chrysotile is concerned and large numbers of people (several millions) are at risk; (iii) controlled use is neither applicable nor effective; (iv) the substitutes for asbestos in asbestos cement (PVA, cellulose) and para-aramids give no cause for concern, asbestos- cement accounting for the vast majority (90 per cent) of the asbestos being used at the time of the ban; (v) there is no evidence of the other substitutes (man-made mineral fibres) being carcinogenic in humans. Among these substitutes, only ceramic fibres, which are very rarely used (to withstand very high temperatures), are carcinogenic in animals and should therefore be employed with due care.

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[166] Landrigan, P.L., *Asbestos – Still a Carcinogen,* 338, New England Journal of Medicine 1619 (May 1998).

[167] *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998.

[168] *Id.*.

[169] Iwatsubo, Y. *et al*, *Pleural Mesothelioma: Dose-Response Relation at Low Levels of Asbestos; Exposure in a French Population – Based Case – Control Study*, American Journal of Epidemiology, 1998, Vol.148, no. 2.

[170] Takahashi, K. *et al., Ecological Relationship between Mesothelioma Incidences/Mortality and Asbestos Consumption in Ten Western Countries and Japan,* Journal of Occupational Health, 1999, 41:8-11.

3.111 The EC emphasize that the scientific data on which France based its case were of very high quality. The substitute fibres are more than 10 microns in diameter, which makes it physically impossible for them to penetrate into the pulmonary alveoli. With regard to the effects of asbestos on health, France based its case on the joint report of INSERM[171], one of the most important world biological and medical research bodies. INSERM's report consisted of a critical and reasoned review of the world scientific literature by a multidisciplinary team of 11 scientific experts. The method and scope of this work (12 chapters of discussion supported by 1,200 bibliographic references) make it fundamentally different from any monograph or fragmentary study. The quality of the work has been acknowledged by the entire scientific community, including the Canadian experts. The United States, in its third-party submission, fully endorses the conclusions of the INSERM report, including those concerning linear extrapolation to low doses. The EC consider, therefore, that Canada cannot criticize France for basing its case on this report. France has been concerned with the question of substitutes for asbestos ever since it began considering a ban. At the same time as it requested a report on asbestos from INSERM, in the autumn of 1995, France requested an initial report on man-made mineral fibres from the *Groupe de surveillance des atmosphères de travail*[172] (G2SAT) in order to obtain an initial insight into the harmfulness of the most suspect fibres which the proponents of the controlled use of asbestos are always stressing. This group based its conclusions on previous scientific research conducted over a period of many years.[173] The conclusions of G2SAT, submitted to the Government in June 1996, were confirmed by the results of the INSERM report on man-made fibres begun shortly after the submission of the report on asbestos. The fibres used as a substitute for asbestos in asbestos-cement were found to have given no cause for concern. This was confirmed by the report of the CSTEE[174] of DG XXIV of the Commission of the European Communities, and then by the United Kingdom's COC.[175] The scientific data on substitute fibres, on which France based its decision to ban asbestos, are thus broadly supported by other scientific authorities. According to the EC, Canada cannot maintain that France has replaced asbestos with the "unknown" risk of substitutes.

3.112 The EC state that, in the light of this assessment of the risk based on sound and internationally recognized scientific findings, France has adopted a risk management regime. As "safe" use is insufficient to eliminate the risk of an excess of cancers and as France is applying, on the one hand, the principle of replacement by a less dangerous product and, on the other, the principle of reduction of the risk to the lowest level technically feasible, it has decided to impose a ban with exceptions. The EC contend that this is the only solution capable of preventing the spread of the risk associated with materials containing asbestos. The measure is sharply reducing asbestos consumption, which is known to be very closely linked with the incidence of asbestos-related diseases. This solution offers every technical guarantee of safety since provision is made for exceptions when substitution does not ensure equivalent performance. At the same time, France has undertaken to explore the question of substitute products[176] in greater depth. It is also simultaneously strengthening the measures designed to protect workers exposed to "*in situ* asbestos", namely, the hundreds of thousands of maintenance workers, as well as the much smaller numbers engaged in more dangerous work such as asbestos

[171] Peto *et al*, *The European Mesothelioma Epidemic*, British Journal of Cancer, 1999, 79 (3/4): 666-672.

[172] *Fibres minérales artificielles et amiante (Résumé)*, Report of the *Groupe scientifique pour la surveillance des atmosphères de travail (G2SAT)*, INRS – DMT no. 69.

[173] The EC refer in particular to the WHO publication, *Environmental Health Criteria 151, Selected Synthetic Organic Fibres*, WHO, Geneva 1993.

[174] *Avis concernant l'amiante chrysotile et les produits de substitution envisageables*, Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), 15 September 1998.

[175] *Statement for Health and Safety Executive (HSE) on Carcinogenic Risks of Three Chrysotile Substitutes*, Committee on the Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC), July 1998.

[176] The EC point out that, as soon as the INSERM report on man-made mineral fibres came out, France adopted an action plan aimed at protecting workers exposed to man-made mineral fibres.

removal and containment. France is also reinforcing its building surveillance measures by monitoring false ceilings, as well as flocking and lagging.

3.113 The EC emphasize that the aim of the Decree is consistent with the WHO and ILO recommendations. It is intended to establish an obligation to replace asbestos and products or materials containing asbestos whenever alternative materials or techniques are available, assuming always that they constitute a lower risk. The Decree provides for temporary exceptions to the rule in those very few cases in which there is no lower-risk substitute capable of ensuring equivalent performance. For these residual uses of asbestos, enterprises must request a waiver and undertake to carry out research with a view to abandoning the use of asbestos as quickly as possible. An enterprise which replaces asbestos with another material must rigorously: (i) ensure that, in the light of the knowledge available, the substitute represents a reduced risk to the health of a worker handling the product; and (ii) test the finished product in order to verify that it offers every technical guarantee of safety appropriate to its end use. Some three years after the Decree came into force, the use of asbestos in France is now much reduced and only involves a few precisely targeted and not very widespread industrial applications. The EC estimate that almost 100,000 tonnes of carcinogenic fibres have therefore been eliminated during this period in the form of materials potentially dangerous for the user and have been kept out of French buildings and factories.[177]

3.114 According to the EC, Canada's case is based on incomplete and largely erroneous data. In its arguments, Canada relies heavily on assertions which have no scientific foundation and, more often than not, are based on old or partial reports that are scientifically obsolete or of very debatable value. Canada makes many erroneous statements in support of its case and seeks to obscure well-established facts by creating confusion or omitting important data. The EC contend that many of Canada's assertions are unfounded or erroneous, for example:

(a) The characteristics of chrysotile:

  (i) The failure to make a distinction between the risk of mesothelioma and the risk of cancer of the lung: Canada regularly omits to point out that, whereas the risk of mesothelioma is lower for chrysotile than for amphiboles, this is not true for cancer of the lung;

  (ii) The assertion that the risk due to chrysotile is "undetectable", whereas many scientific studies show that its effects are indisputable.

(b) The French data:

  (i) The assertion that amphibole fibres were "widely used" in France is absolutely wrong;

  (ii) The assertion that France has favoured French products, whereas the EC has emphasized that most of the products used as substitutes for asbestos are imported into France.

(c) "Safe" use:

  (i) The assertion that there is no scientific evidence of risks linked with so-called "modern" use (also called "controlled" or "safe" use) of chrysotile, whereas numerous scientific publications cited by the EC (but not mentioned by Canada) clearly show the opposite to be true;

[177] The EC note that, in 1994, France imported 35,000 tonnes of asbestos and produced 436,000 tonnes of asbestos-cement (Source: Association Française de l'amiante).

(ii) The assertion that "there are effective methods for reducing dust creation" and that the safe use of asbestos is "based on proven scientific knowledge", whereas all the data by the EC show the opposite to be true.

3.115 The EC state that Canada is seriously confusing the issue or making significant omissions.

(a) Confusing the issue:

(i) Confusing the level of chrysotile fibres in the environmental ambient air with that in the workplace by suggesting that the very low levels of fibres encountered in the ambient air of cities and buildings are the only problem potentially linked with asbestos. The level of 0.0005 fibre per ml of air, which Canada always cites to show that the corresponding risk is "undetectable" or zero, is about 100,000 times lower than that created by certain routine operations on asbestos-cement parts;

(ii) Systematic confusion between friable products and amphiboles with non-friable products and chrysotile. In reality, raw asbestos, whether of the amphibole or chrysotile variety, is always spontaneously[178] friable. It is quite wrong to associate amphiboles exclusively with friable products, such as flocking and lagging, and chrysotile exclusively with non-friable products, such as asbestos- cement. Since amphiboles were banned, all asbestos-containing products, whether friable or non-friable, have been based on chrysotile.

(b) Omissions

(i) Systematic omission of the circumstances of occupational exposure most dangerous to health. Thus, in its description of the circumstances of exposure in the construction industry, Canada mentions construction and demolition activities, but simply disregards the fact that once asbestos has been used in the construction of a building, and until the latter is demolished, any installation containing asbestos is likely, during its life cycle, to require some form of plumbing, heating or electrical work carried out by professionals or amateurs.

(ii) Systematic omission of the high occupational levels of exposure associated with everyday uses. Canada cites only a few figures indicating low levels of exposure, omitting to mention the very high figures encountered daily, although they are well-known and have been widely published;

(iii) Systematic omission of the data on the ill-effects on health associated with the use of chrysotile in Canada itself. Thus, Canada seems to be unaware of its own statistics, which reveal a very sharp and rapid increase in cancers caused by chrysotile. Canada must be aware of the publicly-funded scientific research being carried out in Canada by well-known research teams, the results of which are widely published in the scientific press. Canada never refers to this work, which shows that in Canada the risks due to chrysotile are high and at least as great as in the other industrial countries;

(iv) Systematic omission of the most recent scientific research confirming the risks associated with chrysotile, in particular the reports of international

[178] That is, without human intervention, explain the EC.

> organizations to which Canada itself belongs. Thus, Canada cites two World Health Organization reports, one of which dates from 1986 and the other from 1988. It appears that, for Canada, research and the acquisition of new knowledge came to a halt more than ten years ago. Thus, Canada makes no reference to report 203 of the World Health Organization published in 1998 (although it is clearly identified as being an update of the 1988 report), which recognizes the dangers to health posed by chrysotile asbestos and clearly expresses doubts about the possibility of effectively controlling exposure in the building industry.

3.116 The EC state that Canada is using reports whose scientific value is highly debatable or citing reports too selectively. Canada considers that France's ban on all forms of asbestos is not scientifically well-founded. This criticism is mainly based on two reports. These reports are, however, of very debatable scientific value or cited only selectively, with the omission of those elements that conflict with Canada's point of view. According to the EC, the report of the *Académie Nationale de Médecine*, signed by E. Fournier[179], is of debatable value. As pointed out by Prof. Terracini of the University of Turin[180]: "a major limitation of this report is the total lack of bibliographic references. In addition, it is severely unbalanced on several issues". Drawn up by someone who had never previously published anything in the field of asbestos-related risks[181], the report can be no more than the expression of a personal opinion. In this respect, Prof. Terracini's conclusion is unequivocal:

> "This report has been obviously written by persons with no knowledge of the epidemiological methods and of the subtleties of causal inference. It provides no original information and can hardly be of any use in an overall evaluation of the case".

3.117 The EC state that the report of the Royal Society of Canada was prepared in haste at the request of the Canadian Government.[182] It should be noted, first of all, that on its own admission the Royal Society of Canada's Panel of scientific experts had to work too quickly, as it several times acknowledges (see, for example, page 15 of the English text), was not able to reach a consensus among its members (page 15 of the English text) and worked on an incomplete draft of the INSERM report (page 1 of the English text), which obviously explains certain erroneous interpretations resulting from a misunderstanding of the text. The arguments developed in the Royal Society of Canada report have already been the subject of a detailed analysis which showed that the criticisms of the INSERM report were based on an over-hasty reading of an incomplete document and are not well-founded.[183] The EC note, furthermore, that Canada used the Royal Society of Canada report partially and selectively and, in any event, failed truly to reflect the opinion of the group of scientific experts on the main conclusions of the INSERM report. In this connection, the following extracts from the Royal Society of Canada report should be cited:

> "The Panel agreed with INSERM's findings on the following points: all asbestos fibres are carcinogenic, regardless of their mineralogical nature; the risk of lung cancer is higher for longer and finer fibres for low dose and dose-rate exposures, the linear no-threshold model is used by all

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[179] Académie Nationale de Médecine (Etienne Fournier), *Amiante et protection de la population exposée à l'inhalation de fibres d'amiante dans les bâtiments publics et privés*, Bulletin de l'Académie Nationale de Médecine, Vol. 180, no. 4, April 1996.

[180] B. Terracini, *Review of Technical and Scientific Documents Annexed by Canada to its Submission of April 26*, document of 19 May 1999, submitted to the Panel by the EC on 21 May 1999.

[181] The EC note that an extensive search of the international bibliographical databases failed to reveal any scientific publication by the author of this report concerned with the study of asbestos-related risks.

[182] Royal Society of Canada, *A Review of the INSERM Report on the Health Effects of Exposure to Asbestos*, Royal Society of Canada, Ottawa, 1996.

[183] Terracini, B., *Review of Technical and Scientific Documents Annexed by Canada to its Submission of April 26*, document of 19 May 1999, submitted to the Panel by the EC on 21 May 1999.

> regulatory agencies that have performed quantitative risk assessments; research should be done on substitutes for asbestos; the linear no-threshold hypothesis for low exposure levels is not the only possible strategy in risk assessment, but evidence is not available to demonstrate that a different hypothesis is a superior predictor of risks from low exposures." (pages 4-6 of the English text)

3.118 The EC stress that the points on which the Royal Society of Canada says it agrees with the INSERM report are the essential points on which the French decision to ban asbestos is based.

> "Our hope was that we could give consensual answers. We could not always do so. In retrospect, the hope seems to have been foolishly optimistic. Scientists cannot achieve consensus on contentious issues after two weeks of reading and two days of face-to-face discussion." (pages 14 and 15 of the English text)

3.119 In conclusion, the EC emphasize that Canada's assertion that the experts who analysed the INSERM report "sharply criticized" the methods employed and "very severely criticized" its conclusions is, at the very least, tainted with partiality and does not truly reflect the contents of the Royal Society of Canada report. Moreover, it is inconsistent with almost all the scientific data from the relevant international institutions.

5. "Controlled" or "safe" use of chrysotile asbestos

3.120 **Canada** emphasizes that the public's perception of the harmful health effects of using different types of asbestos in various applications has exerted a greater influence on risk management decisions than risk evaluation has. This phenomenon is the result of a conceptual confusion between the terms "hazard" and "risk". Information on "hazards," erroneously presented as information on "risks", has provoked unjustified fears with regard to the undesirable effects of asbestos, such as cancer, in the population. In Regulation No.1488/94 of the European Commission[184], hazard is described as being "the adverse effects which a substance has an inherent capacity to cause". Risk, on the other hand, is defined as "the likelihood that an adverse effect will be caused under the known or the reasonably foreseeable conditions of use". Thus, it is appropriate to distinguish between the "hazards" associated with chrysotile fibres and the "risks" associated with the modern uses of chrysotile fibres. According to Canada, the characterization of the hazardous properties of a substance is not the same as an evaluation of the real risk of all its uses. The evaluation of the associated hazards is an important element but not sufficient in itself to evaluate the risk, which also encompasses evaluating the exact nature of the substance, data on long-term exposure and estimating the probable risk under current conditions of use. Thus, it is essential that the issue of the risks associated with a product be evaluated in the light of its various uses.

3.121 Canada points out that, today, chrysotile represents more than 97 per cent of the asbestos used. Its use is limited to a certain number of high-density applications, above all construction products based on chrysotile-cement, friction materials based on chrysotile and a number of plastic, resin and bitumen materials containing chrysotile, all of which are safe applications. The distinction between these uses and past uses is vitally important when evaluating the real risks posed by chrysotile. In Canada's view, an evaluation of the effects of asbestos in the workplace or in the environment must take into account the latest risk analyses, the current occupational exposure limits and modern applications using chrysotile exclusively in high-density materials. The risk can be managed through numerous forms of government action. In the case at issue, two forms of government action are examined for the purpose of determining the appropriateness of the French measure: controlled use; and the complete ban on asbestos, without distinction among the types of asbestos fibres and their multiple uses.

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[184] Commission Regulation (EC) No.1488 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No.793/93, O.J., L.161/3.

3.122 According to Canada, the appropriate manner of regulating asbestos must be seen in a broad context. In a world in which global trade is becoming increasingly extensive, it is all the more important to adopt a uniform approach to the formulation of policies and regulations. The most effective and objective way to deal with these matters is to seek an international consensus whenever possible. With regard to asbestos, in Canada's view, the scientific data provide a solid basis for reaching sensible decisions regarding the regulation not only of asbestos, but also of the growing number of potentially hazardous fibres in general, some of which are being used in France as a substitute for asbestos. The lessons to be learned from the uncontrolled use of asbestos point to the importance of establishing appropriate regulations. The most logical and consistent approach to regulation is to reach an international consensus based on the best scientific data. Thus, controlled use means establishing and applying appropriate regulations to ensure the rigorous control of exposure to chrysotile and products containing chrysotile, with the aim of reducing to an undetectable level the risks associated with the extraction, crushing, manufacturing, shipping and handling of this product. Chrysotile is expressly mentioned because the use of amphiboles is banned virtually everywhere at the present time. The principle of controlled use also means that certain uses for which exposure cannot be controlled to an acceptable degree should be banned.

3.123 Canada considers that one of the most in-depth reports on the effects of asbestos and asbestos-containing products is the report published in 1984 by the Royal Commission on Matters of Health and Safety arising from the Use of Asbestos in Ontario. This report, still considered one of the most exhaustive studies of asbestos, recommends that the use of chrysotile be continued under conditions of controlled use.[185] In 1988, under the aegis of the International Programme on Chemical Safety of the World Health Organization (WHO), a working group was convened to evaluate the environmental contamination caused by asbestos. In its recommendations, the working group drew a distinction between the risks posed by brittle, low-density products and the risks posed by high-density products such as chrysotile-cement. The working group recommended that the use of low-density products be discouraged all over the world. It also concluded that the normal use of products containing high-density chrysotile, including chrysotile-cement, does not pose a risk to the general public.[186] In 1989, a group of experts met at Oxford under the aegis of the WHO and formulated recommendations for exposure to asbestos limits in the workplace. In their final report, the participants recommended a maximum exposure of 2 f/ml (weighted average over eight hours), an objective that can be reached everywhere at low cost, and expressed their desire to see efforts made to reduce this rate to 1 f/ml.[187]

3.124 Canada emphasizes that, apart from the regulation of exposure to chrysotile limits in the workplace, the issue of asbestos in buildings, both with regard to occupants and to maintenance and repair crews, has been addressed on several occasions. A study by the HEI published in 1991 concluded that there is not sufficient evidence of health risks to the occupants of buildings where sprayed asbestos is used to justify the removal of intact materials containing asbestos.[188] According to Canada, the conclusions of the HEI are in agreement with those of the experts from around the world who attended a symposium held at Harvard University in 1989 on the health aspects of exposure to asbestos in buildings.[189] The report of this symposium states that the dust diffusion values in buildings where materials containing asbestos have been used are extremely low.[190] The report also

[185] Report of the Royal Commission on Matters of Health and Safety arising from the Use of Asbestos in Ontario, Table of Contents and Overview, Toronto, Queen's Printer, 1984.

[186] International Programme on Chemical Safety, *Report of an IPCS Working Group Meeting on the Reduction of Asbestos in the Environment*, Rome, 12-16 December 1988,WHO, Geneva, 1988, p.19.

[187] WHO, *Exposure to Asbestos Limits in the Workplace*, Report prepared by a WHO committee, Oxford, United Kingdom, 10 and 11 April, 1989, p.12.

[188] *Asbestos in Public and Commercial Buildings: A Literature Review and Synthesis of Current Knowledge* (Executive Summary*)*, Health Effects Institute – Asbestos Research, Cambridge, 1991, p. 1-12.

[189]Spengler, J. *et al.*, *Summary of Symposium on Health Aspects of Exposure to Asbestos in Buildings*, Energy and Environmental Policy Center, Harvard University, 14-16 December 1988, pp. 26 and 27.

[190]*Id.*, p.27.

states that the risk posed by installed asbestos is very low, both in absolute and relative terms, and that this risk is much less acute than most other environmental hazards, including cigarette smoke and radon, for instance.[191] Nonetheless, the report continues, increased protection should be afforded to public works and maintenance crews exposed to brittle asbestos that can be disturbed.[192]

3.125 Canada points out that all international standards on asbestos establish parameters for its controlled use. Chief among these is Convention 162 concerning Safety in the Use of Asbestos and the accompanying Recommendation 172.[193] These standards were adopted in 1986 by representatives of governments, industry and labour unions meeting under the aegis of the International Labour Organization (ILO). Convention 162 recommends strict regulation of chrysotile, but does not recommend a total ban, except for crocidolite and sprayed asbestos. Recommendation 172 sets forth the minimum labour standards to be observed in order to prevent and control the risks associated with occupational exposure to chrysotile. Countries which ratify Convention 162 concerning Safety in the Use of Asbestos make a commitment to implement laws and regulations prescribing the measures to be taken to prevent and control the health risks associated with occupational exposure to asbestos and to protect workers against these risks. In addition, there exists a general reference code, the collection of the International Labour Office entitled *Code of Practice on Safety in the Use of Asbestos*.[194] The guidelines contained in this Code are aimed at preventing, eliminating or reducing as much as possible the exposure to asbestos dust and safeguarding the health of workers engaged in operations that could give rise to such exposure. The first part of the Code deals with workplace regulations, methods of prevention, packaging, shipping and intermediate storage of asbestos, the elimination of debris and the protection of workers' health. The second part deals with prevention in certain activities: mining extraction, the manufacturing and utilization of asbestos products (asbestos-cement, friction products, etc.), insulation work, construction work and demolition work. Finally, the ISO[195] has issued a number of standards applicable, *inter alia*, to the diverse applications making use of asbestos. These standards cover the use of a broad range of modern products containing chrysotile-cement, including tubes, corrugated, ribbed and smooth panels, shingles and pipes. In particular, they contain guidelines for construction sites where asbestos-cement products are in use.

3.126 Canada notes that, in the United States, the attempt by the EPA to ban asbestos failed. In 1989, the EPA adopted a regulation that provided for the prohibition and progressive elimination of 94 per cent of all commercial uses of asbestos over a period of seven years. In so doing, the EPA had wholly disregarded all the evidence submitted to it indicating that the past, outdated uses of asbestos did not provide any justification for a complete ban and that chrysotile asbestos can be used in a safe manner. The EPA did not consider either the uncertainty surrounding the health risks of using substitute products or the additional costs of using such substitute products. The EPA regulation banning asbestos was appealed in court. The Court of Appeals concluded that the risks presented by the EPA were not supported by the scientific facts.[196] The Court ruled that the EPA would have to prove that the products covered by the ban posed an unacceptable risk. Thus, the ban was annulled

[191] *Id*., p.26.

[192] *Asbestos in Public and Commercial Buildings: A Literature Review and Synthesis of Current Knowledge* (Executive Summary), Health Effects Institute – Asbestos Research, Cambridge, 1991, pp.1-12.

[193] Convention concerning Safety in the Use of Asbestos (Convention 162), adopted on 24 June 1986, International Labour Conference, Geneva; Recommendation concerning Safety in the Use of Asbestos (Recommendation 172), adopted on 24 June1986, International Labour Conference, Geneva.

[194] Code of Practice on Safety in the Use of Asbestos, International Labour Organization, Geneva, 1984.

[195] International Organization for Standardization, Standard ISO-7337, 1984.

[196] Ruling of the 5th Circuit Court of the United States dismissing the EPA regulation, handed down on 18 October 1991.

and the EPA was ordered to consider all the evidence that it had initially disregarded. In 1997, practically all the uses that had originally been banned were re-admitted by the EPA.[197]

3.127 Canada points out that, prior to adoption of the Decree, France maintained a policy of controlled use. Indeed, it appears that the legislative provisions on asbestos provided adequate protection to workers and consumers. A review of French legislation shows that the hazardous uses of asbestos were already banned before the Decree. Sprayed asbestos was banned for all buildings in 1978.[198] Amphiboles were banned in 1994, including marketing, use and importation of these products.[199] The levels of exposure to asbestos dust were strictly regulated. Successive reductions in the exposure limits to airborne dust in workplaces had been adopted. The regulation currently in effect in France prescribes a workplace exposure limit of 0.1 f/ml.[200] A large number of products that had traditionally contained asbestos had already been banned by successive Decrees.[201] Finally, measures had been taken to protect the population against passive exposure to asbestos in buildings. A Decree imposes the obligation on all building owners, with the exception of owners of single-family dwellings, to search for the presence of sprayed asbestos or heat insulation containing asbestos and brittle materials likely spontaneously to release asbestos fibres into the air and to verify the good condition of these materials by means of an evaluation grid or dust measurements, so as to determine whether work would be necessary.[202] In light of all these actions, it may be concluded that the French Government had already regulated the risks associated with the use of asbestos, including those deriving from the use of chrysotile fibre, prior to the adoption of the ban. According to Canada, there have been no new scientific findings that would justify the change in the asbestos regulations adopted by France.

3.128 The **European Communities** indicate that Canada implies that chrysotile previously accounted for a smaller proportion of the asbestos consumed. This statement is wrong, as can be seen in the figures for global consumption of chrysotile and amphibole asbestos. In France, for example, since 1945, around 97 per cent of the asbestos used has been chrysotile-cement. Furthermore, the EC highlight below the inadequacies of safe use for protecting the health of workers and the population. The EC welcome Canada's recognition that "The principle of controlled use also means that certain uses for which exposure cannot be controlled to an acceptable degree should be banned" (Canada does not, however, define what these uses are nor their frequency). Like the WHO, the EC consider

[197] See the list of permitted uses in the United States: EPA, Regulation of 5 November 1993, Vol. 58, no. 213. pp. 58964-58968, 40 CFR, Section 765.

[198] Decree No.78-394 of 20 March 1978.

[199] Decree No.94-645 of 26 July 1994.

[200] Decree No.96-98 of 7 February 1996 concerning the protection of workers against the risks associated with asbestos dust inhalation. Canada notes that this Decree establishes the principles of prevention in the three work situations in which a worker is exposed to asbestos by virtue of his activity: manufacturing activities, for which the prohibition is not an exceptional and temporary measure; asbestos removal or containment operations; contact with asbestos during maintenance work. The report of the *Office parlementaire d'évaluation des choix scientifiques et technologiques* emphasizes that, according to the dose-response ratios established by INSERM and in view of the current worker exposure standards (i.e., 0.1 f/ml), "it can therefore be asserted that the measures provided for workers […] appear to be quite appropriate and sufficient". (WTO translation)

[201] Toys, materials or preparations for spraying, finished products in powder form meant for retail sale to the public, merchandise for smokers, catalytic screens and insulation materials in heating equipment using liquefied gas, paints, varnishes, road coating products if the fibre content is greater than 2 per cent, mortar, protective finishes, fillers, sealing products, joining pastes, mastics, glues, decorative powders and wall faces, low-density insulation or soundproofing materials, air filters and filters for the transport, distribution and use of natural gas or city gas, backings for plastic-coated wall and floor liners, finished textiles, bituminized felts for roofing, toasters, heat distribution devices, ironing boards, ironing board covers, iron holders, mobile heaters, insulation panels for the do-it-yourself market, boxed insulation panels for the professional market and materials destined for heat insulation in heating equipment, pipes and cable jackets.

[202] Decree No.96-97 of 7 February 1996 concerning the protection of the population against the health risks associated with exposure to asbestos in buildings.

that all servicing and maintenance operations cannot be controlled because of their frequency and their ubiquity. Moreover, according to the EC, international scientific data show that controlled use does not suffice to prevent the risk of cancer in asbestos-processing industries (manufacture of asbestos-containing products) nor in removal activities. Under such circumstances, the EC consider that it is justified to ban all uses of asbestos.

3.129 The EC point out that Canada cites the reports of the Ontario Commission and the WHO: one of which dates from 1984 and the other from 1988. It appears that, for Canada, research and the acquisition of new knowledge came to a halt more than ten years ago. Thus, Canada makes no reference to report 203 of the World Health Organization published in 1998 (although it is clearly identified as being an update of the 1988 report), which recognizes the dangers to health posed by chrysotile asbestos and clearly expresses doubts about the possibility of effectively controlling exposure in the building industry. The EC stress that this document confirms the conclusions of the INSERM report. The EC note that, according to Canada, "a group of experts met … under the aegis of the WHO … [and] … recommended a maximum exposure of 2 f/ml … [and] … expressed their wish that efforts be made to reduce this rate to 1 f/ml". Here again, the document cited by Canada dates from 1989. The EC note that, since then, many findings have highlighted the risks at much lower levels: some of these findings were analysed in the INSERM report.

3.130 The EC point out that the INSERM experts were aware of the HEI report, cited by Canada, and analysed it in detail in 1996 – observing that:

- It only deals with risks associated with the presence of persons inside buildings containing asbestos, excluding other exposures, occupational exposure in particular; INSERM's mandate related to all exposures; concerning exposure in buildings, INSERM's findings are the same as those of the HEI, but INSERM focused above all on what is considered by all experts to be the major risk of asbestos, namely, occupational exposure.

- The model used by the HEI to establish the very low risks linked to very low levels of exposure usually to be found in well-maintained buildings is exactly the same as that used by INSERM (linear model without a threshold) and so disparaged by Canada. The information concerning this model can be supplemented by citing the report of the Royal Society of Canada, to which Canada often refers: "but the Panel agrees [with INSERM] that regulatory agencies use the model in this form". Lastly, the EC consider that it is tendentious to state, as Canada does, that in France "the hazardous uses of asbestos were already banned before the Decree". This statement takes it as a fact that uses such as work on asbestos-containing materials, which were certainly not banned in France, are not hazardous. The EC reject this statement.

3.131 The EC point out that the available scientific data show that a high mortality rate persists despite the so-called "safe" use of chrysotile asbestos. Surveys carried out more than thirty years after the introduction of a "controlled use" policy in the United Kingdom indicate a significant excess of deaths from lung cancer and mesothelioma, not just among workers in plants where "safe" use was enforced, but above all in the population working outside such plants. According to the manual of the Canadian Asbestos Institute, the "safe" use policy is based on an "at-source" control system which consists of an "agreement" among producers, chrysotile exporters and manufacturers of asbestos-containing products[203], whereby the latter undertake to comply with rules designed to protect their employees and, in particular, to ban the on-site cutting of asbestos-cement. This is possible because Canadian production methods enable "made-to-measure" units to be manufactured at the plant, thus obviating the need for on-site cutting. However, as the manual admits, voluntary

[203] *Safe Use of Chrysotile Asbestos: a Manual on Preventive and Control Measures* (available on the Internet).

participation by manufacturers remains the cornerstone of this policy. The manual also provides for the supply of the products concerned to be stopped, after consultation with the national authorities, in the event of any failure to comply with this "agreement". According to the EC, this procedure is limited in a number of ways: (i) it covers manufacturing companies only; and (ii) it does not protect the huge numbers of occupational users engaged in various activities because manufacturers have no power of supervision over these individuals. The question also arises as to how this "agreement" is implemented when chrysotile is exported. Rigorous implementation should have led to a halt in Canadian exports of chrysotile asbestos to France because the French manufacturers had not introduced "made-to-measure" production. In practice, there is clearly no way of ensuring that the Canadian method is actually applied in the importing countries. The EC state that the available scientific data show that despite the "safe" use of chrysotile asbestos, exposure entails fatal disease in a large number of cases. The data from the United Kingdom indicate a significant excess of deaths from lung cancer and mesothelioma, not just among persons employed outside the plants, but also among persons who started their working lives in plants operating a "safe" use policy after that policy was introduced in the United Kingdom in 1969.

3.132 The EC indicate that there are risks associated with "safe" use during the manufacture of asbestos-based products. Natural asbestos fibre, which is a highly resistant material and has exceptional insulation capacities, was used in France for a wide variety of industrial purposes from 1945 onwards. The Canadian concept of the "modern use of asbestos-cement" does not reflect historical reality. For the past 40 years, the production of asbestos-cement has consisted of "encapsulating" asbestos in cement, but in the EC's view this process does not guarantee the safety of the product. When asbestos-cement is used for occupational, para-occupational or domestic purposes, it is usually sanded, crushed or sawn, thus releasing its carcinogenic fibres into the environment in the form of dust. In addition to its use in the asbestos-processing industry (mainly to produce asbestos-cement), asbestos has been used in a wide range of areas, such as construction (flocking and thermal insulation of piping), production of a wide range of consumer goods (floor tiles, brake linings, textiles and boards) and heavy industry (shipbuilding, metallurgy). The EC contend that the available scientific studies demonstrate the limits of "safe" use. The 1996 HSE[204] study carried out in the United Kingdom on the cancer risks incurred by asbestos workers after 1969, when the "safe" use of asbestos was adopted in that country, should be examined in detail. The EC note that a detailed analysis of the study is in fact attached to the 1996 report by the Panel of the Royal Society of Canada, which has been quoted extensively by Canada without acknowledging its source. However, the study indicates that, in spite of strictly "controlled" use – because it focuses solely on workers in the processing industry - there is a significant net excess of mesothelioma in workers who operated solely under conditions of "controlled use", i.e. after 1969 (when the rules entered into force in the United Kingdom). It follows that "controlled" use does not enable deaths from mesothelioma to be avoided, even in specific manufacturing branches with a limited workforce, which in principle are easy to demarcate and control.

3.133 According to the EC, "safe" use is not applicable to servicing and maintenance activities, but mesothelioma fatalities occur mainly among "secondary users" of asbestos. The aforementioned 1995 study by J. Peto[205] shows that 95 per cent of mesothelioma cases in England and Wales occurred in occupations not covered by "controlled use" policies. Also of relevance is the study by M. Siemiatycki,[206] which is never referred to by Canada, even though it was carried out by one of that country's leading research teams (the one which published the study on women living near asbestos mines). Siemiatycki's study in Montreal concentrates essentially on workers exposed when dealing with asbestos-containing materials. The study points to a net excess of lung cancer cases and a high

[204] Hutchings, S., Jones, J., Hodgson, J., *Asbestos – Related Disease*, Occupational Health Decennial Supplement, London, Health and Safety Service, 1996, pp. 127-152.

[205] Peto, J. *et al.*, *Continuing Increase in Mesothelioma Mortality in Britain*, Lancet, vol.345, p.535 (1995).

[206] Siemiatycki, J., *Risk Factors for Cancer in the Workplace*, Boca Raton, Florida, CRC press, 1991.

risk of mesothelioma associated with chrysotile exposure (risk multiplied by a factor of between 4.4 to 14.6). The worst affected occupations are in the building servicing and maintenance sectors: plumbers, gas fitters, carpenters and electricians are some of the workers most exposed to asbestos. These workers are subjected to exposure peaks that are sometimes very substantially above the current limit values for dust. For example, a roofing worker using a grinder outside to repair corrugated roof sheeting made of asbestos-cement is subjected to a maximum exposure level of 41 f/ml[207], 410 times in excess of the limit.

3.134 The EC contend that, in a legal framework which provides for a total ban on asbestos, the ISO limit continues to be a useful instrument for protecting the health of workers coming into contact with asbestos-containing materials. Such contact is unavoidable, given that millions of tonnes of asbestos were used in France and are still present in many structures. However, merely applying the ISO limit does not contain the risk, and hence "safe" use is not sufficient. The ISO 7337 standard referred to by Canada recommends working methods and tools for cutting asbestos-cement products on-site in such a way as to keep dust emission levels as low as possible. The EC note that, when ISO 7337 was published in 1984, it represented a major step forward in relation to the rules applied prior to that date but it does not guarantee a sufficient level of protection in terms of the health and safety target (maximum limit of 0.1 fibre/ml) adopted by the vast majority of countries. For instance, in the case of a worker using a tool such as a handsaw, application of the ISO standard shows that he is exposed to a level 30 times in excess of the maximum limit of 0.1 f/ml authorized in France and the United States. Cutting an asbestos-cement pipe with a jig saw fitted with a dust collection system (as referred to in this standard) entails exposure of between 7 and 12 times in excess of the maximum limit, whereas manual tools (hammer, chisel) without dust collection entail exposure 20 times in excess of that limit. Although the equipment and rules set out in the ISO standard - which is currently being revised - form the basis of prevention for specialists coming into contact with asbestos-cement materials on-site, they are inappropriate for do-it-yourself enthusiasts or non-specialists (para-occupational or domestic use). The EC state that there is a high level of mesothelioma among servicing and maintenance workers. The aforementioned study by Y. Iwatsubo[208], which was conducted in France on individual cases in the general population (and which covered 405 mesothelioma patients and 389 persons not suffering from the illness between 1987 and 1993) showed a clear increase in the mesothelioma risk among servicing and maintenance workers. Even in Canada, the study[209] carried out by the Quebec Health and Safety Commission (CSST) showed that the risk of mesothelioma has increased steadily in Canada since 1967, essentially among servicing and maintenance workers. The study points to a particularly rapid growth in the incidence of this illness in the maintenance sector. In cases where exposure had been short-term, servicing and maintenance workers were more numerous than any other category. The study also shows that the occurrence of mesothelioma is caused by chrysotile.

3.135 The EC emphasize that "safe" use in the general population at risk is impossible. Apart from hundreds of thousands of construction and servicing and maintenance workers, other persons run the risk of inhaling asbestos dust. Do-it-yourself enthusiasts are a prime example of a section of the general population at risk. Exposure is "unwitting" in so far as many of the individuals concerned are unaware that their activities may expose them to a risk of breathing in asbestos fibres with fatal consequences. As Canada points out, materials containing asbestos-cement have the same innocuous appearance as most of the materials that building workers and do-it-yourself enthusiasts are used to handling. The EC point out that Canada describes para-occupational and domestic exposure situations in the following terms "Thus, in the eyes of the consumer chrysotile-cement products and fibro-cement products are like products in all aspects, unless a data sheet is available showing which

[207] Blotière, C., and Huré, P., *Travaux sur des matériaux contenant de l'amiante – données métrologiques*, Chimie Info. No.60-11/1998 (source EVALUTIL).

[208] Iwatsubo, Y. *et al*., *Pleural Mesothelioma: Dose-Response Relation at Low Levels of Asbestos; Exposure in a French Population-Based Case Control Study*, American Journal of Epidemiology, 1998.

[209] Bégin, R., *et al*., *Work-Related Mesothelioma in Quebec, 1967-1990*, American Journal of Industrial Medicine 22 :531-542 (1992).

fibres makes up their composition".[210] Even when they are aware of the risks associated with asbestos, there is no simple test enabling para-occupational and domestic users to check whether materials not described as dangerous do in fact contain asbestos fibre. Under the current rules, manufacturers are merely required to mark or label the outer packaging of the materials sold.

3.136 The EC conclude that all these data show that it is extremely difficult to pinpoint the risks associated with breathing in asbestos and the use of asbestos products cannot be efficiently controlled. As the HSC notes in its proposed amendments to the rules introduced in the United Kingdom in 1992, efficient control of the use of chrysotile asbestos cannot be guaranteed, even at the stage which in principle is easiest to control, namely production. "Absolute control of the manufacture, and particularly the use of chrysotile asbestos products can never be guaranteed – some people may continue to be exposed, unknowingly, to relatively high levels of fibres during the installation, maintenance or removal/disposal of products containing chrysotile asbestos."[211] Controlled use procedures cannot be effectively applied to safeguard the hundreds of thousands of persons who are exposed on a daily basis in industries where health and safety arrangements are minimal, such as the building industry, which accounts for at least 25 per cent of mesotheliomas. The 1998 WHO Environmental Health Criteria 203[212] state that "it is proven that the risk is probably higher among workers in the building industry and perhaps in other industries where asbestos is used". Given the extremely large numbers of persons concerned, the difficulty of assessing the risk, the complexity of individual and collective protection systems and their negative effect on dexterity, the need to use special equipment and the overall cost engendered by the requisite arrangements mean that asbestos-containing materials cannot viably be used in a manner that will protect workers' health effectively. The EC accordingly consider that the principle of "controlled use" cannot be applied to the indeterminate risks incurred over the very wide spectrum of occupations where workers come into contact with asbestos in many ways, in particular in the servicing and maintenance operations for which "safe" use is not a practicable option. Without actually specifying them, Canada acknowledges that "certain uses for which exposure cannot be controlled to an acceptable degree should be banned".[213] The EC regret that Canada does not specify these uses nor indicate how frequently they occur. In addition, given the population groups exposed unwittingly, it is unacceptable that materials involving such a high risk should continue to be used in France. The various international organizations dealing with the protection of workers against asbestos are well aware of these facts.

3.137 **Canada** notes that the EC classify exposures to asbestos into three broad categories, namely: (i) occupational exposures of workers; (ii) para-occupational and household exposures; and (iii) environmental exposures. They group occupational exposures of workers into two sub-categories, namely "primary" users (e.g. extraction, manufacturing) and "secondary" users (e.g. construction and maintenance). According to the EC, para-occupational and household exposures mainly involve do-it-yourself enthusiasts. Finally, passive or environmental exposures result from asbestos dust emitted by a natural source of geologic origin, an industrial point source or by asbestos in place in buildings and various facilities.[214]

3.138 Canada contends that current uses of chrysotile asbestos do not endanger human health because they are now strictly controlled. These uses include the range of non-friable products where the chrysotile variety alone is used, to the exclusion of the amphibole varieties (crocidolite and amosite), and in which the fibres are firmly bound physically and chemically to the matrix (cement, bitumen, resins, plastics, etc.) of the composite (chrysotile-cement, friction materials, etc.). The

[210] See paragraph 3.423 below.

[211] *Proposals for Amendments to the Asbestos (Prohibitions) Regulations 1992*, Health and Safety Commission (1999), p.4.

[212] *IPCS Environmental Health Criteria (203) on Chrysotile*, World Health Organization, Geneva, 1998.

[213] See para. 3.122 above.

[214] See paras. 3.59 *et seq* above.

French Decree is therefore not necessary to protect health. According to Canada, the EC do not judge the concept of controlled use as proposed by Canada. They judge only one aspect of controlled use, namely responsible use.[215] The EC confuse "controlled use" and "responsible use". The responsible use of chrysotile, to which they refer, is a voluntary self-regulation initiative of Canadian producers and exporters of chrysotile. Its objective is to sell chrysotile only to businesses which abide by the national regulations required to meet the international standards governing the use of chrysotile.[216] Responsible use is only one component among others of controlled use. Canada emphasizes that, contrary to what the EC endeavours to demonstrate, ironically but quite unconvincingly, controlled use does not require that millions of persons exposed occasionally and unknowingly to emissions of asbestos dust be equipped with elaborate "space suits." Controlled use is a regulatory approach based on international standards which relies on scientific data applicable to a wide range of hazardous materials. According to the principles on which this approach is based, only products and materials that can be controlled in such a way that the health risks are eliminated throughout their life cycle are permitted. In the case of chrysotile asbestos, controlled use means the application of appropriate regulations aimed at limiting exposures to asbestos by banning certain types of asbestos and certain uses, and prescribing maximum exposure levels as well as work practices and standards.

3.139 Canada points out that the controlled use approach is not a Canadian invention. It is based on the principles of controlled use outlined in ILO Convention 162.[217] This provides for protective and preventive measures against health risks due to occupational exposure to asbestos. These measures include: (i) making work in which exposure to asbestos may occur subject to regulations prescribing adequate engineering controls and work practices, including workplace hygiene; (ii) prescribing special rules and procedures, including the authorization of a competent authority in the field, for the use of asbestos or of certain types of asbestos or products containing asbestos or for certain work processes; (iii) where necessary to protect the health of workers and technically practicable, replacement of asbestos by other materials or products evaluated as harmless or less harmful; and (iv) total or partial prohibition of the use of asbestos or of certain types of asbestos or products containing asbestos in certain work processes.

3.140 According to Canada, Convention 162 clearly lays emphasis on controlled use and not on banning products. Indeed, the Convention only provides for two specific prohibitions, namely the use of crocidolite and products containing it and the spraying of all forms of asbestos.[218] The general responsibilities of governments, employers' and workers' organizations concerned, as well as a national regulatory framework governing safety in the use of asbestos, are also set out in Convention 162. National regulations should: (i) establish procedures for the notification by the employer of certain types of work involving exposure to asbestos; prescribe adequate engineering controls and work practices to prevent or control exposure to asbestos; (ii) enforce laws and regulations through an adequate and appropriate system of inspection, including appropriate penalties; (iii) prescribe limits for the exposure of workers to asbestos and make employers reduce exposure to as low a level as is reasonably practicable; (iv) measure the concentrations of airborne asbestos dust in workplaces and monitor the exposure of workers to asbestos at intervals; take appropriate measures to prevent pollution of the environment; (v) ensure that employers have established polices and procedures on measures for the education and periodic training of workers on asbestos hazards and methods of prevention and control; (vi) establish standards for respiratory protective equipment and special

[215] Convention concerning Safety in the Use of Asbestos (Convention 162), adopted on 24 June 1986, International Labour Organization, Geneva.

[216] Canada points out that, moreover, the manual to which the EC refer deals not only with responsible use but describes controlled use in detail. This manual is intended for producers only and does not mention work methods at construction sites or for building sub-trades.

[217] Convention concerning Safety in the Use of Asbestos (Convention 162), adopted on 24 June 1986, International Labour Organization, Geneva.

[218] *Id.*, Article 11; Recommendation concerning Safety in the Use of Asbestos (Recommendation 172, adopted on 24 June 1986, Geneva) Article 18.

protective clothing for workers; (vii) recognize contractors qualified to carry out the demolition of plants or structures containing friable asbestos insulation materials, and removal of asbestos from buildings or structures; (viii) ensure that workers who are or have been exposed to asbestos are provided with free medical examinations to supervise their health in relation to the occupational hazard; and (ix) prescribe adequate labelling of containers, including material safety data sheets indicating the asbestos content, the health risks and the appropriate protection measures concerning the materials or the product. Convention 162 is supplemented by the Recommendation concerning Safety in the Use of Asbestos (Recommendation 172), which, in substance, repeats the content of Convention 162 and outlines a set of minimum work standards.[219]

3.141 Canada notes that the ILO's Code of Practice on Safety in the Use of Asbestos is intended for all those who are responsible, in the public or private sector, for ensuring the safety of workers when asbestos is used. It is not intended to replace national legislative or regulatory provisions nor applicable standards, but to serve as a guide for the formulation of similar provisions, in particular for authorities and government agencies, specialized agencies as well as businesses and health and safety committees. This Code of Practice aims to: (i) prevent the risk of exposure to asbestos dust at work; (ii) prevent the harmful effects of exposure to asbestos dust on the health of workers; and (iii) indicate reasonable and practically feasible methods and techniques to reduce occupational exposure to asbestos dust to a minimum.[220]

3.142 Canada indicates that Standard ISO-7337 expressly discourages the use of certain high-speed cutting tools that are not vacuum-equipped and produce excessive quantities of suspended fine dust that can also contain respirable asbestos fibres. France's member committee approved this Standard.[221]

3.143 Canada points out that the use of pre-machined parts and fittings, despite the EC's opinion, is not a far-fetched or utopian solution. According to OSHA: "pre-cut, pre-tapped pipe has received tremendous marketplace acceptance and represents a large majority of sales. [...] This is significant because the use of pre-cut, pre-tapped pipe may reduce or eliminate some types of field fabrication activities."[222] As a result of pre-fabrication, pre-machining, the use of fittings and compliance with work standards, the amount of handling and working of asbestos-cement products is very limited. The ISO has also formulated Standard ISO-14001 - Environmental Management Systems – Specifications and Guidelines for Use.[223] The ISO accreditation of a business confirms that it complies with national environmental standards. For instance, if the environmental standards specify a maximum rate of emission of fibres in the air, Standard ISO 14001 is a guarantee of compliance with these standards by the accredited business. In Canada's view, this is a concrete way of guaranteeing that national standards are observed.

3.144 Canada emphasizes that the practice of controlled use to regulate asbestos, including chrysotile asbestos, is therefore based on well-established international principles. First of all, the permitted uses are based on the varieties of fibre. A clear distinction is made between chrysotile and amphiboles, with certain amphiboles being banned. Secondly, the permitted uses are based on the fixation of the fibres in a binder in such a way that chrysotile asbestos dust cannot be released as a result of normal wear on the product. Almost everywhere, controlled use includes measures such as a

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[219] Recommendation concerning Safety in the Use of Asbestos (Recommendation 172, adopted on 24 June 1986, Geneva).

[220] *Code of Practice on Safety in the Use of Asbestos*, International Labour Organization, Geneva, 1984.

[221] International Organization for Standardization, Standard ISO-7337.

[222] See OSHA, on-line: OSHA:< http://www.osha-slc.gov/Preamble/AmendAsb_data/ASBESTOS_AB4.html> (access date: 20 June 1999).

[223] ISO, Environmental Management Systems – Specifications and Guidelines for its use – Standard ISO-14001, 1995.

ban on processes or products that release or are likely to release dust, for example friable low-density insulation products. Thirdly, the permitted uses are based on control of the average concentrations of asbestos fibres in the workplace. An acceptable limit of 1.0 f/ml or less was recommended by a group of experts that met in 1989 under the auspices of the WHO. The use of dust control equipment combined with the adoption of specific work methods can easily make it possible to meet this limit in mines, processing plants, as well as at the stage of installation of the product, its repair or removal and disposal of the waste.

3.145 Furthermore, Canada states that controlled use involves the implementation of certain practices and methods of working with materials containing asbestos. To be complete, any regulations based on the principles of controlled use must include appropriate measures and guidelines for the marking and labelling, transport, monitoring of the air, medical monitoring, monitoring of construction activities and waste disposal. The WHO recognizes that controlled use is effective. In its 1998 study entitled *Chrysotile Asbestos*, with respect to the controlled use of chrysotile, the WHO concludes, in the following terms:

> "Control measures, including engineering controls and work practices, should be used in circumstances where occupational exposure to chrysotile can occur. Data from countries where control technologies have been applied have demonstrated the feasibility of controlling exposure to levels generally below 0.5 fibres/ml. Personal protection equipment can further reduce individual exposure where engineering controls and work practices prove insufficient."[224]

3.146 Canada considers that the exclusive use of chrysotile asbestos and the adoption of effective methods to reduce dust are the best guarantees of protection of the health of workers. Canada advocates the controlled use of chrysotile asbestos, relying on scientific research conducted by recognized experts and international organizations, including the WHO. In Canada, the hazardous product regulations apply throughout the life cycle of products. More specifically, all activities involving asbestos – extraction, transport, processing, installation and repair, removal and waste disposal – are closely scrutinized in order to protect not only the health of the public and of workers, but also the environment. In Canada, controlled use has resulted in a ban on friable products containing any type of asbestos in order to protect the public, and in the adoption of measures to ensure the health and safety of workers exposed to asbestos. The latter measures generally fall under provincial jurisdiction and, in Quebec, have been instituted mainly through the Regulations on the quality of the work environment and the Safety Code for the Construction Industry, which are administered by the *Commission de la Santé et de la Sécurité au Travail* (CSST) (Occupational Safety and Health Board). These two regulatory texts govern working conditions in chrysotile mines, asbestos product manufacturing plants and businesses specializing in the maintenance and removal of sprayed asbestos.

3.147 Canada indicates that, in the early 1990s, Quebec lowered the permitted exposure limit for chrysotile asbestos to 1.0 f/ml, while this limit was set at 0.2 f/ml for crocidolite and amosite. The province has also banned the use of friable insulating materials, as well as crocidolite and amosite.[225] At the same time, Quebec amended its Safety Code for the Construction Industry in order to ensure that workers who have to handle asbestos intermittently on construction sites are adequately protected. Subsection 3.23 applies to all construction sites where work that is likely to release asbestos dust is carried out. The Code establishes a three-tier classification of work: (i) type I jobs or low-risk activities, i.e. all work with non-friable or high-density products, where the use of hand tools or vacuum-equipped power tools can reduce exposures to well below the exposure limit. Measures must be taken to minimize exposures, prevent the spread of dust and dispose of asbestos waste; (ii) type II jobs - or medium-risk activities - involve minor disturbances or removal of small amounts of friable materials containing asbestos. For example, when removing pipe insulation,

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[224] *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998, p.145.

[225] Quebec Province – *Regulation on the quality of the work environment*, L.Q., 1979.

workers must wear gloves and special protective clothing, as well as a half-face filter respirator; (iii) type III jobs - or high-risk activities - include large-scale removal of friable asbestos-containing materials, spray application of sealants to asbestos-containing materials, etc., and require very stringent workplace practices. For inside jobs, the ventilation system must be turned off, the work area totally enclosed and maintained under negative pressure, a decontamination centre constructed, and appropriate personal protective equipment issued to workers.

3.148 Canada explains that, before commencing work likely to release asbestos dust, the employer must determine the types of asbestos present in the materials and must also train and inform workers about the risks, prevention methods and safe work methods. Regulations have also been introduced in Canada to address the disposal of asbestos waste. Provision is made for safe transportation (covered vehicles, sealed packaging, labelling) and disposal of the waste at approved sites. For instance, solid waste containing asbestos is shipped to solid waste disposal or storage sites. In the case of a sanitary landfill site, the solid waste is compacted in uniform layers and covered over. These regulations apply to friable asbestos waste and not to high-density products.[226] At the federal level, again, the Hazardous Products Act prohibits the use of asbestos in the following products or applications: untreated low-quality textile products which can release fibres under normal use; various consumer products, such as toys, modelling compounds and low-density jointing compounds; the sale of loose or raw asbestos to consumers; all asbestos products destined for application by spraying; and finally, the use of crocidolite or crocidolite-containing products.[227] Regarding labelling, the Workplace Hazardous Materials Information System (WHMIS) was introduced under the Federal Hazardous Products Act. It requires suppliers of all hazardous materials to provide labels with specific pictograms and warning phrases, along with Material Safety Data Sheets, as a condition of sale and importation. WHMIS also requires that workers receive appropriate information and training if called upon to work with or handle such products.[228] It is crucial to measure the emissions of fibres in the air in workplaces, to assess the effectiveness of the control methods and to show that the business complies with the regulations. The measurement of airborne fibres in the workplace is carried out regularly.

3.149 Canada states that, under the Canadian Environmental Protection Act, regulations have been established governing stack emissions from asbestos mines and mills. An emission limit of 2.0 f/ml has been established, in addition to appropriate monitoring methods and administrative controls.[229] Quebec legislative and regulatory provisions prescribe standards for atmospheric emissions of asbestos fibres at all stages of mining operations, including crushing, drying, drilling, storage and processing, as well as conveyors and transfer points, the loading and unloading of asbestos concentrates, not to mention the processing and handling of asbestos waste. In Canada, emphasis is on compliance with requirements. Inspection programmes are in place and strict compliance is monitored so that any necessary legal proceedings can be brought and the maximum penalties imposed.

3.150 According to Canada, the EC rely heavily on a study by the Health and Safety Executive (HSE) entitled "Asbestos-related diseases" to which they refer to show that controlled use is not effective in preventing mesotheliomas and lung cancer among chrysotile-processing workers. This study reveals that workers exposed after 1969 have been affected by exposure to asbestos. In 1969, the standard in England was 2 f/ml, but with an upper exposure limit of 12 f/ml at any time. These levels are much higher than today, in particular the absolute upper limit of 12 f/ml. Secondly, the time required to modernize the obsolete equipment of the period would have to be taken into account. It was only in 1983 that the standard in England was lowered to 1 f/ml in all circumstances. In

[226] Canadian solid waste regulations.
[227] *Hazardous Products Act*, Statutes of Canada, http://canada.justice.gc.ca.
[228] *Id.*
[229] *Canadian Environmental Protection Act and Asbestos Mines and Mills Release Regulations*, Statutes of Canada, http://canada.justice.gc.ca.

Canada's view, the EC wrongly stress the risks of asbestos-related diseases after 10 years of latency in the group, whose exposure to asbestos would have begun after 1969. In fact, in this group, an excess risk of lung cancer, mesothelioma and asbestosis was statistically significant even before the latency period of 10 years. This means that the cohort supposedly exposed to asbestos beginning in 1970 was in fact composed of workers exposed to asbestos prior to 1970 (the explanation advanced by the authors themselves, p.144). Therefore, this is not a genuine cohort of workers exposed for the first time from 1970 onwards. Furthermore, other risk factors (e.g.: smoking rate of 54 per cent in this group versus 42 per cent in the reference population) and other factors not comparable between the cohort and the reference population were already having an impact before the beginning of the exposures to asbestos reported from 1970 onwards. Furthermore, notwithstanding the anomalies and bias cited above, the study cannot constitute a credible test of the Canadian practice of controlled use. In 1969, the new standards constituted only one step toward controlled use; these insufficient improvements were far from equivalent to controlled use as proposed 10 years later. In addition, although England reportedly decided in 1969 to stop importing crocidolite, it did not decrease its imports of amphiboles until 1975 and these imports did not cease until around 1979. Despite all this, there was nonetheless a statistically significant decrease in the risk of mesothelioma and of other asbestos-related diseases because of a decrease in exposures and perhaps the cessation (barring exceptions) of crocidolite imports.

3.151 Finally, Canada wonders why the EC do not cite the INSERM data and analyses to illustrate the trends in France:

> "[Tr.] As a result of the reduction in exposure levels to asbestos in recent decades, practically no further deaths from asbestosis are observed (in the mortality statistics of INSERM in 1990) (INSERM, 1993); 26 deaths from this cause were recorded in France: 24 men and 2 women."[230]

If these are the results of the reductions in exposure brought about by only a partial application of the controlled use advocated by Canada, a control similar to that practised in Canada would undoubtedly yield even more positive results in terms of reduction of disease. The EC rely on the study by Siemiatycki to argue that there is a very strong association between mesothelioma and work in the construction sector.[231] According to Canada, the EC misinterpret the results of this study. The cancers studied occurred in the early 1980s; they were therefore induced 20-30 years earlier, i.e. in the 1950s. There is absolutely no logical link between these mesotheliomas reported between 1979 and 1985 and the safe use of chrysotile introduced at the beginning of this short period of observation.

3.152 Canada points out that the EC can in no way infer from these results that controlled use does not work. Canada notes that the EC start from the assumption that construction work is by nature uncontrollable. When a study shows an association between mesothelioma and construction or building sub-trades work, they conclude that this represents an association with an uncontrollable exposure. The EC cite a study by Y. Iwatsubo.[232] According to Canada, this study does not support a relationship between chrysotile asbestos alone and health effects such as a clear increase in cases of mesothelioma. This study merely reveals what can happen in the absence of a policy of controlled use, two of the main components of which are a ban on amphiboles and control of the average concentrations of chrysotile fibres in the workplace. This study merely reveals the health effects arising from an exposure to mixtures of asbestos fibres that is undefined in terms of concentration and duration.

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[230] INSERM report, p.179.

[231] See para.3.133 above.

[232] Iwatsubo, Y. *et al., Pleural Mesothelioma: Dose-Response Relation at Low Levels of Asbestos; Exposure in a French Population-Based Case Control Study*, American Journal of Epidemiology, 1998, vol.148, no.2. See also para. 3.82 above.Peto, J., *Continuing Increase in Mesothelioma Mortality in Britain* (1995) 345 Lancet 535.

3.153 Canada considers that the same comments apply to the study by J. Peto on which the EC rely to claim that the bulk of mesotheliomas occur in occupations which fall outside the policies of controlled use.[233] Canada cannot agree with the fallacious claim underlying the EC's argument that controlled use is not feasible with respect to servicing and maintenance workers. A letter from researchers in the Netherlands criticizing the article by J. Peto points out that the higher incidence of mesothelioma in their country has nonetheless stopped rising, even though the controls did not come into effect until 1977 in the Netherlands, i.e. eight years later than in the United Kingdom. These authors propose a hypothesis consistent with Canada's position:

> "[…] the exposure of crocidolite asbestos in construction work may have been more extensive in the UK than the Netherlands. In our country, mesothelioma incidence is clustered in areas with shipbuilding and other heavy industry, where crocidolite was used for insulation […] Although we question the projections of Peto and co-workers, we support their statement that too many people are still being exposed to (crocidolite) asbestos without knowing of it, especially those employed in maintenance and demolition.[234]

3.154 Canada notes that the cohort studied by Bégin *et al*.[235], on which the EC base their claim that the risk of mesothelioma has been increasing regularly, extends from 1967 to 1990, and the authors indicate 26 years as the average duration of exposure. Therefore, the cases reported began their exposure between 1941 and 1964. This was obviously not a time when controlled use (low exposure to chrysotile alone) was in effect. According to Canada, the EC's inference that exposures to chrysotile are responsible for the mesotheliomas reported is unjustified and false. In the database of the study by Bégin *et al*., exposures are usually recorded approximately by categories of use; care must therefore be taken not to make a too specific and consequently abusive interpretation of these data. On the contrary, this study suggests that mesothelioma strikes workers in the secondary and tertiary industrial sectors more than workers in the chrysotile mines and mills. However, several processing businesses in the Montreal area have used amphiboles and particularly crocidolite in the past and construction, sub-trades and insulation workers have been exposed to friable products which very frequently contained amphibole asbestos. Furthermore, the data for Quebec are only reliable since 1984; before this date, the incidence of mesothelioma was considerably under-estimated, resulting in an upward bias in the incidence of mesothelioma during the 1970s and 1980s. Canada considers that the EC's interpretation of the Bégin study is incorrect. The data from this study corroborate the existence of a risk of mesothelioma in occupations in the secondary and tertiary sectors more exposed to amphiboles, but they cannot in any way specifically "incriminate" chrysotile and its current uses.[236]

3.155 Canada contends that controlled use in the extraction and processing industries is feasible. The EC have admitted that the control of dust emissions in extraction and processing plants, as well as in plants producing chrysotile-based materials, is effective in controlling the risk of contracting a disease attributable to exposure to asbestos.[237] Canada points out that the EC have backed away from their position in this dispute, but this position is quite simply unfounded. In most countries, the processing of chrysotile fibre takes place in highly automated plants, in which very strict control and health measures are applied. These measures include proper work and maintenance methods, appropriate ventilation and dust control systems, as well as information and training for workers. According to the WHO, there is no risk in the extraction and processing industry: "The overall relative risks for lung cancer are generally not elevated in the studies of workers in asbestos-cement

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[233] Peto, J., *Continuing Increase in Mesothelioma Mortality in Britain* (1995) 345 Lancet 535.

[234] Weill, H. and Hughes, J., *Letter to the Editor: Mesothelioma*.

[235] Bégin, R., *et al*., *Work-Related Mesothelioma in Quebec, 1967-1990*, American Journal of Industrial Medicine, 1992, 22 :531-542 (1992).

[236] McDonald, J.C., McDonald, A., *Work-Related Mesothelioma in Quebec, 1967-1990*, American Journal of Industrial Medicine, 1993, 24:245.

[237] European Commission (G. Lohan, DG III), European justification for Decree No.96-1133 to the Canadian authorities (15 April 1997 following the French notification G/TBT/Notif.97.55).

production and in some cohorts of asbestos-cement production workers."[238] With respect to emissions from crushing in mills, it adds: "In well-controlled mills, this is largely confined in the mill building, and presents low emissions because the mill air is collected and ducted through control devices."[239]

3.156 Canada notes that statistics exist indicating that controlled use is effective. The data collected and compiled by the Asbestos International Association in 1995 cover 28 countries where approximately 25,000 workers are employed. In these countries, 87 to 99 per cent of the workers are exposed to levels of less than 1.0 f/ml.[240] In Quebec, the exposure values at raw material extraction sites and in plants which separate chrysotile asbestos fibres from the raw material have declined by an average of 16 f/ml to less than 1 f/ml following the application of control measures, such as technical processes, since 1973.[241] Canada contends that controlled use is also effective in the processing industry. Technical processes can be adopted in chrysotile-cement plants. These processes involve, *inter alia*, dust emission control and confinement. In chrysotile-cement plants, several operations, such as the internal machining of fittings for example, can be performed in such negative pressure enclosures.

3.157 According to Canada, it is essential to stress the latency period in order to assess the effects attributed to exposure to asbestos. The effects reported today reflect the circumstances of uncontrolled exposure which prevailed more than 20 or 30 years ago, and absolutely cannot be used as evidence that effective control (low exposure) of current uses of chrysotile asbestos (excluding amphiboles) is impracticable and solves nothing. G. Berry and M.L. Newhouse conducted a mortality study (1942-1980) in a plant producing friction materials where chrysotile asbestos was used almost exclusively. Compared to national mortality rates, the authors did not observe any excess mortality due to lung cancer, cancer of the digestive tract or any other cancer. The exposure rates were low, and only 5 per cent of the workers had accumulated 100 fibres-years/ml. The authors stated that the experience accumulated at this plant over a 40-year period showed that chrysotile was not associated with any apparent excess mortality.[242] The extension of the study over a period of seven years enabled the authors to confirm that there was no excess mortality due to lung cancer or other tumours associated with asbestos or to chronic pulmonary diseases. After 1950, air quality control measures were gradually improved in this plant, and since 1970, the concentrations of asbestos have not exceeded 1.0 f/ml. The authors conclude as follows: with proper control measures of the ambient air, it is possible to use chrysotile in the manufacturing industry without causing excess mortality.[243]

3.158 Canada also refers to a study by J. Peto: "Only a few (5 per cent) of British mesothelioma deaths were among workers in regulated occupations".[244] When the latency period is considered, these deaths are due to the regulations in the 1960s. The authors of another study followed 1,970 workers at an asbestos-cement plant where chrysotile was used exclusively and examined their mortality data. They did not note any significant elevation of the standardized mortality ratio for the causes of death examined, i.e. all causes, all cancers, lung cancer and pleural cancer and cancers of the digestive tract. The authors conclude that the general findings of this mortality study suggest that the workers at the chrysotile asbestos-cement plant studied did not face an increased risk with respect to total mortality, mortality due to all forms of cancer, lung cancer and bronchial cancer or to cancers

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[238] *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998, p. 8.

[239] *Id.*, p.24.

[240] Pelnar, V., *Further Evidence of Nonasbestos-Related Mesothelioma: a Review of the Literature*, 14 Scandinavian Journal of Work, Environment and Health, 1998, p.141.

[241] *L'évolution des taux d'empoussièrement dans les mines du Quèbec*, in *L'amiante chrysotile*, un aperçu, Institut de l'amiante, Montreal.

[242] Berry, G. and Newhouse, M.L., *Mortality of Workers manufacturing Friction Materials Using Asbestos*, 40 British Journal of Industrial Medicine, 1983, p.1.

[243] Newhouse, M.L. and Sullivan, K.R., *A Mortality Study of Workers manufacturing Friction Materials: 1941-86*, 46 British Journal of Industrial Medicine, 1989, p.176.

[244] Peto, J. *et al.*, *Continuing Increase in Mesothelioma in Britain*, 345 Lancet, 1995, p.535, cited in *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998, p.123.

of the digestive tract.245 In another study of 5,645 workers at an asbestos-cement plant, in which the authors did not find any increase in mortality resulting from exposure to chrysotile asbestos over a 20-year period at exposure levels equal to or less than 100 mppcf x years (which corresponds to approximately 15 f/ml x years). The authors state that the demonstration that cumulative low and short-duration exposures did not result in a detectable excessive risk of respiratory cancer could serve as a basis for the development of regulations, because these data make it possible to state that there are low degrees of exposure which are not associated with a demonstrable increase in risk.[246]

3.159 Canada mentions a cohort study of 1,176 workers at a Swedish plant producing asbestos-cement containing chrysotile, which did not show any excess mortality associated with exposures of approximately 10 to 20 fibres/ml x years.[247] In another cohort study, this time of a group of 2,167 workers between 1941 and 1983, the authors did not observe any excess incidence of lung cancer or any other excess mortality associated with asbestos at average fibre concentrations of less than 1 f/ml, although the concentrations were probably higher in certain areas of the asbestos-cement plant.[248] Finally, the McDonald study examined what is undoubtedly the largest cohort of asbestos workers ever studied and followed over the longest period, namely the cohort of miners and plant workers at chrysotile mines in Quebec. This study was initiated in 1966 and includes 11,000 workers born between 1891 and 1920 who have been followed since its inception. The researchers made optimal use of all the available measurements of dust concentrations to assess the exposure of each member of the cohort in terms of duration, intensity and period during which this exposure occurred. The mortality data have been published on five occasions, and there is a recent report updating the results of the mortality analysis for the period 1976-1988 period inclusive. One of the main findings of this update is that for several narrow exposure categories of up to 300 mppcf x years, the standardized mortality ratio for lung cancer was around one, with no perceptible trend, and increased significantly above this level of exposure.[249] More recently, the same authors again updated their results, this time on a group of 9,780 men followed until 1992. The results for exposures of less than 300 mppcf x years, which is equivalent to about 900 f/ml x years – or 45 f/ml for 20 years – prompt the authors to conclude that, from the standpoint of mortality, exposure in this industry to less than 300 mppcf x years has been essentially harmless.[250] With respect to the current exposure levels to chrysotile permitted or recommended and the hesitations one might have to convert mppcf to f/ml, even by applying a prudent conversion factor of 1 mppcf = 3 f/ml, the studies cited previously, including the recent updates, constitute a strong argument in favour of the recommendation by the WHO group of experts of an exposure limit value of 1 f/ml for chrysotile asbestos.

3.160 Canada claims that controlled use is effective on construction sites. However, this in no way alters the fact that there are large quantities of amphiboles and friable materials on construction sites. Certain precautions must be taken during the installation of slabs on construction sites and the burying of chrysotile-cement pipes. When, despite pre-machining and the use of fittings, it is necessary to handle and work with asbestos-cement materials, precautions must be taken. On the other hand, studies have shown that exposure levels can be maintained well below 1 f/ml if proper work methods

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[245] Thomas, H.F. *et al.*, *Further Follow-Up Study of Workers from an Asbestos-cement Factory,* 39 British Journal of Industrial Medicine, 1982, p.273.

[246] Weill, H., Hughes, J. and Waggenspack, C., *Influence of Dose and Fibre Type on Respiratory Malignancy Risk in Asbestos-cement Manufacturing,* 120 American Review of Respiratory Disease, 1979, p.345.

[247] Ohlson, C.-G. and Hogstedt, C., *Lung Cancer among Asbestos-cement Workers. A Swedish Cohort Study and a Review,* 42 British Journal of Industrial Medicine, 1985, p.397.

[248] Gardner, M.J. *et al.*, *Follow up Study of Workers manufacturing Chrysotile Asbestos-cement Products* (1986) 43 British Journal of Industrial Medicine 726.

[249] McDonald, J.C. *et al.*, *The 1891-1920 Birth Cohort of Quebec Chrysotile Miners and Millers: Mortality 1976-88,* 50 British Journal of Industrial Medicine, 1993, p.1073.

[250] The results were published in Liddell, F.D.K., McDonald, A.D., McDonald, J.C., *The 1891-1920 Birth Cohort of Quebec Chrysotile Miners and Millers: Developments from 1904 and Mortality to 1992,* 41 Annals of Occupational Hygiene, 1997, p.13.

are followed. Similarly, according to Canada, the application of simple work methods that do not generate dust will protect employees during the removal of chrysotile-cement. According to the WHO, it is friable materials that pose a problem: "Some asbestos-containing products pose particular concerns and chrysotile use in these circumstances is not recommended. These uses include friable products with high exposure potential". However, Canada notes, the controlled use which the EC claim is too difficult is associated with the use of friable materials, not with the current uses of chrysotile.

3.161 Canada states that the typical exposure levels for various operations performed with low-speed hand tools during the installation of chrysotile-cement products are essentially below 0.1 f/ml and differ significantly from those the EC mention with respect to the application of Standard ISO-337, which they severely criticize. They consider this standard inadequate to guarantee a sufficient level of protection in light of the health objective (limit of 0.1 f/ml) adopted by France. Firstly, based on the rates of dust emission mentioned above, the exposures in many operations remain below the limit of 0.1 f/ml. Secondly, the limit adopted by some countries is lower than that proposed by the WHO. While it is the prerogative of each country to adopt the values it chooses, it does not follow that the higher rates of asbestos dust produced by using certain tools create circumstances of exposure in which workers do not benefit from adequate protection. Also, in cases where exposure rates are higher than the limit of 0.1 f/ml, these rates nonetheless remain well below the value of 1 f/ml suggested by the WHO to guarantee a sufficient level of health protection of workers. In conclusion, Canada points out that, after a presentation of the exposure data concerning the application of Standard ISO-7337, which gives rise to some confusion, the EC recognize that the equipment and the rules outlined in Standard ISO-7337 "form the basis of prevention for specialist workers coming into contact with asbestos-cement materials on-site […]".

3.162 Canada does not agree with the EC's claim that France cannot protect servicing and maintenance workers from exposure to asbestos. This category includes building carpenters, plumbers and electricians. This claim ignores the fact that it is past uses, particularly sprayed-on applications of asbestos (notably amphiboles), that are the cause of the health problems attributable to asbestos in France. That is the conclusion of several epidemiologists, including Dr. Camus, in whose view:

> "In the industrialized countries, friable asbestos products inherited from the past represent by far the greatest potential for exposure and risk today and in the decades to come. In comparison, the potential for exposure to new chrysotile products composed of rigid matrices (mainly cement) seems to be very low and much easier to control. Prevention efforts must therefore focus on the actual risk of asbestos products in place."[251] (WTO translation)

3.163 According to the WHO in 1998:

> "Data from industries where control technologies have been applied demonstrated the feasibility of controlling exposure levels generally below 0.5 f/ml. Personal protective equipment can further reduce individual exposure where engineering controls and work practices prove insufficient."[252]

3.164 Canada shares the view that construction workers who work with the parts of buildings containing sprayed-on asbestos are likely to be exposed to asbestos. However, the ban on chrysotile asbestos and the Decree do not alter this situation in any way. The exposure of these workers to asbestos is the consequence of past products and uses, which are prohibited today. The circumstances of workers who work with the parts of buildings containing sprayed-on asbestos cannot be compared in any way with the conditions of servicing and maintenance workers who handle asbestos-cement

[251] Camus, M., *L'amiante et les risques pour la santé,* April 1999, pp.9 and 10.
[252] *IPCS Environmental Health Criteria (203) on Chrysotile,* WHO, Geneva, 1998, p.144.

products. Canada considers that the EC and France cannot use studies or findings concerning the former to justify measures intended to protect the latter.

3.165 With regard to controlled use and do-it-yourself enthusiasts, Canada considers France's concerns to be unfounded for four reasons. First of all, Canada wishes to point out that the EC have not established that intermittent exposures to chrysotile fibres, even at high concentrations, would create a detectable health risk. Secondly, this concern is based on a false perception, that the cutting of high-density non-friable materials containing chrysotile releases large quantities of chrysotile fibres. In fact, even using tools that are not recommended by the guides on safety in the use of asbestos, such as high-speed power tools, the dust emitted contains only a tiny quantity of respirable chrysotile fibres. Thirdly, most of the chrysotile fibres that are released following the use of high-speed saws have been chemically altered.[253] They have a different form in terms of structure and chemical composition. For this reason, they are less hazardous. The same is true of the dust released following the abrasion of chrysotile-based resin or plastic products: this dust contains tiny quantities of chrysotile fibres. Fourthly, cutting any cement material using inappropriate tools such as a high-speed saw releases silica and quartz. Silica is a group 1 type carcinogen according to the IARC classification. The risk incurred by a person who cuts a cement pipe depends on the tool used (high-speed power tool for example) and not on the presence of chrysotile fibres in the cement. Whether or not chrysotile is present, the person should wear an appropriate mask or use the appropriate tools such as hand tools or low-speed power tools producing coarse dust or chips.

3.166 Canada considers that the codes of practice intended for all those who are responsible for ensuring the safety of workers when chrysotile asbestos is used and recommended by the ILO or the ISO also support the position that the handling of products in which chrysotile fibres are solidly set in a binder does not expose workers or do-it-yourself enthusiasts to asbestos dust which presents a detectable risk to their health. Unlike professionals, private individuals are likely to work with chrysotile-cement products only very sporadically. According to Canada, the exposures received by these weekend do-it-yourself enthusiasts will only be a fraction of those received by professionals. Consequently, if professionals who work with chrysotile-cement products on a daily basis are not subject to any detectable risk, then logically the risk for private individuals will be even less. Private individuals will generally not carry out heavy operations such as sawing, sanding or demolition of materials. Do-it-yourself enthusiasts will rather perform light work occasionally, for example, drilling a hole to run a cable. Finally, if he works with cement products, whether containing chrysotile or not, a do-it-yourself enthusiast will have to follow simple protection methods, if only because of the presence of other carcinogenic materials such as crystalline silica.

3.167 Canada disagrees with the EC's assertion that the overall costs of the measures necessary to ensure effective control of the uses of asbestos are such that the use of asbestos-based materials in conditions that would effectively protect the health of workers is not viable. Most of the measures necessary to implement effective control of applications of asbestos do not entail exorbitant costs. Even if the measures required to control the applications of asbestos should in practice prove too costly, Canada maintains that the economic agents should then be allowed to make the decision to choose the controlled use of chrysotile or the use of substitute fibres or products.

3.168 In conclusion, Canada states that effective protection measures for extraction and processing workers have existed since the 1970s. The methods used for this purpose involve relatively simple technologies, such as increased ventilation of work areas, more effective filtration of air containing dust, grinding and processing operations under negative pressure to prevent dust from escaping, exhaust hoods in the workstations directly exposed to fibres, wet-process manufacturing techniques and the mechanization of processes. Workers in the construction, servicing and maintenance sectors are occasionally exposed to friable asbestos products (of all varieties) in the course of their occupational activities. It should be recalled, however, that friable products are not the subject of the

[253] See para.3.51 above.

present debate. Workers exposed to peaks have a lifetime risk of approximately 20 to 300 per million, which is an "undetectable" risk, i.e. a risk which cannot be demonstrated or measured empirically.[254] Canada maintains that the controlled use of chrysotile asbestos and of current products is possible for all occupations, even those where workers may occasionally be exposed. It is a matter of enforcing an appropriate framework of use, in the same way as for numerous other hazardous substances used in the workplace.

3.169 The **European Communities** assert that the so-called "safe" use is ineffective and inapplicable. Attempts to make "safe" use of asbestos concern only a small number of jobs. Canada's attempt to establish a "safe use" policy is based on "at-source" controls consisting, in particular, of an agreement between the producer-exporters of chrysotile asbestos and the manufacturers of products or materials containing chrysotile. This agreement provides for the transmission of information on the risk and the means of protection to be used by producer-exporters of raw asbestos. It also provides for an undertaking on the part of the manufacturers to inform their employees of the risks associated with inhaling asbestos and to provide the indispensable collective and individual protection equipment. This "understanding" covers only the relatively small asbestos manufacturing sector and presupposes the voluntary participation of the industry. Subsequently, the asbestos-containing products and materials are widely distributed among a very extensive range of users for installation in buildings, industrial plants and vehicles. The installers are professionals assumed to be aware of the risks or occasional professional or non-professional users who may be totally unaware of the risks. Any warnings about the presence of asbestos and the risks associated with using the product (labelling, notices, etc.) have disappeared by this stage, in which the products and materials have already been unpacked and installed (for example, a painted sheet of asbestos-cement in a building or a gasket in an engine).

3.170 According to the EC, "safe use" cannot be applied in the servicing and maintenance sectors. During the entire life cycle of an asbestos-containing product or material in a building, factory or vehicle, servicing and maintenance will be required and the workers are liable to be seriously exposed, throughout their working life, to risks of which they are unaware. Building and industrial maintenance workers constitute a group with high exposure to the risk of mesothelioma and lung cancer. In France, there are several hundred thousand of these workers spread over a wide variety of sectors (metallurgy, construction, vehicle repair, etc.), whereas before asbestos was banned the workers employed by enterprises engaged in the primary processing of raw asbestos into materials - those supposed to be sufficiently well informed to be able to control the risk - numbered less than 1,500. Servicing and maintenance workers may be frequently and unwittingly exposed to peaks of exposure several hundred times higher than the exposure limit established in France, as in many other countries: dry-cutting asbestos-cement generates 41 fibres/ml, or 410 times the limit value.

3.171 The EC point out that, as Canada indicates, the ISO 7337 standard proposes preventive measures (moistening of the material or dust extraction) and recommends the use of hand tools or low-speed tools with a view to limiting fibre emission. These practices are also recommended by the public health authorities in many other countries to limit the exposure of those required to work on-site with materials known to contain asbestos. The large volume of metrological data recorded at work stations at which such equipment is used, including on asbestos-cement, shows that the recommendations of ISO 7337 are inadequate and that the exposure threshold, which itself does not provide absolute protection, is almost always exceeded, the levels being 30 times the limit value for a

[254] CONSAD Research Corporation, Economic Analysis of the Proposed Revisions to the OSHA Asbestos Standards for Construction and General Industry, Washington, D.C.: OSHA, United States Department of Labor, 1990; Health Effects Institute-Asbestos Research, *Asbestos in Public and Commercial Buildings: A Literature Review and Synthesis of Current Knowledge, Final Report*, Cambridge, MA., Health Effects Institute-Asbestos Research 1991, pp.4-74.

handsaw and five to 12 times the limit value for a jig saw with dust extraction.[255] Numerous data documenting this finding can be found in the international scientific literature.[256] In most servicing and maintenance situations, because of time and ergonomic constraints, the specialized tools recommended by ISO 7337, which are often heavy and take a long time to set up, are not used (for example, when a hole is to be cut in an asbestos-cement roof, the tool might have to be connected to a cumbersome dust extraction system or a remote water supply network). Thus, the rules of "safe use" cannot be effectively applied on the scale of the hundreds of thousands of people daily exposed to asbestos in sectors as difficult to regulate from the standpoint of occupational health as the construction sector, which generates at least 25 per cent of the cases of mesothelioma.

3.172 The EC point out that all the scientific data available show that the "safe" use of asbestos cannot prevent large numbers of deaths from mesothelioma or lung cancer, neither in the confined sector of asbestos-containing material production nor in the highly dispersed sectors of construction, servicing and maintenance, and demolition. In particular, the Health and Safety Executive (HSE) study, carried out in the United Kingdom on a population of asbestos-processing workers rigorously subjected to the rules of "safe use" since 1969, shows that the application of these rules cannot prevent a significant excess of mesotheliomas, even in a sector seemingly easy to manage and supervise (involving fixed work stations in a factory environment).[257] The studies already mentioned by J. Peto[258], Y. Iwatsubo[259] and the CSST[260] (*Commission de la Sécurité et de la Santé au Travail*) in Quebec stress the seriousness of the risk for servicing and maintenance workers and indicate an abnormally high level of mesotheliomas in these occupations. The Canadian study shows that in Canada the risk of mesothelioma has been increasing steadily since 1967 and that the increase in the incidence of this always fatal disease has been particularly rapid in the servicing and maintenance sector. Thus, the limitations of all the various attempts to make "safe" use of asbestos have now been revealed and the serious public health failures to which they have led can only be checked by completely halting the spread of the risk.

6. Substitute fibres for chrysotile

3.173 **Canada** points out that, due to the versatility of chrysotile, there exist more than 150 substitute fibres. These substitutes reproduce, for certain specific uses, the thermal resistance, reinforcement capability, chemical resistance and even the acoustical and thermal insulating properties of chrysotile. The most common substitute fibres are aramid fibres, polyvinyl alcohol (PVA) fibres, cellulose fibres, glass fibres, ceramic fibres, rock wool and wollastonite.[261] The

[255] Blotière, C., Huré, P., *Travaux sur des matériaux contenant de l'amiante – données métrologiques*, Chimie Info no. 60-11/1998.

[256] Tossavainen, A., *Some Comments on the First Written Submission by Canada, dated 26 April 1999, in the Case "Communautés européennes – Mesures concernant l'amiante et les produits en contenant"*, 22 June 1999.

[257] Hutchings, S., *Asbestos-Related Disease*, Occupational Health Supplement, London, Health and Safety Executive, 1996, pp.127-152

[258] Peto, J. *et al., Continuing Increase in Mesothelioma in Britain*, vol.345, Lancet, 1995, p.535.

[259] Iwatsubo, Y. *et al., Pleural Mesothelioma: Dose-Response Relation at Low Levels of Asbestos; Exposure in a French Population-Based Case Control Study*, American Journal of Epidemiology, 1998, vol.148, no.2.

[260] Bégin, R., *et al., Work-Related Mesothelioma in Quebec, 1967-1990*, American Journal of Industrial Medicine, 1992, 22 :531-542 (1992).

[261] See Cossette, M., *Substitutes for Asbestos*, (December 1998) on the technical properties of the main fibres used to replace chrysotile. The paper also deals with substitute products for products based on chrysotile fibre and notes certain undesirable environmental consequences related to the manufacture of the substitute products. Finally, the paper delves into the economic, energy policy and safety considerations related to the use of substitute fibres and products. See also Anderson, A., *Fibers in Friction Materials*, (December 1998). A. Anderson is the chairman of the sub-committee on health and the environment (Brake Committee) of the Society of Automotive Engineers and was formerly responsible for friction materials at the scientific laboratories of the Ford Motor Company.

prohibition of chrysotile and the conversion to substitute fibres and fibro-cements have caused an increase in the use of substitute fibres. The conversion took place, however, without sufficient risk analysis. The still undetectable risk associated with modern uses of chrysotile has been replaced by the unknown risks associated with the use of substitute products . Moreover, the use of substitute fibres contributes to an increase in risks associated with products containing substitute fibres that are of lower quality in terms of their physical, chemical and mechanical resistance.[262] The decision to ban chrysotile was announced the day after the publication of the summary of the INSERM report. In this report, however, the authors admitted that they did not investigate the risks posed by substitute fibres and concluded:

> "Although, because of the time limit given to it, the group did not wish to take up the question of substitute fibres, the lack of epidemiological data concerning their harmlessness in the long term cannot hide the findings reached in experimental systems, which show the capacity to cause pathological modifications. Appropriate research should be carried out and developed as a matter of urgency before use of substitute fibres becomes general."[263] (WTO translation)

3.174 Canada claims that there has been a total conversion to substitute fibres, despite INSERM's formal warning. It was not until June 1998, one and a half years after the adoption of the Decree, that the Executive Summary – and not the full report – of another INSERM study, on substitute fibres, was published. In the Executive Summary, it is acknowledged that:

> "Fibres on which very few toxicological data exist are today being used … on a large scale as a replacement for asbestos; the novelty of their use for such applications is accompanied by a lack of data on their potential effects on human health."[264] (WTO translation)

3.175 From the beginning, the Executive Summary admits that great vigilance is in order with respect to the possible effects of using substitute fibres:

> "Any new fibre proposed as a substitute for asbestos or for any other use should *a priori* be suspected of being pathogenic because of its structure, although this does not prevent an analysis of the possible effects of its physico-chemical characteristics."[265] (WTO translation)

3.176 INSERM also stresses that its study is limited to the risks of substitute fibres in the respiratory system, even though the health risks on the whole cannot be confined to respiratory ailments:

> "This approach is restrictive in the sense that it focuses in the first place on respiratory diseases. It can be seen that dermatosis caused by fibres affects a large number of workers in contact with such materials … It might be suggested that it would be preferable not to confine studies to the respiratory system, particularly because of the development of vitrous fibres that are soluble in a biological environment. Solubilized products may, sometimes, reach other organs." [266] (WTO translation)

3.177 Canada points out that the Executive Summary also highlights the differences in the experimental exposure levels used to evaluate the risks of substitute fibres compared to those for

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[262] Cossette, M., *Substitutes for Asbestos*, (December 1998) and Anderson, A., *Fibers in Friction Materials*, December 1998.

[263] INSERM report, p.434.

[264] INSERM, *Synthèse – Effets sur la santé de substitution à l'amiante*, INSERM joint report, Paris, 1999, p.1 (hereinafter "*Substitutes – Executive Summary").*

[265] *Id.*, p.2.

[266] *Id.*

chrysotile fibres, even though the modern uses of substitute fibres are similar to those of chrysotile fibres.[267]

> "It has been noted that, in general, the animals have been exposed to a number of substitute fibres that is much lower than the level used during experimental exposures to asbestos. It is likely that similar concentrations of asbestos fibre would have yielded results that were of little or no significance in studies of carcinogenicity."[268] (WTO translation)

3.178 Canada indicates that Directorate General XXIV (consumer protection policies) of the Commission of the EC stated that "for substitute materials (for chrysotile), there is no significant epidemiology base to judge the human health risks (...) hence the conclusion that specific substitute materials pose a substantially lower risk to human health, particularly public health, than the current use of chrysotile, is not well founded."[269] Dr. J. M. G. Davis' paper[270], *The Biological Effects of Fibres Proposed as Substitutes for Chrysotile Asbestos: Current State of Knowledge in 1998*, conducts a review of the scientific literature on substitute fibres for asbestos and concludes that:

> "Replacement is premature in the present state of our knowledge."[271] […] The need for full toxicological testing of new fibre products is recommended before these products are marketed. [...] It is of much concern to find that of the three fibre types suggested as chrysotile substitutes, polyvinyl alcohol, para-aramid and cellulose, only one type of aramid (Kevlar) has been tested in a way at all close to what is required."[272]

3.179 Canada considers that France has replaced the undetectable risk associated with modern uses of chrysotile with the unknown, and perhaps greater, risk associated with the use of substitute fibres for asbestos.[273]

3.180 The **European Communities** note that the majority of substitute products for asbestos, particularly chrysotile asbestos, are non-fibrous products, for example, PVC. Canada never refers to these products, which competed with asbestos-cement long before the ban. In France, for example, the decision to stop production of asbestos-cement pipes was taken by industrialists before the announcement of the ban because the competition from PVC and ductile iron made this sector non-viable from the economic perspective. The main purpose of the policy adopted in France in 1996 is to replace materials containing asbestos by other harmless materials, particularly non-fibrous materials,

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[267] The full INSERM report entitled *Effets sur la santé de substitution à l'amiante* was published in November 1999, i.e. after the parties had presented their written rebuttals to the Panel. Canada referred to this report at the second substantive meeting with the parties. See paras. 3.325-3.327.

[268] *Substitutes – Executive Summary*, p.33.

[269] Opinion on a study commissioned by Directorate General III (Industry) of the European Commission on *Recent Assessments of the Hazards and Risks Posed by Asbestos and Substitute Fibres, and Recent Regulation of Fibres World-Wide* (Environmental Resources Management, Oxford). Opinion expressed on 9 February 1998, European Commission, DG XXIV, 1998, p. 1.

[270] M.A., Sc.D., FRC. Path. (Fellow of the Royal College of Pathology). Davis, J.M.G., *The Biological Effects of Fibres Proposed as Substitutes for Chrysotile Asbestos: Current State of Knowledge in 1998*, 1998 [hereinafter Davis].

[271] See Davis, p. 1.

[272] *Id.*, p. 6. Canada notes that the report of the Ontario Royal Commission also cautions against the conversion to substitute fibres: "We conclude that the health hazards caused by exposure to asbestos fibres depend very much upon the dimensions of the fibres, and that long, thin, respirable fibres are of primary concern. This leads us to be extremely cautious about concluding from the evidence (on) substitute fibres (that they) will not present health hazards in the future. […] [W]e believe it would be risky to allow the exposure of workers to respirable fibres longer than 5 microns, with small diameters, *of any material,* if those fibres are likely to be very durable in the lungs" (p.359).

[273] Canada notes that the United States Court of Appeal in the matter of the EPA, (see para.3.126 above) rightly emphasized that "Eager to douse the dangers of asbestos, the agency [EPA] inadvertently actually may increase the risk of injury", *Corrosion Proof Fittings v. Environmental Protection Agency*, (5th Circuit 1991), p.35.

for example, by replacing asbestos-cement roofing by galvanized steel or aluminium sheets of an equivalent size or larger, replacing asbestos-cement pipes by ductile iron or PVC (plastic) pipes. According to the EC, fibres to replace asbestos can only be used in certain materials if their harmlessness or their lower level of risk in comparison with asbestos has been irrefutably proved by the international scientific community. The risk assessments proposed by INSERM conclude that, for the various fibres analysed, the risk of cancer is sometimes "plausible" and sometimes "cannot be excluded", sometimes "there is no convincing element indicating an excess risk" (WTO translation)[274]; this is far from the certainties concerning chrysotile, a proven carcinogen according to all the international authorities. It can also be emphasized that none of the substitute products for asbestos is classed in group 1 of the IARC (proven carcinogen for humans).

3.181 The EC indicate that aramid fibres, polyvinyl alcohol (PVA) fibres, cellulose fibres, glass fibres, ceramic fibres, rock wool and wollastonite are only used as an asbestos substitute in very limited cases where it is not possible to find a non-fibrous substitute. For asbestos-cement materials, which accounted for more than 90 per cent of asbestos use in France, industrialists now use cellulose fibres (the same as those always used in the paper industry), polyvinyl alcohol and aramid fibres, for which the available toxicological data are quite reassuring. According to the EC, it is wrong to state that "The conversion [from asbestos to substitute fibres] took place without sufficient risk analysis". None of the substitute products for chrysotile has been classified as carcinogenic for humans at the international level. Moreover, the replacement of asbestos by less harmful substitute fibres has been done in stages and exercising the utmost caution concerning their harmfulness. The French text provides for the possibility of requesting waivers from the ban on asbestos whenever there is no technically comparable substitute that is less dangerous than asbestos.

3.182 The EC point out that the task entrusted to INSERM by the French Government in 1995 was first to assess the state of scientific knowledge on the risks and dangers of asbestos. Canada indicates that only the Executive Summary of the INSERM report on substitute fibres for asbestos was published in June 1998. This statement is wrong. The full text, in the form of a provisional working document, was published at the same time as the Executive Summary, as was done for the report on asbestos in July 1996. In order to provide transparency and ensure that the findings - which are necessarily succinct in a summary document - are based on detailed scientific arguments, it is INSERM's policy to provide access to the full text in provisional form (because printing a report in accordance with the requirements of scientific publications necessarily takes a very long time).

3.183 The EC point out that replacement is a necessity acknowledged internationally. In 1986, ILO Convention 162 on asbestos recommended that national legislators should make provision, whenever possible, for the "replacement of asbestos or of certain types of asbestos or products containing asbestos by other materials or products or the use of alternative technology, scientifically evaluated by the competent authority as harmless or less harmful …" (Article 10(a)).[275] The WHO press release of 26 July 1996[276] also states that it is necessary to effect such replacement, including chrysotile. The WHO states that "consideration should be given to replacing chrysotile by harmless substitute materials whenever it is possible to do so". In 1998, the WHO report drawn up as part of the International Programme on Chemical Safety[277] recommended the use of substitute materials where they are available. Since 1990, in its framework Directive on the health and safety of workers, the European Community has advocated the principle that a dangerous agent or procedure should be replaced by a harmless or less harmful agent or procedure in so far as one exists. In the case of cancer risks, the principle is set out in the Directive on carcinogenic agents, which specifically states that a

[274] *Substitutes – Executive Summary*, pp.15-17.
[275] Convention concerning Safety in the Use of Asbestos (Convention 162), ILO.
[276] WHO press release of 26 July 1996.
[277] *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998.

carcinogen should be replaced by a less dangerous agent in so far as this is technically possible.[278] The EC note that the French Decree contested by Canada in the present case complies with the recommendations of the ILO and the WHO. Substitute products can only be used to replace asbestos if they entail a lower risk for workers according to current scientific knowledge. In view of the proven carcinogenicity of chrysotile and the impossibility of controlling the risk, the French Government opted to prevent any proliferation of the risk by applying the principle recommended by the WHO and the ILO and endorsed by the European Union for carcinogenic risks: replacement by a less dangerous product in so far as this is technically possible.

3.184 The EC point out that the wide variety of substitute products reflects the diverse possible uses of asbestos. There is no natural or synthetic product with the same set of properties as asbestos. Accordingly, there is no one substitute for asbestos, but various substitutes which are sometimes combined with each other for certain applications. When referring to "substitute products", Canada appears to be referring solely to mineral fibres, whereas in fact a very wide range of products and materials is used to replace asbestos. It goes without saying that the materials obtained after asbestos is replaced have different physical and mechanical properties from the asbestos-containing material. As a result, each substitution operation entails careful checks by manufacturers on the properties of the new material and, sometimes, a complete redefinition of the product's field of application (watertight gaskets and braiding, for example).

3.185 The EC explain that these substitute products can be of three types. Firstly, products which do not use fibres: (i) replacement of asbestos-cement pipes by ductile iron or PVC (plastic) pipes, which were on the market long before France banned asbestos; and (ii) replacement of asbestos-cement roofing by galvanized steel or aluminium sheets of an equivalent size or larger. Secondly, products using fibres shown to be harmless or less harmful: (i) replacement of asbestos in cement-fibre materials by cellulose, PVA or aramid fibres (asbestos-cement accounted for more than 90 per cent of asbestos use in France); and (ii) replacement of asbestos in friction surfaces (brakes, clutches) by metal (copper), aramid fibres or granular materials. Thirdly, products containing less harmful man-made mineral fibres: (i) replacement of asbestos in watertight braiding (textile-asbestos) by glass fibres or rock fibres in most cases, or by ceramic fibres, which are essentially used as a substitute for amphibole asbestos and for very rare uses (above 1,200°C). The cost of using these fibres is considerably higher than that of using asbestos (50 per cent more).

3.186 The EC point out that none of the substitute products for chrysotile is classified as carcinogenic for humans. The lower carcinogenicity of the fibres regarded as most dangerous was already known in France when the decision was taken to ban asbestos. In the course of discussions on the eventuality of a ban, the Ministry of Labour asked the *Groupe sur la surveillance des atmosphères de travail (G2SAT),* which meets under the aegis of the French Senior Council for the Prevention of Occupational Risks, to draw up a report using existing international data on the comparative carcinogenicity of asbestos and man-made mineral fibres. The report[279], which was presented in June 1996, indicates a clear hierarchy in the relative toxicity of substitute fibres. The results were confirmed by a 1997 survey on synthetic mineral fibres carried out by INSERM. None of the man-made mineral fibres investigated showed proven carcinogenicity for humans. According to this report, glass wool and slag wool do not cause fibrosis or cancers in animals; rock wool only causes fibrosis in animals and then only at very high levels of exposure. These fibres are used only for

[278] Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), OJ L 196, 26.7.1990, p.1. Council Directive 97/42/EC of 27 June 1997 amending for the first time Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), OJ L 179, 8.7.1997, p.4.

[279] *Fibres minérales artificielles et amiante* (summary); INRS, Documents pour le médecin du travail n°69.

certain rare applications (watertight braiding as a substitute for textile asbestos); ceramic fibres cause cancers and fibroses in animals and have been diagnosed as the cause of pleural plaques in humans. These fibres are used mainly as a substitute for amphibole asbestos in very restricted and highly specific cases (temperatures in excess of 1,200 degrees). The European Community Directive[280] relating to the classification of man-made mineral fibres placed mineral wool in category III (unproven suspicion of carcinogenicity in animals) and ceramic fibres in category II (proven risk for animals). The EC point out that ceramic fibres essentially provide a substitute for amphibole asbestos and their use is strictly regulated (Labour Code, Articles R-231-55 *et seq*.). None of the substitute products for chrysotile is classified as carcinogenic for humans (group 1). Since it is known that chrysotile asbestos is classified as a "proven carcinogen for humans" (group 1), according to the EC, there is therefore a clear hierarchy of risk.

3.187 The EC emphasize that there are no data giving rise to concern as to the carcinogenicity of fibres used as a substitute for asbestos in cement fibres. The findings of the Scientific Committee on Toxicity, Ecotoxicity and the Environment are unambiguous in this connection. The SCTEE was set up by Commission Decision 97/579/EC of 23 July 1997 setting up scientific committees in the field of consumer health and food safety (Official Journal L 237 of 28 August 1997, p.18). The SCTEE's brief is to provide the Commission with high-quality scientific opinions in all cases in which it has to be consulted. It may also be consulted on other issues of special relevance to consumer health and food safety. Its composition and work are based on the principles of excellence, independence and transparency. The SCTEE has examined the comparative carcinogenicity of chrysotile and the main fibres used as a substitute for asbestos in cement fibres (which accounted for more than 90 per cent of the asbestos used when the ban came into force in France). The investigation focused on cellulose fibres, para-aramid fibres and PVA.

3.188 The EC indicate that the SCTEE's[281] findings are unambiguous as to the hierarchy of risks. Its conclusions are as follows: (i) the SCTEE notes that the three fibres investigated have been used for many years[282] and yet no worrying data have emerged over this long period as to their carcinogenicity; (ii) there is no doubt whatsoever that chrysotile is carcinogenic; (iii) chrysotile also causes asbestosis and chronic illnesses, which is not the case for the fibres investigated; (iv) chrysotile has carcinogenic effects on the lung and causes mesothelioma, whereas there is no evidence to suggest that para-aramids do so (no long-term research is available for the other two fibres, but it should be recalled that they have been in use for many years); (v) predictive studies - i.e. experimental studies on animals - show that chrysotile has far more substantial and lasting inflammatory and proliferative reactions; and (vi) the substitute fibres are considerably larger (in diameter) and have much less fragmentation capacity than chrysotile, which has very high "fibrillation" (separation of fibres lengthways into even finer fibres). The result is that the substitute fibres are far less respirable. Three interdependent parameters were used to assess the risk associated with substitute products as compared with chrysotile asbestos: (i) the dose of fibres in the air: the fibre's diameter determines how long it remains suspended in the air; accordingly, the smaller the diameter, the higher the carcinogenic risk; (ii) the physical characteristics of fibres, in particular their dimension (diameter and length) and their fragmentation capacity ("fibrillation"); the greater the degree of fibrillation, the higher the risk of the fibres being inhaled, and thus the higher the risk of cancer; and (iii) the biopersistence (or "durability") of the fibre in the lung tissue and inside the macrophages, given that long fibres are eliminated slowly. It is accepted that a ratio of length to diameter of more than 3:1 entails a higher risk of cancer. The SCTEE's study thus concludes that chrysotile asbestos is present in high concentrations in the air because of its small diameter and is very easy to inhale because of its high degree of fibrillation. The substitute fibres for asbestos-cement are

[280] Directive 97/69/EEC, of 5 December 1997.

[281] *Avis concernant l'amiante chrysotile et les produits de substitution envisageables*, Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), 15 September 1998.

[282] The EC point out that polyvinyl alcohol fibres (PVA) have been used since 1936; para-aramid fibres have been on the market for about thirty years.

PVA and cellulose fibres. Para-aramids are used for other applications (brakes, friction). These three types of substitute fibre are the most frequently used.

COMPARATIVE TABLE OF THE CHARACTERISTICS OF FIBRES EXAMINED BY THE SCTEE

	Length (microns)	**Diameter (microns)**	**Fibrillation**
Chrysotile	> 5	< 1	+++
PVA	> 5	10 – 16	+/-
Para-aramids	> 5	10 – 12	(requires considerable abrasion to produce a large number of fibrils)
Cellulose	> 5	12 – 40	Exposure data suggest that fibril production is very limited

3.189 The EC note that, from these observations, the SCTEE unanimously concluded that: (i) there is sufficient evidence to show that all forms of asbestos, including chrysotile, are carcinogenic; (ii) on the other hand, there is no evidence of cancer being caused in humans by fibres of any of the three substitute products examined; and (iii) consequently the dangers of chrysotile are probably greater (in the scientific sense) than those associated with the substitute fibres examined. The SCTEE adds that, in its opinion, no study which might have led it to a different conclusion was omitted from the examination.

3.190 The EC also note that the findings of the Committee on the Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC)[283] transmitted to the Health and Safety Executive (HSE) in July 1998 confirm the results of the SCTEE study. This Committee also examined cellulose fibres, para-aramid fibres and PVA fibres. In particular, the COC's work focused on comparisons between the results of carcinogenicity studies and studies on the physical properties of fibres (dimensions, fibrillation). Its conclusions were identical to those of the European Committee. In addition, the COC noted that the levels of exposure to those fibres were considerably lower than those associated with the use of chrysotile. The COC concluded its study as follows:

> "The evidence presented to the Committee on fibre dimensions, studies in animals including that of biopersistence in the lung, indicate that the carcinogenic risk posed by PVA fibres, p-aramid fibres or cellulose fibres is likely to be less than posed by chrysotile … Additional reassurance can be gleaned by noting that these materials are unlikely to form significant amounts of respirable fibres under normal working conditions and that occupational exposures to these materials will be below the control limit for chrysotile."[284]

3.191 The EC emphasize that, in France, as in many other countries, manufacturers had for more than ten years been seeking asbestos-free substitutes which would meet their technical requirements and would be compatible with their health and safety obligations. In the vast majority of situations, zero-risk substitution is possible: either (i) by using non-fibrous products which are not carcinogenic (such as plaster for fire protection instead of limpet spraying); or (ii) by using fibres on which no worrying data have emerged after decades of use (cellulose or PVA in cement fibres). Moreover, replacement by man-made mineral fibres is strictly regulated: (i) mineral wool (glass or rock fibres), which have not been proven dangerous even to animals in high doses and which are used for a limited number of applications (watertight braiding); these fibres are subject to occupational exposure limits and to the rules designed to protect workers against chemical risks; and (ii) ceramic fibres, for which manufacturers are currently seeking replacements; these fibres are subject to rules which are even

[283] *Statement for Health and Safety Executive (HSE) on Carcinogenic Risks of Three Chrysotile-Substitutes*, Committee on the Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC), July 1998.

[284] *Id.*, p.5.

stricter than those concerning chemical risks. Under these rules, ceramic fibres must be replaced by a less dangerous agent wherever technically possible, and their sale to the general public is prohibited.

3.192 The EC point out that exceptions to the asbestos ban are possible where using asbestos is a safer option. Manufacturers may qualify for exemption from the asbestos ban where no asbestos-free substitute performing an equivalent function is available which, on the one hand, represents less of a danger to workers and, on the other, offers users all the technical safety guarantees. When replacing asbestos by a substitute material, it is necessary to follow a carefully defined procedure laid down in the specifications which set out the performance requirements that the manufacturer's substitute material must satisfy under very precise conditions of use. Once selected, the substitute product must not just be tested but must also undergo feasibility studies over a period of time. This may take the form of qualification or approval procedures carried out by domestic or international third parties; these procedures are lengthy and complex in sectors such as the aerospace, nuclear or chemical industries. The EC also note that the Decree contested by Canada does not make the use of substitute products mandatory, be they fibrous or non-fibrous.

3.193 In the EC's view, in many instances it is not necessary to use fibrous substitute products. Asbestos-cement can be fully replaced by products with no indication of carcinogenicity; these may be either non-fibrous products (ductile iron, plastic) or fibrous products (cellulose, PVA). In the case of fire protection products, for instance, there is no need to use substitute fibres. In France, traditional plaster-based products or hydraulic binders loaded with mineral aggregates such as perlite or vermiculite have been used to protect concrete or steel structures against fire since 1978 when flocking was banned. In practice, manufacturers decide to use fibrous substitute products only if these are the sole products offering the requisite technical performances (previously obtained using chrysotile). Residual use of asbestos is made on an occasional, highly specialized basis. It is most common in the nuclear, chemical, petrochemical and aerospace industries.

3.194 The EC contend that Canada cannot claim that Decree No.96-1133 is designed to "promote" domestic substitute products because France records a substantial trade deficit for PVA and para-aramid fibres. It should also be noted that PVA fibres are produced in only two plants worldwide, one in Japan and one in China. As regards cellulose fibres, the fraction used to produce fibro-cement is extremely small. The bulk of the cellulose raw material (94.5 per cent) is used by the paper industry and the remainder (5.5 per cent) goes mainly to the textile and construction industries. France imports about 40 per cent of the cellulose it uses, mainly from Canada and the United States. In 1998, France imported 380,000 tonnes from Canada, against 371,000 tonnes in 1997 and 366,000 tonnes in 1996.[285]

3.195 **Canada** asserts that the undetectable risk associated with current uses of chrysotile has, as a result of the Decree, been improperly replaced by the unknown risk of substitute fibres. At the most, science indicates that, although certain substitutes can be considered "less harmful" than chrysotile, their harmlessness has not been proved. Furthermore, the ban on chrysotile promotes a false sense of security among the population, which is likely to reduce the vigilance of workers, do-it-yourself enthusiasts and the population in general when chrysotile substitutes are used. According to Canada, this is the key issue, i.e. whether the ban on asbestos effectively protects the French population while restricting international trade as little as possible. The most common chrysotile substitute fibres include aramid fibres, polyvinyl alcohol (PVA) fibres, cellulose fibres, glass fibres, ceramic fibres, rock wool, slag wool, glass wool and wollastonite.

3.196 In Canada's view, nothing is less certain than the "proven" character of the safety or low toxicity of substitute fibres, as the EC assert. First of all, the EC stress that substitute fibres "have been in use for many years". Although little accustomed to criticizing others for a lack of historical perspective, Canada considers that use of approximately 20 years does not constitute "use for many

[285] Source: COPACEL and the French customs.

years" of substitute fibres. It is sufficient here to refer to the CSTEE (DG XXIV) document, which speaks more appropriately of a "relatively short"[286] period of use extending over "approximately 20 years."[287] Similarly, a working group which reported on substitute fibres to the British Health and Safety Executive (HSE) noted:

> "Carcinogenic risks posed by chrysotile-substitutes and chrysotile cannot be based predominantly on an epidemiological assessment since substitute fibres have only been used for periods of up to approximately 20 years." [288]

3.197 Canada notes that INSERM itself warns against the fact that "[Tr.] very few toxicological data exist"[289] on asbestos substitute fibres. Canada also draws attention to the conclusions of the CSTEE (DG XXIV), to which the EC refer extensively, with respect to the safety of substitute fibres:

> "For substitute materials [to chrysotile], with the exception of vitreous fibres, there is no significant epidemiology base to judge the human health risks [...] hence the conclusion that the use of specific substitute materials poses a substantially lower risk to human health, particularly public health, than the current use of chrysotile, is not well founded."[290]

3.198 Canada points out that the CSTEE (DG XXIV) also states that: "no epidemiological studies or observations in humans of the long-term effects of p-aramid or PVA have been reported in the scientific literature".[291] It goes on to add: "overall, acute and subacute toxicity data on the three substitute fibres are very meagre and do not allow for a proper comparison with chrysotile".[292] The WHO, in a study on substitutes published in 1993, which is similar in scope to the 1998 report on chrysotile, states in conclusion that:

> "All fibres that are respirable and biopersistent must undergo testing for toxicity and carcinogenicity. Exposures to these fibres should be controlled to the same degree as that for asbestos."[293]

3.199 Canada notes that the Occupational Safety & Health Administration of the United States Department of Labor underlines the risk of using substitute fibres and products:

> "Although the introduction of asbestos substitutes and alternatives enables manufacturers to avoid contact with asbestos, many of these surrogates pose occupational health hazards of varying degrees."[294]

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[286] *Avis concernant l'amiante chrysotile et les produits de substitution envisageables*, Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), 15 September 1998.

[287] *Statement for the Health and Safety Executive (HSE) on Carcinogenic Risks of Three Chrysotile Substitutes*, Committee on the Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC), July 1998. Canada points out that the EC use expressions such as "for a very long time", "long period" and "use for many years", but these do not appear in the CSTEE text.

[288] *Id*.

[289] *Substitutes – Executive Summary*, p.1.

[290] Opinion on a study commissioned by the Directorate General III (Industry) of the European Commission on *Recent Assessments of the Hazards and Risks Posed by Asbestos and Substitute Fibres, and Recent Regulation of Fibres World-Wide* (Environmental Resources Management, Oxford). Opinion expressed on 9 February 1998.

[291] *Avis concernant l'amiante chrysotile et les produits de substitution envisageables*, Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), 15 September 1998.

[292] *Id.*

[293] *IPCS Environmental Health Criteria (151): Selected Synthetic Organic Fibres*, WHO, Geneva, 1993, p.76.

[294] See United States Department of Labor (OSHA), *Asbestos - Final Regulatory Impact and Regulatory Flexibility Analysis*, on-line:
OSHA <http://www.osha-slc.gov/Preamble/AmendAsb_data/ASBESTOS_AB4.html> (access date: 22 June 1999).

3.200 Canada asserts that, not only is the safety or low toxicity of substitute fibres not "proven", what is more, the EC and the United States misrepresent the situation of substitute fibres in an effort to compensate for the irrationality of the total ban on asbestos and the blind use of substitute fibres. For example, the United States claims that "none of these [replacement] fibers have been found to cause either malignant or non-malignant respiratory diseases similar to those associated with asbestos exposure in humans".[295] Canada considers that this is not true, as can be seen from the IARC data and its classification of carcinogenic substances. The IARC classifies substances according to the following four categories:[296]

(a) group 1: the agent (mixture) is carcinogenic to humans. The exposure circumstance entails exposures that are carcinogenic to humans;

(b) group 2 (two classifications):

(i) group 2A: the agent (mixture) is probably carcinogenic to humans. The exposure circumstance entails exposures that are probably carcinogenic to humans;

(ii) group 2B: the agent (mixture) is possibly carcinogenic to humans. The exposure circumstance entails exposures that are possibly carcinogenic;

(c) group 3: the agent (mixture, or exposure circumstance) is unclassifiable as to carcinogenicity in humans;

(d) group 4: the agent (mixture, or exposure circumstance) is probably not carcinogenic to humans.

3.201 Canada explains that these groups are not based on the toxicity of the substances, but rather on the available information. To the EC, which state that chrysotile is a carcinogenic agent in group 1, Canada responds that this category, which covers three and a half pages in the IARC document, includes many products such as silica, tobacco smoke and wood dust; it also includes alcoholic beverages, salted fish and oral contraceptives. The IARC warns against the reasoning of saying that a substance in group 1 is more hazardous than a substance in group 2.

> "These categories refer only to the strength of the evidence that an exposure is carcinogenic and not to the extent of its carcinogenic activity (potency) nor to the mechanisms involved. A classification may change as new information becomes available."[297]

For example, a substance may be classified in group 2B if there is sufficient data from animal experiments confirming its carcinogenicity, but the data for humans are still "inadequate". Rock, glass and slag wools and refractory ceramic fibres are classified in group 2B, i.e. possible carcinogens. Polyvinyl alcohol, aramid and glass fibres are classified in IARC group 3, which is characterized by "inadequate" evidence of carcinogenicity in humans and "inadequate" or "limited" evidence from animal experiments. For Canada, it is not surprising that knowledge is still insufficient with respect to substitute fibres that have been used industrially for only about 20 years. According to the French *Institut national de recherche et de sécurité* (INRS) (National Research and Safety Institute), "[Tr.] some authors are of the opinion that glass fibres should be considered

[295] See Section IV below.

[296] See IARC, Evaluation Method, on-line: IARC < http://193.51.164.11/monoeval/Eval.html> (access date: 16 June 1999).

[297] *Id.*

carcinogenic."[298] The IARC, for its part, reveals that glass fibre can cause mesotheliomas, at least in animals.[299]

3.202 Canada also indicates that the United States claims that none of the chrysotile substitute fibres have been associated with respiratory diseases similar to those associated with asbestos. However, the United States Occupational Safety and Health Administration (OSHA) points out the hazards of synthetic mineral fibres:

> "Several epidemiologic studies have demonstrated statistically significant elevations in the risk of lung cancer and other respiratory system cancers among workers employed in fibrous glass and mineral wool manufacturing facilities. [...] The most recent follow-up of fibrous glass exposed workers in the U.S. study still demonstrate a significant excess of lung cancer. [...] Numerous studies have demonstrated that fiber glass and mineral wools produce lung cancer, mesotheliomas, and sarcomas in experimental animals."[300]

The accumulation of evidence has prompted the United States to classify glass fibre, glass wool and ceramic fibres as "reasonably anticipated to be a carcinogen".[301]

3.203 Canada notes that the French INRS states that refractory ceramic fibres "[Tr.] cause mesotheliomas with an experimental incidence comparable to and indeed greater than (at high doses) asbestos (chrysotile)".[302] Again according to the INRS: "[Tr.] In light of the results of animal experiments, RCFs [refractory ceramic fibres] are carcinogenic and fibrogenic when inhaled".[303] According to the United States EPA, these fibres are probable carcinogens.[304] The EC cite the larger diameter of three of the substitute fibres, namely PVA, para-aramid and cellulose fibres, to argue that they pose a lower health risk. However, this is a "nominal diameter" which does not prevent a significant proportion of fibres from having a diameter which falls well within the range of respirable diameters.[305]

3.204 According to the WHO in a 1993 study on substitute fibres:

> "All fibres that are respirable and biopersistent must undergo testing for toxicity and carcinogenicity. [...] The data available suggests para-aramid fibres fall within this category. Furthermore, other respirable organic fibres should be considered to fall within this category."[306]

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[298] *Fibres minérales artificielles et amiante (Résumé)*, Report of the *Groupe scientifique pour la surveillance des atmosphères de travail* (G2SAT), INRS – DMT No.69.

[299] See IARC, Vol. 2, para. 5.1, available on-line: IARC <http://193.51.164.11/htdocs/monographs/Vol02/Asbestos.html> (acces date: 10 June 1999); IARC Vol. 14, para. 5.1 available on-line: IARC < http://193.51.164.11/htdocs/monographs/Vol14/Asbestos.html> (access date: 10 June 1999).

[300] See United States Department of Labor (OSHA), *Synthetic Mineral Fibers: Hazard Description*, on-line: OSHA <http://www.osha.gov/oshinfo/priorities/synthetic.html> (access date: 22 June 1999).

[301] *Id.*, OSHA refers to the National Toxicology Program, Seventh Annual Report on Carcinogens, United States Department of Health and Human Services, Public Health Service, 1994.

[302] *Fibres minérales artificielles et amiante (Résumé)*, Report of the *Groupe scientifique pour la surveillance des atmosphères de travail* (G2SAT), INRS – DMT No.69.

[303] *Id.*

[304] Canada See notes that the United States EPA classifies refractory ceramic fibres as probable carcinogens. See the EPA site on refractory ceramic fibres, available on-line: EPA <http://www.epa.gov/iris/subst/0647.htm>.

[305] Dunnigan, J., Nadeau, D. and Paradis, D., *Cytotoxic Effects of Aramid Fibres on Rat Pulmonary Macrophages: Comparison with Chrysotile Asbestos*, (1984) 20 Toxicology Letters 277.

[306] *IPCS Environmental Health Criteria (151): Selected Synthetic Organic Fibres*, WHO, Geneva, 1993, p.76.

In light of the IARC classification, the WHO, EPA and INRS data, and the two INSERM reports, Canada considers that one cannot therefore objectively speak, as the EC do, of the "proven" safety or lower toxicity of substitute fibres. In Canada's view there is "no clear hierarchy in the relative toxicity" of chrysotile fibres and substitute fibres, as the EC claim and would like to believe.

3.205 Canada considers that the use of chrysotile substitute fibres has an impact not only in terms of creating a risk for the French population because of the toxicity of substitute fibres and the false sense of security that the Decree promotes. The use of substitute fibres also has a direct impact on the question of controlled use, one of the key issues in this dispute. Canada notes that, in order to counter Canada's argument that there is a means less restrictive for international trade than a total ban, the EC cite "the impossibility" of the controlled use of chrysotile. Yet, in the same breath, they minimize the risks of substitute fibres by stating that the strict regulations which govern them eliminate any hazard. For Canada, these strict regulations constitute nothing less than a controlled use of substitutes.

3.206 Canada notes that the EC claim, for example, that refractory ceramic fibres, despite their known toxicity, do not pose a risk to the French population since they are strictly regulated, citing in support of their argument the relevant articles of the Labour Code. They continue to praise controlled use, boasting that "replacement by man-made mineral fibres is strictly regulated". Concerning glass and rock wools, the EC claim that "These fibres are subject to occupational exposure limits and to the rules designed to protect workers against chemical risks." As for refractory ceramic fibres, the French population is apparently protected since "These fibres are subject to rules which are even stricter than those concerning chemical risks." Canada is quite intrigued by this about-face as to the merits of controlled use and wonders why the EC cite the feasibility of controlled use for substitute fibres and summarily reject the feasibility of controlled use in the case of chrysotile fibres?

3.207 According to Canada, the EC are endeavouring to make the replacement of chrysotile by fibres "shown to be harmless or less harmful" a "necessity acknowledged internationally". There are two major flaws in this reasoning. The first flaw is that replacement must be done only when necessary. The ILO, through Convention 162[307] and Recommendation 172,[308] therefore provides for replacement "where necessary". As Canada has already pointed out, high-density non-friable chrysotile materials account for 97.5 per cent of the current uses of chrysotile. These are no longer the friable products that the WHO, like Canada, considers problematic. In Canada's opinion, it is these friable products whose replacement must be contemplated and that have already been largely replaced (97.5 per cent).

3.208 Canada notes that, as the EC emphasize, the WHO is of the opinion that replacement must be done whenever it is possible to replace chrysotile asbestos with "safe substitute materials". As Canada has stressed, the chrysotile substitute products used in France are not, as the WHO prescribes, "safe". Chrysotile asbestos is not replaced by products "shown to be harmless or less harmful". Nor is it replaced by products which, according to the ILO, should be "harmless or less harmful".[309] The replacement of chrysotile asbestos by substitute fibres in fibro-cement and friction products is not a "necessity acknowledged internationally". At best, the Decree on a ban, which imposes replacement,

[307] Convention concerning Safety in the Use of Asbestos (Convention 162), adopted on 24 June 1986, International Labour Organization, Geneva, Article 10. Recommendation concerning Safety in the Use of Asbestos (Recommendation 172), adopted on 24 June 1986, International Labour Conference, Geneva, Article 12.

[308] Recommendation concerning Safety in the Use of Asbestos (Recommendation 172), adopted on 24 June 1986, International Labour Conference, Geneva, Article 12.

[309] Convention concerning Safety in the Use of Asbestos (Convention 162), adopted on 24 June 1986, International Labour Organization, Geneva, Article 10; Recommendation concerning Safety in the Use of Asbestos (Recommendation 172), adopted on 24 June 1986, International Labour Conference, Geneva, Article 12.

is an unjustified restriction on international trade in violation of the WTO Agreements.[310] At worst, it is a measure which endangers the French population by replacing an undetectable risk by an unknown risk and by fostering a false sense of security.

3.209 The **European Communities** assert that the principle of replacing one substance by another that is less dangerous or harmful or by a new technique is a general rule of primary prevention applicable to human and environmental protection. It is based on abolishing the risk at the source by totally abandoning the use of the substance shown to be harmful in order to eliminate its effects. Where the use of asbestos fibres is concerned, this basic rule is applied by all the international bodies that draft recommendations designed to protect human health. According to the EC, positions on this rule have been taken repeatedly: (i) by the ILO[311], since 1986; (ii) by the WHO[312], in particular in its press release dated 26 July 1996 concerning the chrysotile variety of asbestos, according to which "when available, substitute materials evaluated as safer than chrysotile should be considered"; and (iii) by the European Community in its 1990 framework Directive on the health and safety of workers and later in the Directive on carcinogens.

3.210 The EC point out that, when banned in France, asbestos fibre was not being used as such but mainly as a component in the following products or materials: (i) asbestos-cement materials (pipes, ducts, roof tiles, roof and wall cladding, planting tubs, etc.), which accounted for more than 90 per cent of the chrysotile used in France; (ii) friction materials (clutch and brake linings); (iii) insulation (board, felt); (iv) textile products (sealing braid, tape, blankets); (v) seals and gaskets; and (vi) miscellaneous products (mouldings, plastics, glues, coatings, mortars, etc.). Since asbestos has so many uses, there is no single natural or synthetic product which, alone, could serve as a universal replacement for asbestos in all the products and materials that contain it. According to the EC, there is thus no single substitute for asbestos, only replacement solutions which rely on different substitutes depending on the application, sometimes used in combination to provide a material or product with equivalent performance. Thus, the ban on asbestos is being applied by steering the market for asbestos-containing products and materials towards: (i) existing alternative technologies which do not rely on a substitute for asbestos (ductile iron or plastic pipes, aluminium roof and wall cladding, etc.); and (ii) products and materials containing one or more substitutes, some of which are fibrous but less dangerous.

3.211 The EC state that, depending on the application, asbestos has been replaced by: (i) cellulose, polyvinyl alcohol and polypropylene fibres in asbestos-cement materials; (ii) para-aramid fibres and glass fibres (combined with other non-fibrous materials) in brakes and other friction products; (iii) man-made mineral fibres (glass, rock) and often non-fibrous materials (perlite, vermiculite, silicates, etc.) for insulating panels, blocks and coatings; (iv) para-aramid and man-made mineral fibres combined, depending on the technical requirements, with metal thread (steel) or carbon or polytetrafluoroethylene (PTFE) fibres in asbestos-containing textile products, seals and various moulded products; or (v) special glass fibres (calcium and magnesium silicates) or refractory ceramic fibres in products designed to withstand very high temperatures. The price of asbestos fibres varies from F 5 to 9 per kilo depending on the origin and the physical characteristics of the fibres. The various substitute products, whether or not fibrous, are generally more expensive than asbestos (with the exception of some which cost more or less the same). The finished products containing asbestos substitutes are all more expensive than the asbestos-containing products serving the same purpose. In general, the price ranges of the main substitutes are as follows: (i) less than or about F 12/kg: cellulose, man-made mineral fibres (glass, rock), perlite, vermiculite; (ii) from F 12 to 60/kg: glass filaments, steel thread, polypropylene and polyvinyl alcohol fibres; (iii) from F 60 to 120/kg: special

[310] Canada notes that the Decree "in no way makes it mandatory to use substitute products", but it does make it unavoidable, as the EC note.

[311] Convention concerning Safety in the Use of Asbestos (Convention 162), adopted on 24 June 1986, International Labour Organization, Geneva, Article 10.

[312] *Chrysotile Asbestos evaluated by Health Experts*, Press Release 51, WHO, 26 July 1996.

glass fibres (high-temperature), polytetrafluoroethylene (PTFE) fibres; and (iv) from F 120 to 200/kg: para-aramid and refractory ceramic fibres.

3.212 The EC indicate that these various substitutes are used as replacements for asbestos only on a very small-scale as compared with their widespread use in other industries: (i) between 10 and 20,000 tonnes of cellulose for fibro-cement, as compared with about 5 million tonnes consumed in France in the paper and textile industries; (ii) only a few thousand tonnes of polypropylene or polyvinyl alcohol fibres, which are mostly used in the textile and packaging industries; and (iii) less than 1 per cent of man-made mineral fibres, mainly used for insulating buildings. In general, France imports about 40 per cent of the cellulose it uses, in particular from Canada[313] and the United States. Thus, in 1998, France imported 380,000 tonnes from Canada as compared with 371,000 tonnes in 1997 and 366,000 tonnes in 1996. The EC also note that there are only two factories in the world that produce polyvinyl alcohol fibres, one in Japan and the other in China. Finally, overall, France's trade balance for these two products is regularly in deficit.

3.213 The EC assert that none of the substitutes for chrysotile is classified as carcinogenic for humans. The main substitutes are cellulose and polyvinyl alcohol fibres used to replace chrysotile in materials and products formerly made of asbestos-cement, together with the para-aramid fibres used in jointing, textiles and friction products. According to the EC, these are substances which give no cause for concern after decades of massive use throughout the world for other purposes. Thus: (i) cellulose fibres have also been used for several centuries for making paper pulp (several million tonnes are consumed in France every year); (ii) polyvinyl alcohol has been widely used since 1936 for making film for wrapping food and in the textile industry; and (iii) since the 1960s, para-aramid fibres have been extensively used for making clothing and twine. Only fibres less than 3 microns in diameter can penetrate deep into the lungs. The fibres which must be taken into account in making a metrological assessment of a working environment have been defined by the WHO[314] in accordance with the following dimensional parameters: (i) length greater than 5 microns; (ii) diameter less than 3 microns; (iii) ratio of length to diameter greater than 3 microns [3:1]. The polyvinyl alcohol and para-aramid fibres used to replace asbestos are 2 to 8 mm (i.e. 2,000 to 8,000 microns) long and 10 to 16 microns in diameter. Cellulose fibres, which are 12 to 40 microns in diameter, can give rise to finer particles (fluff), which are said to irritate the respiratory pathways. These fibres are more than 10 microns in diameter, which means that it is physically impossible for them to penetrate into the pulmonary alveoli.

3.214 The EC consider that the results of the CSTEE[315] and COC[316] studies are unambiguous as regards the carcinogenicity of chrysotile and the fact that the three fibres mentioned above have given no cause for concern over their long period of use. Man-made mineral fibres such as glass or rock fibres are used for gaskets, friction materials and sealing braid required to withstand temperatures up to 1,200ºC. These substances have been the subject of studies analysed in two reports[317] which have concluded that they are less harmful for humans than chrysotile asbestos. The EC emphasize that, unlike chrysotile fibres, which have a diameter of from 0.1 to 1 micron and which separate lengthways into even finer crystalline fibrils (0.020 micron), all the synthetic fibres used in France to replace chrysotile, whether of organic (polyvinyl alcohol, para-aramid) or mineral (glass, rock) origin,

[313] The EC note that, in 1984 and 1985, Canada produced 20 million tonnes of cellulose (source: *Alternatives to Asbestos, the Pros and Cons*, Society of Chemical Industry, United Kingdom, 1989).

[314] Determination of airborne fibre number concentrations, WHO, Geneva 1998.

[315] *Avis concernant l'amiante chrysotile et les produits de substitution envisageables*, Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), 15 September 1998.

[316] *Statement for the Health and Safety Executive (HSE) on Carcinogenic Risks of Three Chrysotile Substitutes*, Committee on the Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC), July 1998.

[317] *Fibres minérales artificielles et amiante (Résumé), Report of the Groupe scientifique pour la surveillance des atmosphères de travail* (G2SAT), INRS – DMT No.69. INSERM, *Substitutes – Executive Summary.*

retain the diameter determined by the manufacturing process throughout the life cycle of the fibre, even when emitted by a material in the process of being machined. Refractory ceramic fibres, classed as group 2 carcinogens (i.e. carcinogenic in animals but not in man), are only used in industry for a few applications where very high temperatures must be withstood. In accordance with the substitution principle, they are progressively being replaced by other, less harmful substances as technology evolves.

7. The INSERM report

3.215 **Canada** states that, at the request of the *Direction des Relations du Travail* (Ministry of Labour) and the *Direction Générale de la Santé* (Ministry of Social Affairs), INSERM mandated a "joint commission of experts" to study the health effects of the main types of exposure to asbestos. This group of 11 researchers was set up in the summer of 1995 and met some ten times between August 1995 and March 1996. It submitted its Executive Summary to the French Government on 21 June 1996. This Executive Summary was made public in July 1996 and the final report in November 1997.[318] The final report has two sections: an analysis section and an Executive Summary. The analysis section contains a review of the scientific literature and summarizes the state of knowledge, allowing for a better understanding of the health risks of various circumstances of exposure to asbestos. In particular, this section covers measurement methods, the physico-chemical properties of asbestos, the main circumstances of exposure and the epidemiology of diseases linked to asbestos. The Executive Summary contains a recapitulation and presents the findings and recommendations on future studies and research to be carried out.

3.216 Canada notes that the main findings in the Executive Summary are as follows: concerning the evaluation of the risks, INSERM estimated the number of deaths in France in 1996 attributable to passive exposure to asbestos at 1,950. Concerning risk management, the group of experts pointed to certain facts: (i) asbestos is carcinogenic and should be replaced with substitute fibres, as soon as technically possible, in accordance with European law; however, the researchers do not have sufficient information on the risks of substitute fibres; (ii) chrysotile entails a level of risk comparable to or lower than the other types of asbestos, depending on the diseases considered; (iii) there is not enough data on the number of persons exposed to asbestos to assess the risks under varying situations of exposure; (iv) the risk assessment was effected on the basis of the regulation legal exposure limits; (v) the quantification of the risks is different from an evaluation of the risks, which would involve ethical, social, economic and political considerations; (vi) the researchers express grave reservations about the systematic removal of sprayed asbestos from buildings; (vii) extreme caution is called for with regard to the control of the conditions of occupational exposure to asbestos; and (viii) the researchers question the low level of compensation afforded to persons suffering from diseases caused by occupational exposure to asbestos.

3.217 Canada notes that the group also issued recommendations on future studies and research to be carried out in the following areas for which the data are still insufficient: (i) knowledge of site contamination; (ii) knowledge of exposure of people; and (iii) monitoring the trend in health risks associated with exposure to asbestos in order to assess the risk of low-level exposure. Finally, the research group makes the following recommendations: (i) further epidemiological research should be conducted into the risks associated with exposure to asbestos, as the researchers had not been able to gain an in-depth understanding of the topic; (ii) given the lack of data on the safety of substitute fibres, research should be conducted into this area without delay; (iii) more extensive research into the control of environmental health risks should be conducted; and (iv) a policy of coordinated studies and research into the environmental health risks should be elaborated. According to Canada, the INSERM report does not offer any new scientific findings. However, it proposes a model for assessing the risks of contracting lung cancer and mesothelioma from low-level exposure, which is

[318] INSERM, *Rapport sur les effets sur la santé des principaux types d'exposition à l'amiante*, INSERM joint report, Paris, INSERM publications, 1997, p.239.

based on a simple extrapolation of the risks observed from higher levels of exposure, without distinction between amphiboles and chrysotile. The report indicates, however, that: "[Tr.] This extrapolation does not produce certain scientific knowledge, but only an aid to understanding the implications for risk management."[319]

3.218 Canada submits to the Panel four studies that are critical of the INSERM report. The studies are by the Royal Society of Canada[320], Dr. Graham W. Gibbs[321], Dr. Jacques Dunnigan[322] and the epidemiologist Michel Camus.[323] Furthermore, certain key conclusions of the INSERM report obviously contradict a study by the French *Académie nationale de médecine*.[324] The critical studies reveal that INSERM studied the health effects of asbestos on the basis of hypothetical exposure situations that bear no relationship whatsoever to actual exposure. INSERM did not have at its disposal any data whatsoever on the number of persons exposed to asbestos in France. It did not sufficiently emphasize the fundamental pathogenic distinction between amphibole fibres and chrysotile fibres. The conclusions of the INSERM report are based on the risks associated with exposure sustained in the context of outdated asbestos applications, i.e., the use of amphiboles or fibre mixtures in brittle materials such as spraying asbestos and heat insulation. Moreover, the methodology of the INSERM report utilizes a linear risk model that assigns, by pure extrapolation, theoretical risks to low-level exposure, even though no epidemiological study to date has detected a higher health risk resulting from low-level exposure. Finally, the INSERM report does not investigate substitute fibres, a problem that the researchers themselves considered to be "inseparable"[325] from the question of whether to ban chrysotile. Canada also notes that the INSERM report was qualified by Claude Allègre, France's Minister for Education, as "mediocre". Mr. Allègre also said that "[Tr.] There is nothing exceptional about the report in terms of scientific rigour, courage or scientific initiative […] The report contains no clear findings and can be used to support any and all arguments."[326]

3.219 According to Canada, the INSERM report is based on hypothetical data[327] and does not study the exposure actually sustained by the French population. Instead, it proceeds to make "the most plausible, though uncertain estimates".[328] The INSERM researchers themselves concluded that "[Tr.] there is currently a great deal of uncertainty about occupational or passive exposure that has existed or

[319] INSERM report, p. 239.

[320] Royal Society of Canada, *A Review of the INSERM Report on the Health Effects of Exposure to Asbestos*, Ottawa, 1996 [hereinafter "RSC"]. Canada notes that the RSC formed an international committee of independent experts to review the INSERM report. This committee, which was chaired by Dr. F. Kenneth Fare, Ph.D. (Montreal) was composed of the Canadian Michael Brauer, Sc.D. (Harvard, Berkeley), the American Kenny S. Crump, Ph.D. (Montana State), the Briton John M.G. Davis, MA, Sc.D. (Cambridge), FRC. Path., and Enzo Merler, MD (Padua).

[321] M.Sc., Ph.D., LRSC, ROH.: Gibbs, G., *A Review of the Report: "Rapport d'expertise collective INSERM"*, October 1996 [hereinafter "Gibbs"].

[322] Ph.D.: Dunnigan, J., *Commentaire sur le "Rapport d'expertise collective INSERM"*, September 1996 [hereinafter "Dunnigan"].

[323] Ph.D. Camus, M., *L'amiante et les risques pour la santé*, April 1999.

[324] Académie nationale de médecine (Étienne Fournier), *Amiante et protection de la population exposée à l'inhalation de fibres d'amiante dans les bâtiments publics et privés*, Paris, 1996.

[325] INSERM report, p. 428.

[326] Comments reported in *Le Monde*, 18 October 1997, p.13.

[327] Canada notes that, two months before the appearance of the INSERM report, the Académie nationale de médecine considered it crucial that scientific reports on the risks associated with asbestos should be based on real data, not hypothetical data. According to the Académie: "A cautious attitude should undoubtedly always be adopted with regard to the purity of the air inhaled, but speaking or writing on asbestos in general without taking into account the doses or quantities actually present in the air inhaled is at the best a sign of ignorance and at worst an attempt at blackmail. We therefore refer to quantities measured." (WTO translation) (Académie nationale de médecine (Étienne Fournier), *Amiante et protection de la population exposée à l'inhalation de fibres d'amiante dans les bâtiments publics et privés*, Paris, 1996, p. 10).

[328] INSERM report, p. 232.

now exists within the population".[329] In Canada's view, therefore, the INSERM researchers could only have based their conclusions on hypothetical exposure data. These "hypothetical" conclusions concerning the number of deaths attributable to asbestos among an exposed population (for example 10,000) cannot be applied to the French population because the number of persons exposed to asbestos in France, and the rate of exposure, remain unknown.[330] Canada notes that the Royal Society of Canada (RSC) writes that "… the report fails adequately to address the relevance of the available studies to the key present question: are current exposures associated with increased risk?" (underlined in the original).[331] This shortcoming undermines the usefulness of the INSERM report, prompting the RSC to express its concern over the fact that "… the risk characterization is less satisfactory because actual exposure data were not used".[332] The RSC stresses that the hypothetical estimation of exposure inevitably results in an overestimation of the risks actually incurred by the French population.

> "Not only does the failure to look at realistic exposures result in less specific guidance on the actual situation in France, but the assumed exposures are likely to be much greater than those experienced by the French population. […] INSERM's estimates have been based on permissible occupational and environmental levels in France. This methodology is not wrong, provided that it is clearly understood that the predicted deaths are not based on the exposure profile of the French population. The conditions of exposure are hypothetical. […] the report should have emphasized that actual exposures are in all likelihood substantially lower, and so, correspondingly, are the actual risks facing the French public."[333]

3.220 Canada notes that, when calculating ongoing indoor passive environmental exposure, INSERM applied the high exposure level of 0.025 f/ml.[334] For occupational exposure levels, it applied another very high rate, 0.1 f/ml.[335] Moreover, INSERM applied these exposure levels to the risk models applicable to cohorts for whom the exposure levels were between 2 f/ml and 250 f/ml[336], i.e., at levels that are 20 to 10,000 times higher. In its conclusions and recommendations, INSERM stresses the fact that, besides having used hypothetical exposure rates, the number of persons actually exposed to asbestos – the collective risk of the French population – is unknown and has not been the subject of any research. Canada points out that the conclusions presented as the risk per 10,000 persons refer to a population of 10,000 persons actually exposed to the hypothetical – and exaggerated – levels applied by INSERM:

> "The estimates we have furnished correspond to 'individual' risks; we in fact estimated the probability that a person who *might* find himself in a hypothetical situation of exposure to asbestos would develop lung cancer or a mesothelioma because of this (it is indeed an individual risk, even if it is expressed in terms of 'per 10,000'." [italics in the original]."[337] (WTO translation)

3.221 Canada notes that, according to INSERM, "These figures alone do not give an overall estimate of the number of deaths from cancer in France at the present moment attributable to exposure

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[329] *Id.*, p. 423.
[330] *Id.*, p.235, see also pp. 234, 237, 238.
[331] RSC, *A Review of the INSERM Report on the Health Effects of Exposure to Asbestos*, Ottawa, 1996 p.3 of the English text.
[332] *Id.*, p.4 of the English text.
[333] *Id.*, pp.4 and 12 of the English text. Canada indicates that Dr. Gibbs is of the same opinion as the RSC: "In interpreting the risks provided in the report, it is important to recognize that risk estimates given in the report are, in general, *not based* on actual or estimated exposures but on the current or proposed 'legal' limits in France." (Gibbs, p.2).
[334] INSERM report, p. 232. Canada notes that this level is the maximum legal limit in France for indoor passive exposure. For a critique of this approach, see Camus, M., *L'amiante et les risques pour la santé*, April 1999, p.8.
[335] *Id.*
[336] INSERM report, pp.233-38.
[337] *Id.*, pp.428 and 429.

to asbestos" (WTO translation).[338] The report concludes that "it is essential to obtain information on the number of persons exposed to asbestos […] in order to be able to estimate the number of cases of lung cancer and mesothelioma caused by exposure to asbestos […] in the French population ('collective' risk')."[339] (WTO translation). INSERM estimates the number of cancer deaths in 1996 linked to exposure to asbestos at 1,200. It arrives at this number by applying to all of France the results of a study of the population of Glasgow, without analysing the methodology of this study or the rates of exposure to asbestos of this population.[340] Yet INSERM points out that "[Tr.] France began using asbestos later and used less asbestos than other countries, and no doubt proportionately smaller quantities of amphibole-type fibres. Because of these differences, there is no simple way to transpose to France the results of the projections regarding mesotheliomas [and cancers] recently produced for Great Britain".[341] As for the number of mesothelioma deaths, Canada notes that INSERM does not reveal how it arrived at its estimate of 750. Canada also notes that the French Senate and National Assembly[342] and the *Académie nationale de médecine* estimate this number at 600, of which up to 30 per cent are "unrelated to asbestos".[343] Furthermore, according to the *Académie nationale de médecine*, an exposure of 0.025 f/ml for eight hours a day over 60 years would entail a risk of contracting mesothelioma of "one case per million, a figure equivalent to zero in biological mathematics".[344]

3.222 In Canada's view, INSERM's risk estimates do not pay sufficient attention to the crucial distinction between the effects of amphiboles and those of chrysotile. Moreover, the risk estimations presented as being linked to chrysotile exposure are often based on parameters for exposure to amphiboles or amphibole-chrysotile mixtures. According to Canada, it is well known that the pathogenic potential of amphiboles is much greater than that of chrysotile[345] and, even if it did not pay

[338] *Id.*, p.235. See also p.236.

[339] *Id.*, p.429. INSERM also emphasizes that "this information is practically non-existent in our country and it should now be collected so that we can have an overall estimate of the number of persons concerned by the various situations of exposure to asbestos and the risks they are running because of this". (WTO translation)

[340] De Vos Irvine, H. *et al.*, *Asbestos in Lung Cancer in the West of Scotland* (1993) 306 British Medical Journal, 1503. This study is included in Wilkinson, P. *et al.*, *Is Lung Cancer Associated with Asbestos Exposure When There are no Small Opacities on the Chest Radiograph?* (1995) 345 Lancet 1074. INSERM applied the rate of 5.7 per cent of cancers linked to asbestos in Glasgow to the total 21,617 cancer cases in France in 1996 to arrive at 1,200 deaths by cancer linked to asbestos (INSERM report, p.250). According to the authors of the study, De Vos Irvine, H. *et al.:* "A comparison of international cancer registry data shows that the west of Scotland experiences one of the highest incidence rates of lung cancer in the world." (p.503). The RSC makes a point of the lack of scientific rigour on the part of INSERM with regard to this conclusion. It is of the opinion that "INSERM'S estimates of asbestos-related deaths in France in 1996 [were] based on an estimate from the literature specific for Great Britain without critical analysis of the methodology, or establishment that the estimate was applicable to France (RSC, p.3 of the English text; See also Gibbs, p.13).

[341] INSERM report, p.409. In Canada's view, INSERM's error can clearly be seen in the following example. According to INSERM's conclusions, there would be 543.5 cancers in a population of 10,000 people subject to an occupational exposure of 0.1 f/ml for 40 hours a week over 45 years. However, only 21.5 of these cancers would be linked to exposure to asbestos (INSERM report, p.234). Thus, according to INSERM's data, a little less than 4 per cent of the cancer deaths (21.5/543.5 = 4 per cent) of a population highly exposed to asbestos (0.1 f/ml for 40 hours a week over 45 years) would be linked to asbestos. Why then did INSERM apply the 5.7 per cent from the Glasgow study to the entire French population, which was not subject to exposure of 0.1 f/ml for 40 hours a week over 45 years? Canada notes that, even if one accepts the 4 per cent rate at which INSERM arrived, the number of cancer deaths in 1996 attributable to past exposure to asbestos would be 864 (4 per cent x 21,617), not 1,200.

[342] Le Déaut, J.-Y. et Revol, H., *L'amiante dans l'environnement de l'homme: ses conséquences et son avenir*, Office parlementaire d'évaluation des choix scientifiques et technologiques, National Assembly no. 329 / Sénat no. 41, 1997, p.29.

[343] Académie nationale de médecine (Étienne Fournier), *Amiante et protection de la population exposée à l'inhalation de fibres d'amiante dans les bâtiments publics et privés*, Bulletin de l'Académie nationale de médecine, Vol. 180, no. 4., pp.8 and 9.

[344] *Id.*, p 9.

[345] Dunnigan, p. 4.

sufficient attention to this fact, the INSERM report nonetheless recognizes the much higher mesothelioma risk associated with exposure to amphiboles, compared to chrysotile exposure.[346] In this regard, Dr. Gibbs remarks that "when they [INSERM] estimate the risk of mesothelioma, they fail to take into account the differences in risk associated with these various fibre types."[347] He continues: "The INSERM report grossly overestimates the mesothelioma risks due to exposure to 'commercial chrysotile' only. The hypothetical risks in the report would be more accurately characterized as those associated with amphibole or mixed commercial amphibole-chrysotile exposures."[348] The comments of the RSC are similar:

> "The Panel *believes* that the risk of mesothelioma from chrysotile exposure is likely overestimated, since it is based on a single study that involved a small amount of crocidolite in addition to chrysotile, and ignored several studies of pure chrysotile exposure, all of which indicate a smaller mesothelioma risk than calculated by INSERM."[349] [italics in the original]

3.223 Canada indicates that, in addition to mentioning the use of risk estimation parameters associated with amphiboles or mixed fibres, Dr. Gibbs points out that INSERM applied the parameters deriving from the exceptionally high risk levels of the textile industry sector, as opposed to the risks posed by the chrysotile-cement sector, which accounted for more than 90 per cent of the modern uses of chrysotile in France prior to the adoption of the Decree:

> "The INSERM authors have chosen to use as their factor for estimating lung cancer risk, a value reflecting risks in the textile industry sector or mixed asbestos fibre industries. The use of such a factor may be reasonable if INSERM reports that the factor reflects mixed exposure or is based on the odd man out – the high textile risk. The INSERM report is misleading in inferring that these are the risks associated with commercial chrysotile. They do not reflect the values which are relevant to the chrysotile friction industry, mining and milling industries or chrysotile asbestos-cement industry."[350]

3.224 Canada states that INSERM examined outdated exposure, but did not consider any risk study based on current chrysotile exposure. Under the misleading sub-title "3.1.1. Estimation of the risks associated with exposure to asbestos" (WTO translation), the report claims that 1,950 deaths were linked to exposure to asbestos in 1996. According to Canada, these deaths are in no way attributable to the current circumstances of exposure to chrysotile. Considering the latency period of 15 to 50 years in the case of mesothelioma and 15 to 30 years in the case of cancers[351], the 1,950 deaths are the result of exposure caused by the outdated practices of the 1950s and 1960s. Moreover, Canada considers that it is very likely that these exposures were to amphibole-chrysotile mixtures and pure amphiboles. Important reservations are in order with regard to this conclusion of INSERM. The RSC states that:

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[346] INSERM report, p.412. The Académie nationale de médecine confirms that amphiboles are "currently considered to be the most dangerous" and that chrysotile is "considered as not very dangerous because it is broken down spontaneously in the human organism […] Chrysotile is a form of asbestos that has only caused mesothelioma in cases of massive and prolonged exposure. This can be explained by its solubility in the organism." (WTO translation). (Académie nationale de médecine (Étienne Fournier), *Amiante et protection de la population exposée à l'inhalation de fibres d'amiante dans les bâtiments publics et privés*, Bulletin de l'Académie nationale de médecine, Vol. 180, no. 4, p.2).

[347] Gibbs, p. 6. The Royal Society of Canada adds that "the differences between chrysotile and amphiboles may have been underestimated by INSERM, particularly for mesothelioma". (RSC, p.6 of the English text).

[348] Gibbs, p. 8.

[349] RSC, p.12 of the English text.

[350] Gibbs, p.9. See also Camus, M., *L'amiante et les risques pour la santé*, April 1999, p.8.

[351] Académie nationale de médecine (Étienne Fournier), *Amiante et protection de la population exposée à l'inhalation de fibres d'amiante dans les bâtiments publics et privés*, Bulletin de l'Académie nationale de médecine, Vol. 180, no.4, p.4.

> "the INSERM estimates of 750 deaths in France from mesothelioma and 1,200 from lung cancer in 1996 refer to deaths in 1996 but from occupational exposures at a much earlier date; they are not deaths due to exposures in 1996. Although INSERM is well aware of this, their report is not explicit enough." [underlined in the original][352]

3.225 Canada notes that, according to INSERM, "the immense majority of these deaths can indisputably be explained by circumstances of occupational or para-occupational origin"[353], which is to say, exposure that is neither environmental exposure nor exposure to asbestos indoors[354], and which, according to INSERM itself, poses no risk whatsoever according to the epidemiological data.[355] Canada notes that, two months prior to the publication of the INSERM report, the French Académie nationale de médecine published a study urging calm in the face of the widespread fears incited by exaggerated media coverage of cancer and mesothelioma cases. The Académie resolutely stated that the extremely low current levels of exposure are not a source of health risks.[356] Canada is surprised that INSERM paid no heed to this observation, which was well-known in French scientific circles at the time.

3.226 Canada also points out that INSERM did not investigate the case of intermittent exposure to modern chrysotile applications. According to INSERM:

> "It is clearly established that the highest risks of mesothelioma are now in occupations where conditions of exposure are intermittent … In the 1960s, the main professions affected were the production and use of asbestos […] In contrast, in the 1980s and 1990s, the highest risks concerned work that involved handling materials [i.e. friable materials] containing asbestos."[357] (WTO translation)

3.227 Canada points out that the INSERM report does not look into the question of exposure to chrysotile fibres during intermittent operations on structures made of chrysotile-cement, such as sanding, sawing and drilling. INSERM could only have observed, in accordance with existing studies, that the emission levels in such cases are extremely low or even non-existent.[358] Moreover, structures made of chrysotile-cement, by their nature, require very little maintenance, and when they do, the fibre emissions can be minimized by observing simple procedures and safety precautions. Dr. Gibbs points out that the risks identified by INSERM do not correspond to the values applicable to the

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[352] RSC, pp.6 and 9 of the English text. According to J. Peto, expressing his opinion of the comparison between present and past exposure rates: "It might therefore be thought that none of the data that have been collected permit any truly scientific prediction of the likely effects of the limits to exposure that have now been set. This may indeed be the case." (Doll, R. and Peto, J., *Asbestos: Effects on Health of Exposure to Asbestos,* Her Majesty's Stationery Office, U.K., 1985, p. 44).

[353] INSERM report, p.420. See also RSC, p.9 of the English text.

[354] As emphasized by the RSC on p.9 of the English text.

[355] According to INSERM: "At present there are no solid direct epidemiological data that enable an assessment to be made of the health effects linked to urban passive environmental or building exposures. […] Even without recalling that such studies would have little chance of directly noting a health effect, if it is low, it has to be recognized that we do not have any reliable epidemiological data." (WTO translation) (INSERM report, pp.404 and 405).

[356] Académie nationale de médecine (Étienne Fournier), *Amiante et protection de la population exposée à l'inhalation de fibres d'amiante dans les bâtiments publics et privés*, Bulletin de l'Académie nationale de médecine, Vol. 180, no. 4, pp.5 and 9.

[357] INSERM report, pp.424 and 400.

[358] See in particular the French study of the *Laboratoire d'hygiène et de contrôle des fibres minérales*: Baujon et Authier, *Détermination des concentrations de fibres d'amiante dans l'atmoshpère lors de la pose sur chantier de plaques ondulées et d'ardoises en amiante-ciment, Laboratoire d'hygiène et de contrôle des fibres minérales*, Paris, July 1993. Canada notes that, according to this study, the use of self-boring screws during the process of installing corrugated panels gives rise to an emission of 0.022 f/ml. Moreover, the installation of roof tiles can give rise to emissions of 0.007 f/ml, depending on the method used. These peak exposure levels, which are well below the exposure standards in effect in France, can be further reduced by dampening the materials. Furthermore, workers can be protected from inhaling the fibres simply by wearing a mask.

friction materials industry, nor to the mining, machining or asbestos-cement industries.[359] Canada also refers to the conclusions of the *Académie nationale de médecine*, which determined that: "[Tr.] no illness due to asbestos has yet been formally proven in France outside an occupational type of exposure".[360] These conclusions run counter to those of INSERM and underscore the growing scepticism with regard to the scientific value of the arguments presented as justification for the banning of chrysotile. According to Canada, these doubts, in fact, originated in the French scientific community.[361]

3.228 Canada states that, in its risk assessment, INSERM used a linear model that over-estimated the risks of low exposure. This model offers a method of extrapolating the risk of low exposure to chrysotile from the risk of high exposure. Canada points out that the epidemiological data, however, indicate no detectable risk whatsoever deriving from low exposure, as INSERM itself acknowledged in the case of environmental exposure and indoors exposure to asbestos.[362] INSERM admits that to date, it does not possess "[Tr.] direct and unequivocal scientific expertise on the value of the risk of lung cancer and mesothelioma that may exist among humans exposed to 1f/ml or lower levels".[363] The estimates that INSERM arrives at "[Tr.] have to be considered as *orders of* magnitude given that there is no definite knowledge regarding the risk of cancer at resulting from exposure to levels below 1 f/ml [italics in the original]."[364] INSERM saw its role as being " [Tr.] to provide scientifically verified elements of knowledge concerning the health risks linked to exposure to asbestos, but risk management is not its responsibility".[365] Nonetheless, INSERM performs extrapolations for low exposure even though "[Tr.] This extrapolation does not produce certain scientific knowledge, but only an aid to understanding the implications for risk management."[366] Canada considers that the INSERM report, however, as a scientific evaluation of the risks, should be more than "an aid to understanding" based on "plausible uncertain estimates"[367] when it leads to the adoption of a Decree instituting a total ban such as that adopted by France.

3.229 Canada notes that Dr. Dunnigan remarks that "the authors of the report themselves acknowledge that the methodological basis used to generate risk data at low levels of exposure to chrysotile asbestos cannot provide 'certain scientific knowledge'."[368] He considers that:

> "the INSERM report alone cannot serve as a sufficiently credible and comprehensive basis on which to conclude that the only way of protecting the health of workers and of the general public is purely and simply to ban all varieties of asbestos and all its uses."[369] (WTO translation)

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[359] Gibbs, p.10.

[360] Académie nationale de Médecine (Étienne Fournier), *Amiante et protection de la population exposée à l'inhalation de fibres d'amiante dans les bâtiments publics et privés*, Bulletin de l'Académie nationale de médecine, Vol. 180, no. 4, p. 4.

[361] Canada notes that Dr. Jacques Dunnigan characterizes the limited usefulness of the INSERM report as follows: "If it was necessary to ban certain uses of chrysotile (for example, friable materials), this is not the case for other uses of asbestos, in particular chrysotile-cement, in which the fibres are bound in such a way that there is practically no risk of emissions at unacceptable levels, by using known and proven control techniques. We believe that monitoring of hygiene and observance of the standard are a better guarantee of protection than blind use of substitute fibres whose long-term effects are not sufficiently known, as is in fact acknowledged by the authors of the INSERM report." (WTO translation) (Dunnigan**,** p.7).

[362] INSERM report, pp.404 and 405.

[363] *Id.*, 226.

[364] *Id.*, pp.234, 235, 237 and 238.

[365] *Id.*, p.376.

[366] *Id.*, p 239 and 414.

[367] *Id., p.*232.

[368] Dunnigan, p.7. Canada notes that INSERM acknowledges that "the level of occupational exposure envisaged is 10 to several hundred times lower than that existing in the cohorts on which the risk models were elaborated". (WTO translation) (INSERM report, p.233).

[369] Dunnigan, p.7.

3.230 Canada adds that, citing studies in support of his view, Dr. Gibbs also notes the existence of exposure levels below which the health risks are undetectable.[370] In line with the other criticism, the RSC notes the error in the conclusions drawn from the extrapolations of low-exposure risks from high-exposure risk data: "the transfer of risk coefficients calculated from high exposure settings […] involves possible errors".[371] Canada notes that the INSERM conclusions on the risks associated with low exposure are in sharp contradiction to the most recent scientific publications.

3.231 Canada indicates that one of the consequences of the Decree adopted on the heels of the INSERM report has been the replacement of chrysotile fibre by substitute fibre. The ban on chrysotile as the way of managing the risks cannot therefore be viewed in isolation. In this respect, INSERM reveals that the Decree banning asbestos could have unsuspected consequences:

> "It must be noted that the group of experts was unable or unwilling to consider some key questions relating to the problem of risks associated with human exposure to fibres. Because of the short time frame, the health risks associated with exposure to substitute fibres were not addressed […] The problem [the ban on asbestos] is, however, inextricably linked to the choice of substitute fibres […] The group of experts considers that it does not have sufficient information to decide on the possibility of replacing asbestos by a substitute product that is completely without risk in all the situations in question."[372] (WTO translation)

Canada indicates that, after having reviewed the INSERM report, all the experts cited above concluded that the report is not supported by real, current data relative to the exposure of the French population to the modern uses of chrysotile. This report cannot be seen as a credible, scientifically grounded basis for justifying a measure as excessive as the total ban on chrysotile and all its uses.

3.232 Canada points out that, following INSERM's recommendation on further studies on risks associated with substitute fibres, INSERM was commissioned to prepare another report, this time on the health risks of substitute fibres. The Executive Summary of this report was made public in June 1998, a surprising 18 months after the ban on asbestos took effect. As Canada notes[373], the Executive Summary points to the scarcity of data on the substitute fibres and the novelty of their use, stating that little is known about their effects on human health. It also states that, had experiments on asbestos been conducted with exposure levels similar to the ones used for testing substitute fibres, it is likely that the experiments on asbestos would have shown that asbestos poses little, if any, significant risk. The full INSERM report on substitute fibres has still not been published, one year after the release of its Executive Summary.[374] Canada states that, when the WTO consultations were held in Geneva on 8 July 1998, the EC assured the Canadian delegation that the publication of the full report was imminent. In Canada's view, it increasingly appears that France is more concerned with banning chrysotile than informing the French population of the danger of substitute fibres, the use of which is effectively imposed because of the ban on chrysotile. Canada considers that the telling criticisms of the INSERM report by France's Minister for Education, Mr. Claude Allègre, by the French *Académie nationale de médecine*, the Royal Society of Canada, and internationally renowned scientific experts, cast considerable doubt on whether the INSERM report constitutes a credible basis for so extreme a measure as a ban on a hitherto widely used product.

3.233 The **European Communities** emphasize that INSERM ranks among the most important biological and medical research institutes in the world. It comprises some 200 research laboratories

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[370] Gibbs, p.10.

[371] RSC, p.6 of the English text. The RSC also points to the potential for error associated with the integration of different measurement techniques (p.6 of the English text). Regarding the evaluation of measurement techniques, see Camus, M., *L'amiante et les risques pour la santé*, April 1999, p.4.

[372] INSERM report, pp.376 and 428.

[373] See paras.3.174 *et seq.* above.

[374] INSERM report entitled *Effets sur la santé des fibres de substitution à l'amiante*, published in November 1999

employing around 10,000 researchers and covers all fields of biomedical research and all relevant scientific disciplines. It is a government research body, financed by the French State and placed under the dual responsibility of the Ministry of Research and the Ministry of Health, and it is totally independent of economic or other interests linked to the asbestos and substitute fibres industries. In the EC's view, INSERM thus had all the competence and independence required to give a scientific opinion on the threat posed by asbestos to human health. INSERM's report was drawn up by 11 scientific experts from various disciplines, who also gave hearings to several other experts. As its name suggests[375], the report was commissioned by the authorities to provide information on the risks connected with the main types of exposure to asbestos. INSERM's mandate was not to make recommendations on how to combat the harmful effects of asbestos, but to make available the scientific knowledge necessary for any decision to be taken. The INSERM report was based on an analysis of numerous international scientific research projects on the effects of asbestos. The EC emphasize that most of its findings, including all those on which France based its decisions, have been approved by the international scientific community, including the Panel of the Royal Society of Canada, which the Canadian Government commissioned to analyse the contents of the report.

3.234 The EC point out that the INSERM report's principal conclusions, especially those on the carcinogenic nature of chrysotile, the absence of a harmlessness threshold, the importance of intermittent exposure among end-users of asbestos and the very large number of workers affected by this type of exposure, have since been confirmed by recent studies and by international bodies such as the WHO. The first of its kind in France on the subject of asbestos, the INSERM report comprises a critical and well-argued review of the international scientific literature. The methodology and scope of this work (12 chapters of discussion, supported by 1,200 bibliographical references and followed by a summary of some 60 pages) radically distinguish it from any monograph or fragmentary study advocating one or other of the theories which have contributed to the debate. The report itemizes the main effects which exposure to asbestos is known to have on human health: asbestosis, benign pleural damage, bronchial cancer and mesothelioma. Even though 166 new cases were recognized as occupational diseases in France in 1995, asbestosis is a disease whose most serious forms have become rare in industrialized countries as a result of the reduction in levels of exposure. For this reason, the Executive Summary focuses on the risk of bronchial cancer and mesothelioma.

3.235 The EC note that the authors of the report drew the following main conclusions:

(a) Most cases of pleural mesothelioma that have emerged to date in industrialized countries are of occupational or para-occupational origin. Among the occupations affected, the cases which now occur involve the handling of asbestos-containing materials installed in buildings or equipment. The diverse occupations which carry a high risk of mesothelioma include welders, dockers, laboratory technicians, painters and decorators, jewellers, metal workers, car mechanics, railway workers, workers in thermal power stations, etc. If the number of deaths caused by mesothelioma is compared with the number of people in each occupation, it is found that the jobs which are proportionally most affected are sheet-metal workers (including shipyard workers) and industrial coachbuilders; then come plumbers, carpenters and electricians. The building trades alone currently account for one quarter of all deaths from mesothelioma. Since the 1950s and 1960s, the number of cases of mesothelioma has been growing by 5-10 per cent each year, depending on the country. In France the growth rate has been 25 per cent every three years; the rate of seven cases per million inhabitants per year between 1979 and 1981 reached 16 cases per million inhabitants per year between 1991 and 1993. The number of deaths caused by asbestos in France in 1996 is estimated by INSERM at some 1,950 (750 cases of mesothelioma and 1,200 cases of lung cancer). The risks associated

[375] INSERM, *Effets sur la santé des principaux types d'exposition à l'amiante*, INSERM joint report, Paris, INSERM publications, 1997.

with exposure, which may be occupational or para-occupational (domestic cleaning of work-clothes worn by workers handling asbestos) or environmental (geological or industrial in origin), have been incontestably proved. As regards the effects on health of "passive" exposure in buildings, a risk cannot be ruled out even though the epidemiological data are not sufficient to demonstrate what that risk is. As to whether lung cancer can be causally attributed to occupational exposure to asbestos, the group of experts concluded, on the basis of an analysis of available data, that such cancer can develop where no prior fibrosis is present. As regards the role of tobacco, the group of experts pointed out that the proportion of cases of lung cancer attributable to asbestos is identical in smokers and non-smokers. In other words, the fact that a worker who has developed lung cancer smokes does not mean that the cancer is not due to asbestos. It follows that, where an individual has been exposed to asbestos and has developed lung cancer, the fact that the person concerned smokes gives no indication as to the probability of asbestos having had a role in causing the cancer.[376] This information, fundamental to the recognition of the occupational origin of diseases, provided justification for the arrangements implemented under the December 1995 plan.

(b) The group of experts considers that the carcinogenic effects of asbestos fibres cannot be differentiated according to whether the fibres are of the chrysotile or amphibole type. It found that the carcinogenic effects of asbestos fibres marketed under the designation "chrysotile" were just as serious as the effects of fibres of the amphibole type, as far as lung cancer was concerned. As regards the risk of mesothelioma, the effect of chrysotile fibres is incontestable, even though less serious than that of certain amphiboles. The morphological characteristics rather than the geological origin of the fibres seem to be the decisive factors, with the longest fibres being the most carcinogenic. In order to estimate the risk of low levels of exposure (<0.1 fibre/cm^3), INSERM's experts extrapolated to low levels, on a linear basis and without a threshold, the risks observed at high levels of exposure. This hypothesis (i.e. that there is a linear relationship between the risk and the level of exposure and that there is no threshold) is among the theories currently accepted on the subject of carcinogens and is, for example, included in the ILO encyclopaedia. It is therefore the most plausible hypothesis. The estimate is said to be "uncertain" because it is not based on observations which can validate or invalidate it beyond any doubt. INSERM's expert group estimated, on this basis and in line with knowledge to date, what additional risk of cancer would arise over a lifetime from continuous exposure to asbestos in various reference situations, for example: (i) for 10,000 men aged between 20 and 65 who are subject to continuous occupational exposure (1,920 hours) corresponding to 0.1 f/ml or cm^3, the risk is of 30 additional deaths; (ii) for 10,000 people (half of them men, half women) who are subject to continuous passive exposure during their school years (between the ages of 5 and 20) and during their working lives (1,920 hours between the ages of 20 and 65) corresponding to 0.025 f/ml (or 25 fibres per litre), the risk is of nine additional deaths.

3.236 The EC point out that any doubts with regard to the carcinogenicity of chrysotile asbestos have been removed by the joint report: chrysotile is carcinogenic, just as much as amphiboles when it comes to lung cancer but less than amphiboles when it comes to mesothelioma (ratio of 1 to 3 but same order of magnitude). As regards mesothelioma, this information has been largely confirmed by the study published by Camus *et al.*[377] on cancer mortality among women living in close proximity to chrysotile asbestos mines in Quebec. This study shows a net excess of mesothelioma cases (the risk is

[376] Document on the link between tobacco and asbestos.

[377] Camus M. *et al.*, *Non-occupational Exposure to Chrysotile Asbestos and the Risk of Lung Cancer*, New England Journal of Medicine, 1998, vol.338, no. 22: pp.1566-71.

at least seven times higher than among women living elsewhere in Quebec). Moreover, low doses do have an effect. The limit of 0.1 f/ml or cm^3 therefore corresponds to a not negligible risk of 30 extra cancer cases per 10,000 people exposed. The values above which work must be carried out to protect populations (25 fibres per litre) carry a theoretical residual risk of nine extra cases of cancer per 10,000 people exposed. The EC indicate that this figure should be compared with the level of risk which is usually recognized as applying to the population in general, namely one extra case of cancer per 1 million people. The risk population is large. For 1996, the report gave an estimate of 1,950 deaths due to asbestos (750 cases of mesothelioma and 1,200 cases of lung cancer). The vast majority of mesothelioma cases are of occupational or para-occupational origin. However, a new aspect which emerged during the period 1980-1990 was that it was no longer those working in the asbestos industry (i.e. asbestos production and processing), who were most at risk. The highest risk is now observed among people handling asbestos-containing materials (e.g. sheet-metal workers, industrial coachbuilders, plumbers, carpenters, electricians, heating engineers and cable specialists). The EC emphasize that the population concerned comprises all finishing trades in the construction industry, as well as a good number of other occupations, in other words, several million people, of whom (despite a low individual risk) a large number will contract mesothelioma. The French study recently published by INSERM[378] shows that around 25 per cent of men born between 1930 and 1939 have been exposed to asbestos during their working life.

3.237 The EC consider that procedures for controlled use cannot be implemented effectively when hundreds of thousands of people are exposed daily in sectors with little supervision as regards health and safety, such as the building industry, which accounts for at least 25 per cent of mesothelioma cases. The study by Y. Iwatsubo[379] confirms that in France most cases of mesothelioma occur among servicing and maintenance workers. The EC therefore consider that the principle of "controlled use" cannot be applied to the diffuse risks affecting a range of very varied trades practised in extremely diverse situations and involving in particular servicing and maintenance work, where it is not possible to implement rules on "safe use". The EC point out that Canada itself acknowledges the limits of controlled use since it recognizes that certain applications have to be prohibited where exposure cannot be controlled.

3.238 The EC note that "safe" use is not a guarantee even when it is practised. Safe use is contested in two quite official publications:

(a) A study conducted by the Quebec Workers' Health and Safety Commission (CSTT). This study shows that the risk of mesothelioma increased steadily in Canada between 1967 and 1990, principally among servicing and maintenance workers. Of the 120 cases of mesothelioma identified in the study, 49 were miners and mill workers, 50 were workers in the asbestos industry and 21 were servicing and maintenance workers. Of the 25 per cent of these cases which involved short exposure, the most affected group were the servicing and maintenance workers. The study shows that the occurrence of mesothelioma is indeed due to chrysotile asbestos and that the incidence of the disease is growing more rapidly in the servicing and maintenance sector. This shows that, even in Canada, which specializes in safe use, the efficacy of the method remains to be proved. The EC note that, despite the existence of this CSTT study, the Canadian party declared during the consultation meeting held on 8 July 1998 that it did not have any study at its disposal which covered the servicing and maintenance sector.[380]

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[378] Goldberg M. *et al., Past Occupational Exposure to Asbestos among Men in France,* Scandinavian Journal of Work and Environmental Health, 1999 (in press).

[379] Iwatsubo, Y. *et al., Pleural Mesothelioma: Dose-Response Relation at Low Levels of Asbestos Exposure in a French Population-Based Case Control Study*, American Journal of Epidemiology, 1998.

[380] Bégin, R. *et al., Work-Related Mesothelioma in Quebec, 1967-1990,* American Journal of Industrial Medicine, vol.22, 1992, pp.531-542.

(b) an HSE study[381], mentioned in the annex to the report produced for Canada's Royal Academy in 1996 following the publication of the INSERM report. It shows that despite strictly controlled use - it focuses exclusively on production workers -, there was still a 1.28 per cent excess of mesothelioma cases, as opposed to 4.61 per cent among people who had worked prior to 1969, when legislation was introduced in Great Britain. From this it can be concluded that controlled use does not prevent deaths from mesothelioma, even in specific sectors of industry employing limited numbers which are easy to regulate and control.

3.239 The EC point out that the confirmed carcinogenicity of chrysotile and the impossibility of controlling the risk in all situations prompted the French Government to stop the risk spreading by applying the principle laid down at European Union level for carcinogenic risks and also recommended by the WHO[382] and the ILO[383]: replacement by a less dangerous product where technically possible. The European Union, in its general Directive on the health and safety of workers, lays down the principle that a dangerous agent or process should be replaced by a safe or a less dangerous agent or process where one exists. As regards cancer risks, the Community Directive on carcinogens[384] contains the same principle in that it expressly provides for the replacement of a carcinogen by a less dangerous substance where this is technically possible. The WHO press release of 26 July 1996 states that safe substitutes should be used to replace chrysotile whenever this is possible. Moreover, in a "criterion document" dating from September 1998, the WHO states that the risk is probably higher among construction workers and perhaps also among other user groups. The ILO Encyclopaedia of occupational health and safety states that the most effective means of prevention is to avoid the use at the workplace of substances which are recognized as causing cancer in humans.

3.240 The EC assert that the INSERM report thus confirmed the necessity of the measures taken in 1996 in accordance with the guidelines adopted in July 1995. It also provided additional information, on the basis of which the French Government took a coherent set of further measures. The manufacture, import, export and sale of asbestos-containing products, including asbestos-cement, were prohibited with effect from 1 January 1997. This decision was enacted in the form of Decree No.96-1133 of 24 December 1996 laying down a general prohibition on asbestos to apply as of 1 January 1997. Asbestos-cement products were banned totally. A few very limited and strictly regulated exceptions are allowed for industrial uses where no substitute product would ensure the safety of workers and users. The purpose of the ban is to stop the spread of the risk posed by the manufacture and marketing of asbestos-containing products, in other words to prevent the "inflow". The EC emphasize that, contrary to the impression given by Canada, there was never any intention of promoting the systematic removal of asbestos already present. The prohibition measure is based on reasoning similar to that followed by Canada when it banned amphiboles[385]: the aim is to replace a dangerous agent by agents considered less dangerous on the basis of available scientific knowledge. The measure was taken at a time when the *Groupe scientifique pour la surveillance des atmosphères de travail* (G2SAT), working under the Senior Council for the Prevention of Occupational Risks, had already produced a report setting out the hierarchy of the risks from the most suspect replacement fibres (mineral wools and ceramic fibres). Following the prohibition of asbestos, a redundancy programme was needed to assist companies forced to reduce their staff as a result of ceasing to

[381] Hutchings, S. *et al., Asbestos-Related Diseases*, Occupational Health Decennial Supplement, London, Health and Safety Executive, 1996, pp.127-152.

[382] *Chrysotile Asbestos evaluated by Health Experts*, Press Release 51 of 26 July 1996, WHO.

[383] *Encyclopedia of Occupational Health and Safety*, 4th edition 1998, ILO, Geneva (Chapter 2 by P. Boffeta, pp.2 and 3). This concept has been in the Encyclopedia since the 1983 version.

[384] Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work.

[385] See para.3.54 above.

manufacture asbestos-based products. Three firms were affected: of a total of 1,370 employees, 490 found themselves surplus to requirements but 400 of them qualified for early retirement. One establishment employing 126 people was closed.

3.241 The EC indicate that the authorized exposure threshold, applicable to the manufacture of products containing chrysotile, was brought down to 100 fibres per litre (as opposed to 300, the limit which was originally to apply until 1 January 1998). Since 1994, the limit for occupational exposure in the United States has been set by the Occupational Safety and Health Administration at 0.1 fibre/cm^3 (or ml). France adopted the same value in 1996 since it was the lowest limit value obtained by phase-contrast optical microscopy. A lower value would have required the replacement of all existing measuring equipment.[386] This provision was designed to reduce further exposure to the inhalation of asbestos dust in manufacturing or processing plants which qualified for an exemption.

3.242 The EC explain that a certification procedure by an accredited organization was introduced at the beginning of 1997 for firms called upon to remove or to contain asbestos. This procedure makes it possible to verify the quality of the work carried out and the quality of the measures taken to protect the health of the workers. The certificate is issued following a study carried out within the company to investigate working methods, the training provided for managers and workers, and the equipment available; the study is followed by an on-site audit to assess the quality of actual practice. Since the summer of 1997, companies have only been allowed to carry out the removal of "friable" asbestos (such as flocked asbestos or lagging) if they possess a certificate qualifying them to do so. The aim of this measure is to tighten up the management of the serious risks involved in asbestos removal (especially removal of flocked asbestos). The surveillance measures applicable to flocked asbestos and lagging have been extended to false ceilings. The EC emphasize that at no time was it planned, as in the United States, to call for the systematic removal of all asbestos. On the contrary, information was widely circulated stating that a higher risk could be created if asbestos were removed too quickly or in the wrong circumstances.

3.243 The EC point out that technological and scientific monitoring was stepped up. Two measures were adopted: (i) epidemiological monitoring of mesothelioma cases was introduced, with the assistance of INSERM, in order to ascertain the conditions in which tumours appear and to measure the actual risks of exposure; and (ii) INSERM was asked to produce a joint experts' report on the risks linked to the fibres used as substitutes for asbestos. The EC note that, in any event, the use of replacement products classed as dangerous is subject to legislation on chemical hazards (obligation to conduct risk assessment and protect workers, recommended limit values, etc.). If the replacement products are classed as carcinogens, the rules are even stricter and the principle of replacement by a less dangerous product where technically possible applies.

C. LEGAL ARGUMENTS

3.244 The **European Communities** claim that, according to the general procedural rule applicable to the settlement of disputes, first spelled out by the Appellate Body in its report on *United States – Measure affecting Imports of Woven Wool Shirts and Blouses from India*[387], and since restated on several occasions[388], it is for the complaining party to establish inconsistency with a provision of a WTO Agreement before the burden of proving consistency with that provision shifts to the defending party. In this instance, Canada has not produced any convincing evidence to show that the contested measure infringes any of the provisions invoked. In particular, Canada has not produced any evidence

[386] The EC note that the average concentration of asbestos fibres in the air inhaled by workers is measured over eight hours.

[387] Report adopted on 23 May 1997, WT/DS33/AB/R, p.14 of the English text.

[388] See in particular *EC Measures concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body, WT/DS26/DS48/AB/R, adopted on 13 February 1998, para.104.

that so-called "safe" use offers a feasible and reliable way of protecting the health of all those affected.

1. Agreement on Technical Barriers to Trade ("TBT" Agreement)

(a) Applicability of the TBT Agreement

3.245 **Canada** contends that the main objective of the TBT Agreement is to prevent technical regulations and standards from creating unnecessary barriers to international trade. Canada also recognizes the right of Members to take the necessary measures to ensure the protection of people's health and lives. According to Canada, the Decree is subject to the disciplines of the TBT Agreement and is incompatible with its Article 2.2, 2.4, 2.8 and 2.1. More specifically, the Decree is an unnecessary barrier to trade. It is neither based on existing international standards nor on the performance of asbestos fibres and products containing such fibres. Finally, the Decree prevents these products being imported into the French market and is discriminatory in the domestic market with respect to these same imported products.

3.246 Canada contends that the TBT Agreement applies to the Decree because it is a "technical regulation" within the meaning of Annex 1 to the TBT Agreement. The Decree is a technical regulation because it considers all asbestos fibres and all materials, products or devices that contain such fibres, with the exception of four, as products that are supposed to pose risks for people's health and safety. The Decree prohibits all chrysotile products for which there is a substitute that represents "a lesser occupational health risk than chrysotile fibre" and which, for the purposes of the end-use, gives "technical guarantees of safety" equivalent to the guarantees for chrysotile fibre. More specifically, the Decree is a technical regulation because it contains several aspects of the above definition. It is a document that sets forth a characteristic of a product, a process and a production method for a product, and administrative provisions applicable to a product. The document also deals with labelling requirements. Moreover, compliance with the contents of the document is mandatory.

3.247 According to Canada, the ordinary meaning of the word document is "anything … written … relied upon to record or prove something".[389] The Decree contested is something written, i.e. a general administrative instrument issued by the Executive and designed to make the public aware of the Government's decision to consider unacceptable any risk of exposure to all varieties of asbestos. The Decree was issued by the French Prime Minister. It was published in the Official Journal of the French Republic. It is therefore a document, in accordance with the definition. The ordinary meaning of the word "characteristic" is "that which constitutes a recognizable distinctive feature".[390] The Decree describes a recognizable distinctive feature of the products. In fact, in accordance with its purpose, which is to ban asbestos totally, the main provisions of the Decree are designed to prohibit asbestos fibre, regardless of whether it is amphibole fibre or chrysotile fibre, in the manufacturing and processing of materials, products and devices that are placed on the French market. The characteristic of these materials, products and devices, as laid down in the Decree, is the absence of asbestos fibres. The Decree refers in particular to the processing of all varieties of asbestos fibres, whether or not included in materials or products. By so doing, it imposes restrictions on the processes and production methods related to asbestos fibres, including chrysotile fibres. On an exceptional and temporary basis, chrysotile fibre is permitted in the manufacturing and processing of four products, if there is no supposedly less harmful substitute fibre. Moreover, the Decree stipulates that these manufacturing and processing activities are subject to the standards governing exposure to asbestos dust in places of business.[391] With respect to the aspects in the second part of the definition, Canada

[389] *Dictionnaire Robert, (Robert* French Dictionary*),* 1993 edition.
[390] *Id.*
[391] Article 4 of the Decree. This incorporates and refers back to Decree No.96-97 of 7 February 1996 concerning the protection of the population against the health risks associated with exposure to asbestos in buildings.

points out that the Decree includes administrative provisions applicable to products which, exceptionally, contain chrysotile fibre. In Article 3, the Decree provides for a sophisticated declaration mechanism for the purpose of obtaining an exemption from the ban on asbestos.[392] The Decree also deals with the labelling requirements for a product. It sets out rules for labelling chrysotile-containing products that are covered by a temporary exemption from the ban.[393] Finally, with respect to the mandatory aspect of the document, it is prescribed that all the above provisions of the Decree are binding. Compliance with the characteristics of the products and their related processes and production methods, as well as with the applicable administrative formalities, is mandatory. Article 5 provides for the penalties applicable in the event of a breach.

3.248 Canada claims that the fact that the Decree qualifies as a technical regulation under the TBT Agreement is confirmed in France's notification to the Committee on Technical Barriers to Trade. France gave notice of the measure it took pursuant to Article 10.6 of the TBT Agreement on 21 February 1997.[394] It also recognized the applicability of the TBT Agreement in the notification document. According to Canada, the EC also recognized the applicability of the TBT Agreement in the justification given pursuant to Article 2.2 thereof.[395] They maintained that the Decree was not more trade-restrictive than was necessary in order to fulfil legitimate objectives, i.e. the protection of human health and safety, taking account of the risks non-fulfilment would create. Finally, at the consultations on 8 July 1998, in his opening statement, the representative of the EC conceded the applicability of the TBT Agreement to the French measure. The relevant passage is as follows:

> "The only relevant provisions therefore seem to be those of the TBT Agreement. It is for that reason, indeed that the EC notified the French measures as technical regulations under the TBT Agreement."[396]

3.249 Canada concludes that, by describing the characteristics of the products, by specifying the related processes and production methods, by setting up a declaration mechanism for the purpose of obtaining exemptions from the ban on asbestos, by the labelling provisions for chrysotile-containing products covered by an exemption, as well as by its mandatory nature, the Decree banning asbestos falls within the meaning of "technical regulation" under Article 1 of Annex 1 to the TBT Agreement. According to Canada, the EC themselves recognized the applicability of the TBT Agreement in official documents to the WTO and during the consultations which preceded the establishment of the Panel.

3.250 The **European Communities** maintain that the Agreement on Technical Barriers to Trade (TBT) does not apply to the Decree. Even if the Panel were to consider that the TBT Agreement is applicable, the EC maintain that the Decree is not incompatible with the provisions of the said Agreement.

3.251 The EC claim that, contrary to Canada's argument, the Decree cannot be construed as a "technical regulation" within the meaning of the TBT Agreement, which does not cover general prohibitions on the use of a product for reasons to do with the protection of human health. In order to interpret the provisions of this Agreement correctly, it should be remembered that the "customary rules of interpretation of public international law", in particular those arising out of the 1969 Vienna Convention on the Law of Treaties, must be used to interpret the provisions of the General Agreement and of the WTO Agreement. Those rules call for an examination of the ordinary meaning of the terms of a treaty, read in their context and in the light of the object and purpose of the treaty considered.

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[392] Order of 24 December 1996 on the declaration form for exemptions from the ban on asbestos.

[393] Article 4 of the Decree. This incorporates and refers back to Decree No.88-466 of 28 April 1988 concerning products containing asbestos.

[394] Notification G/TBT/Notif. 97.55, 21 February 1997.

[395] European Commission, Directorate General III (Industry), Office A, "Industrial Policy", Unit III/A/1 "International industrial relations", Document III/A/1/MPP/CR/amp/fcanada (dated 15 April 1997), p.2.

[396] Opening statement by the representative of the European Communities at the consultation held in connection with this case, Geneva, 8 July 1998 (document submitted to the Panel by Canada).

The Appellate Body has indicated in this regard that "A treaty interpreter must begin with, and focus upon, the text of the particular provision to be interpreted. It is in the words constituting that provision, read in their context, that the object and purpose of the states parties to the treaty must first be sought."[397] Therefore, an interpreter is not free to adopt a reading that would result in reducing whole clauses or paragraphs of a treaty to redundancy or inutility.[398]

3.252 The EC contend that the TBT Agreement does not cover general prohibitions. It follows from the preamble (notably the third and fifth paragraphs), from the background to the TBT Agreement and from the actual wording of several of its provisions that the fundamental objective of this Agreement is to monitor the adoption and application of the "standards" and "technical regulations" that cover the detailed characteristics of products or their methods of production. The TBT Agreement could, for example, be applied to monitor a "technical regulation" that set a minimum resistance level for seat belts. Another example would be a "technical regulation" that laid down percentages for ingredients in chocolate and prescribed methods of production. On the other hand, it is not the object and purpose of the TBT Agreement to deal with general prohibitions such as that applied by the French Decree to asbestos and asbestos-containing products. According to the EC, this specific object and purpose of the TBT Agreement can be seen clearly in Annex 1 thereto, which gives the definition of what should be understood by "technical regulation": "Document which lays down product characteristics or their related processes and production methods …". In this specific case, the definition means that the TBT Agreement cannot apply to the Decree. It follows from the above definition that a technical regulation is a document which lays down the characteristics or processes and production methods with which a specific/identified product must comply, in particular if it is to be released for free circulation on a given market.

3.253 The EC claim that the definition of technical regulation should not therefore apply to prohibition measures that cover all products in general. These products should continue to be covered by the General Agreement alone. To adopt any other approach would be equivalent to nullifying the effect of certain provisions of the GATT, in particular Articles I and III, which are applicable in cases of general prohibitions. The TBT Agreement must be considered as the specific application of the principles of the GATT 1994 to technical regulations. In the EC's view, it is inconceivable that the negotiators of the TBT Agreement wished it to apply in every case to Members' regulatory measures affecting products, and in particular to general prohibition measures. The position of the EC is fully supported by the position taken by other Members and other Panels. The Panel report on *United States - Gasoline* noted that:

> "The United States argued that the TBT Agreement had been designed to elaborate on the disciplines of Article III of the General Agreement for a very specific subset of measures (technical regulations, standards and conformity assessment procedures). The fact that a measure was in writing, mandatory and applied to products did not make it a technical regulation. Excise taxes, for instance, met all these criteria but were not 'technical regulations'. Similarly, the term 'technical regulation' was not so broad as to cover all government regulatory actions affecting products. For example, government regulations requiring factory smokestacks to have devices to reduce emissions were not technical regulations, though they were in writing, mandatory and specified 'characteristics'. [....] The United States concluded that the complainants were interpreting the term 'technical regulation' out of context and such an interpretation, if accepted, would introduce into the TBT Agreement many measures which were in fact not intended to be covered."[399]

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[397] *United States – Import Prohibition of Certain Shrimp and Shrimp Products* (hereinafter *United States – Shrimps*), Report of the Appellate Body, WT/DS58/AB/R, adopted on 6 November 1998, para.114.

[398] *United States – Standards for Reformulated and Conventional Gasoline*, (hereinafter *United States – Gasoline*), Appellate Body and Panel Report, WT/DS2/9, adopted on 20 May 1996.

[399] *United States – Gasoline*, Appellate Body and Panel Report, WT/DS2/9, adopted on 20 May 1996, para.3.77.

3.254 The EC claim that the French Decree is not a "technical regulation" within the meaning of the TBT Agreement. The Decree, taken as a whole, is a general ban on asbestos fibres and asbestos products. The prohibition applies to production, processing, importation, exportation, disposal, supply, sale, and marketing. The Decree specifies neither the characteristics nor the production processes and methods for asbestos fibres, asbestos-containing products nor the products exempted from the prohibition measure.

3.255 The EC contend that the Decree does not lay down "product characteristics". The EC fully agree with Canada's conclusion that the Decree constitutes a document, but they are surprised by Canada's choice of a definition for the word "characteristic". According to the very *Robert* dictionary on which Canada's argument is based, the word "characteristic" may be used either as an adjective or a noun. The first definition given by Canada ("which constitutes a recognizable distinctive feature") is the definition corresponding to the adjective. On the other hand, the second definition (that which serves to characterize) given by *Robert*, and strangely forgotten by Canada, specifically corresponds to the noun. It is on the latter definition that the Panel should base its analysis because, in the above-mentioned definition in Annex 1, the word "characteristic" is used as a noun and not as an adjective. In the light of this definition, the French Decree cannot be regarded as "laying down product characteristics". The EC note that Canada maintains that the characteristic is "the absence of asbestos fibres" and that the products covered are "materials, products and devices that are placed on the French market". However, the EC do not consider that in the French measure the words "the absence of asbestos fibres" serve to characterize products placed on the French market because "the absence of asbestos fibres" does not constitute a characteristic, much less the characteristic of products placed on the French market. One of the critical weaknesses of Canada's argument lies in the fact that it has eliminated the existence of a possessive phrase, as denoted by the word "of", between "the characteristics" and "a product". For the Decree to be able to lay down the "characteristics" of a product, it would have in one way or another to designate the product(s) to which the said "characteristics" relate. The Decree does not designate any product but lays down the principle of prohibition. It follows that the contested measure cannot be examined on the basis of the TBT Agreement as it has general scope and does not concern any specific product whose characteristics are spelled out in the French Decree. In the light of the foregoing, for the EC it is clear that the Decree does not lay down the "characteristics" of asbestos fibres but simply prohibits their use on French territory. It is equally clear that the Decree does not lay down the "characteristics" of asbestos-containing products. Nor does the Decree define the technical characteristics of the products, which may enjoy an exemption from the general prohibition laid down. Such products may or may not contain asbestos.

3.256 The EC assert that the Decree does not lay down "production processes and methods relating to a product". The term "process" may be defined as a "means, a practical method of doing something, of obtaining a result".[400] The term "method" may be defined as a "logically ordered set of principles, rules or stages making it possible to reach a result".[401] The Decree does not lay down any means or ordered set of rules governing the production (extraction and processing) of asbestos fibres. The prohibition applies to asbestos fibres, so it is not possible to say how they should be produced because they may no longer be produced. The same is true of asbestos-containing products. In terms of the definitions given for production "process" and "method", the Decree does not specify any means nor lay down any ordered set of rules governing the manufacture of asbestos-containing products. It merely bans any type of asbestos-containing product. In other words, the prohibition applies to asbestos-containing products, and nothing is said about how they should be produced. Nor does the Decree define the production processes and methods for the products that may be exempted from the general ban. Such products may or may not contain asbestos. The EC therefore conclude that the Decree is not a technical regulation within the meaning of the TBT Agreement, neither for asbestos fibres nor for asbestos-containing products, nor even for products enjoying temporary

[400] *Larousse* French dictionary.
[401] *Id.*

exemptions. This conclusion follows logically from the object and purpose of the TBT Agreement, which is not to cover general prohibition measures.

3.257 According to the EC, the fact that France has notified the Decree to the Committee on Technical Barriers to Trade in no way prejudges the applicability of the Agreement. The Decree was notified, in good faith, for the sake of transparency vis-à-vis all the Members of the WTO and in response to repeated requests by Canada. Any other interpretation would create additional obligations for WTO Members and would induce them to discontinue, or at least reduce, notifications of their general legislation to WTO Committees. According to the EC, Members must therefore continue to notify their legislation, without notification as such having any legal consequences for the status of the measure concerned or entailing any obligations to which Members are not normally held.

3.258 **Canada** reiterates that the TBT Agreement applies to the Decree and claims that the EC's interpretation, based on Article 31 of the Vienna Convention on the Law of Treaties, is incorrect. In this regard, Canada points out that the three third parties to the dispute unanimously recognize the applicability of the TBT Agreement in this case. The EC are therefore alone in disputing its applicability. Canada maintains that the EC's interpretation is not based on Article 31 of the Vienna Convention and the Decree falls specifically within the scope of the TBT Agreement because it represents the type of measure covered by the definition of "technical regulation" in Annex 1 to the Agreement. Including general prohibitions within the scope of the TBT Agreement is not contrary to either its object or its purpose, which are to prevent technical regulations and standards from creating unnecessary obstacles to international trade.

3.259 Canada claims that the EC depart from the ordinary meaning of the terms of the definition of "technical regulation" and refer to the preamble and history of the TBT Agreement to assert that its object and purpose are not to deal with general product prohibitions, but to lay down the characteristics or processes or production methods which a specific product must meet. This distinction made by the EC between prohibitions that apply to all products without distinction and measures aimed particularly at a specific product is not supported by the TBT Agreement. There is no provision which stipulates that general prohibitions do not fall within the scope of the TBT Agreement. The EC's interpretation of Annex 1 to the Agreement is contrary to the principle of effectiveness.[402] According to this principle, a treaty must be given the interpretation which renders it meaningful and effective, rather than that which would render it ineffective. However, in Canada's view, the consequence of the EC's interpretation would be that it would suffice to give a measure intended to hinder trade the form of a general prohibition in order to allow that measure to evade the disciplines of the TBT Agreement. Thus, as the United States notes, by manipulating the form of a measure, it would be possible to render the TBT Agreement ineffective. Contrary to what the EC claim, their interpretation in such circumstances is not supported by the precedents. The excerpt from the Panel Report in *United States – Gasoline* cited by the EC does not relate to a position taken by the Panel but rather to an aspect of the American arguments in this case. The Panel that examined this case never sanctioned this American claim and did not discuss it. Furthermore, this excerpt, cited out of context, is contradicted by the position expressed by the United States in this dispute. In interpreting the TBT Agreement as applying only to a description of characteristics or of processes and production methods specific to a particular product and not to general prohibitions that apply to any product without distinction, the EC take into account only one part of the provisions of the Decree, in this case those concerning the ban on asbestos, and fail to mention the transitional provisions. However, in Canada's view, in order to determine whether the Decree satisfies the criteria of the definition of "technical regulation", all its provisions must be examined, both those concerning the ban on asbestos and those dealing with exceptions to this ban.

[402] *United States – Gasoline*, Report of the Panel, WT/DS2/R, adopted on 20 May 1996, *Japan – Taxes on Alcoholic Beverages*, Report of the Panel, WT/DS8/R, WT/DS10/R, WT/DS11/R, adopted on 1 November 1996, para.6.22.

3.260 Canada maintains that the Decree is a "technical regulation" as this expression is defined in Annex 1 to the TBT Agreement. Five of the elements of the definition of a "technical regulation" are found in the Decree. These are: (i) a description of the characteristics of a product, including by the negative; (ii) a description of the related processes and production methods; (iii) a description of the administrative provisions which apply to a product; (iv) the marking or labelling requirements which apply to a product; and (v) mandatory compliance.

3.261 Firstly, Canada points out that the term "characteristic" means "a distinguishing trait, quality or property".[403] In this sense, the Decree describes a distinctive characteristic of a product. Indeed, in accordance with its objective, which is to prohibit asbestos totally, the main provisions of the Decree are intended to prohibit asbestos fibres, regardless of whether they are of the amphibole or chrysotile variety, in the manufacture and processing of materials, products and devices marketed in France. The characteristic of these materials, products or devices, in whose manufacture and processing asbestos fibre may not be incorporated, is thus laid down in the Decree. This characteristic is that no product shall contain asbestos. Secondly, the Decree also covers the processing of all types of asbestos fibres, whether or not they are incorporated in materials or products. In so doing, it imposes restrictions on processes and production methods involving asbestos fibres, including chrysotile fibres. The principle of a total ban is accompanied by a limited number of exceptions. Chrysotile fibres are permitted in the manufacture and processing of products when no substitute fibre deemed less harmful exists. The Decree stipulates that the manufacture of chrysotile-based products is subject to the standards of exposure to asbestos dust in buildings.[404] Hence, the Decree lays down a production process for products containing chrysotile as defined by the EC. Thirdly, by instituting a reporting mechanism to obtain or maintain an exemption from the ban on asbestos, the Decree specifies the administrative provisions applicable to products. Canada considers that the EC confirm this point when they describe in detail the registration procedure under the annual reporting process in the context of exemptions from the ban on asbestos. Fourthly, the Decree also deals with requirements regarding marking or labelling of a product. It sets out labelling standards for chrysotile-based products that are the subject of a provisional exemption from the ban.[405] Fifthly, compliance with the main provisions of the Decree is mandatory. Products which are marketed in, offered for sale in or imported into France must not contain asbestos. Compliance with the ban on asbestos is mandatory, unless the public authorities agree to grant a waiver, in which case compliance with the terms and conditions of the exception are mandatory. Fines are applicable in case of non-compliance.

3.262 Canada claims that, by notifying the Committee on Technical Barriers to Trade, the EC recognized that the Decree is a technical regulation and consequently the TBT Agreement applies.[406] Furthermore, the EC provided the Committee on Technical Barriers to Trade with a justification of the Decree based on the disciplines of Article 2.2 of the TBT Agreement.[407] The EC certainly considered this Committee the competent forum to receive the notification and the justification. The EC's most recent official statement concerning the applicability of the TBT Agreement was made during the consultations of 8 July 1998, when the representative of the EC stated that the provisions of the TBT Agreement were the only provisions invoked by Canada that seemed relevant to contesting

[403] Canada notes that the EC try to show that the Decree does not define the characteristics of a product because Canada made a mistake by citing the definition of the adjective rather than the noun "characteristic". Having made the necessary correction, this in no way alters the sense of Canada's argument.

[404] Article 4 of the Decree. This incorporates and refers back to Decree No.96-97 of 7 February 1996 concerning the protection of the population against the health risks associated with exposure to asbestos in buildings.

[405] Article 4 of the Decree. This incorporates and refers back to Decree No.88-466 of 28 April 1988 concerning products containing asbestos.

[406] Notification G/TBT/Notif.97.55, 21 February 1997.

[407] European Commission, Directorate General III (Industry), Directorate A, Industrial Policy, Unit III/A/1 Industrial aspects of international trade relations, Document III/A/1/MPP/CR/amp/fcanada (dated 15 April 1997), p. 2.

the Decree.[408] Canada concludes that, in the light of the foregoing, it is clear that the Decree is a "technical regulation" and, therefore, subject to the TBT Agreement.

3.263 The **European Communities** contend that the TBT Agreement does not cover general prohibitions. A measure cannot fall within the TBT Agreement unless it satisfies, in particular, the definition of "technical regulation" contained in Annex 1 to the Agreement. The fact that the definition of "technical regulation" is narrow is not a matter of chance, but signifies that the authors intended to limit the scope of the Agreement. This is equally apparent from the text of Article 1.2 of the TBT Agreement itself. The object and purpose of the TBT Agreement, like that of the TBT Agreement of 1979, is to "further the objectives of the GATT 1994" (second preambular paragraph) in the fields of standardization and conformity assessment in order to ensure that technical regulations and standards do not create unnecessary obstacles to international trade (third and fifth preambular paragraphs). According to the EC, it follows from the above that the purpose of the TBT Agreement is to deal with technical regulations and standards.[409] It is not to solve market access problems linked with general prohibitions. However, this does not result in a legal vacuum for measures of this type inasmuch as they continue to be covered by other legal provisions, in particular Article III of the GATT.

3.264 The EC maintain that the Decree does not fall within the scope of the TBT Agreement. As far as asbestos fibres are concerned, it is not the purpose of the Decree to lay down the characteristics of asbestos or of processes and methods of asbestos production. The Decree purely and simply bans asbestos as a product or a raw material. As far as other products are concerned, the Decree means that they may not contain any asbestos. This, however, would not be enough for the Decree to be equated with a "technical regulation" within the meaning of the TBT Agreement. In fact, where these products are concerned, the EC emphasize that the Decree does not identify the products that must not contain asbestos. All products, without more precise identification, are subject to the ban. This applies both to cement and to any other product (for example, tennis rackets). Furthermore, the EC repeat that the Decree is not concerned with the characteristics of other products (whether or not containing asbestos). In fact, the horizontal prohibition on incorporating asbestos in products has the effect of prohibiting, on French territory, products that contain asbestos. The general prohibition eliminates these products from the French market. A technical regulation, on the other hand, presupposes that the product concerned can always be supplied on the market. This is comparable, for instance, to a situation where a domestic law prohibits in general and without discrimination the production, importation and use of drugs, alcohol, etc. on grounds of public health. The EC note that even Canada does not dispute the fact that the declared objective of the Decree is to protect human health; Canada only disputes the existence of a risk in this case, not the intention of the French authorities to protect human health. Thus, in the EC's view, it cannot be maintained that the Decree lays down the characteristics of a product which no longer exists. The same applies to the production processes and methods for the product, which are linked to its characteristics. The Decree does not lay down production processes and methods for a product which no one any longer has the right to manufacture.

3.265 The EC therefore reaffirm their conclusion that the TBT Agreement is not applicable to a measure imposing a general ban on a product, in this case asbestos and asbestos-containing products.

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[408] Opening statement by the representative of the European Communities at the consultations held in connection with this case, Geneva, 8 July 1998 (document submitted to the Panel by Canada).

[409] The EC note that, on its Web site www.wto.org/eol/e/wto03/wto.3_5.htm, the WTO describes a "technical regulation" as follows:

> "Technical regulations and standards set out specific characteristics of a product – such as its size, shape, design, functions and performance, or the way it is labelled or packaged before it is put on sale. In certain cases, the way a product is produced can affect these characteristics, and it may then prove more appropriate to draft technical regulations and standards in terms of a product's process and production methods rather than its characteristics *per se*."

As regards the provisions of the Decree concerning exemptions from the ban, the EC reiterate that these provisions do not fall within the scope of the TBT Agreement. The EC have already pointed out that the Decree does not define either the technical characteristics of the products that may be exempted from the general ban adopted. These products may or may not contain asbestos. In addition, this very limited number of products will anyhow be phased out as soon as substitute products that can ensure a lower level of risk and guarantee the same security for users become technically available. So, even in the case of limited and transitional exceptions, the sole preoccupation of the French authorities has been to protect human health because, for the time being, there are no alternative products that can guarantee a lower level of risk to human health (for example, the risk of accidents if the use of asbestos were to be banned immediately in situations of exposure to very high temperatures, etc.) The EC add that the Decree does not define either the production processes and methods for the products that may be exempted from the general ban adopted. These products may or may not contain asbestos. It follows from these two observations that the provisions of the Decree concerning exemptions from the general ban do not fall within the scope of the TBT Agreement either. In fact, it is neither the purpose nor the effect of the French measure to lay down the characteristics of these products or to impose production processes or methods for their manufacture.

(b) Article 2.1 of the TBT Agreement

3.266 **Canada** claims that the Decree is incompatible with Article 2.1 of the TBT Agreement because it subjects chrysotile fibre and chrysotile-cement products imported from Canada and from any other country to less favourable treatment than like PVA, cellulose and glass fibres, and like fibro-cement products, of French or foreign origin. Article 2.1 of the TBT Agreement restates the principles of non-discrimination set forth in Articles I:1 and III:4 of the GATT. In order to determine incompatibility with Article 2.1 of the TBT Agreement, the Panel must determine: (i) that the measure in question is a technical regulation; (ii) that the products involved are like products; (iii) that these like products are of French origin or originate in any other country; and (iv) that, by virtue of the technical regulation, imported chrysotile fibre and chrysotile-cement products are subject to less favourable treatment than like products. Given that the allegations of incompatibility with Article 2.1 of the TBT Agreement are being submitted to examination by a Panel for the first time, Canada maintains that examination of the matter should take into account the precedents relating to Articles I:1 and III:4 of the GATT 1947 and the GATT 1994.[410]

3.267 Canada asserts in the first place that, as it has shown in the paragraphs regarding the applicability of the TBT Agreement, the Decree banning asbestos is a "technical regulation" and is subject to the application of Article 2. Secondly, as Canada has pointed out in relation to Article III:4[411], Canadian chrysotile fibre is like PVA, cellulose and glass fibre. Similarly, chrysotile-cement products are like fibro-cement products. Thirdly, Canada contends that there are substitute fibres of French origin that are "like products" to chrysotile fibre. There are also fibro-cement products of French origin that are "like products" to chrysotile-cement products of Canadian origin. PVA fibres from China, Korea and Japan intended for the manufacture of fibro-cement products are also imported into France. Lastly, in 1997, France imported over 157,000 tonnes of fibro-cement products originating in "any other country".[412]

3.268 Canada contends that chrysotile fibres and the products containing them are subject to less favourable treatment than substitute products of French or foreign origin. Following the criteria

[410] Canada indicates that, in so doing, it relies on the interpretation of the status of panel reports, whether or not adopted, by the Appellate Body in its Report *Japan – Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, adopted on 6 November 1996.

[411] Canada refers in general to the arguments it puts forward below in relation to Article III:4 of the GATT.

[412] Tariff Classification 6811. Source: Eurostat, CD-ROM.

applied to Article III:4 of the GATT, a technical regulation is incompatible with Article 2.1 of the TBT Agreement if this regulation subjects imported chrysotile fibre and chrysotile-cement products to treatment less favourable than that accorded to like PVA, cellulose and glass fibres, and to like fibro-cement products of national origin or originating in any other country.[413] The terms of Article 2.1, providing that "treatment no less favourable" be accorded, are identical to the terms of Article III:4 of the GATT: "shall be accorded treatment no less favourable". In Canada's view, the inclusion in the TBT Agreement of terms similar to those of the GATT reveals the intention of the Members to have them interpreted in the same manner. Article 2.1 thus includes the same obligation with respect to national treatment as that set forth in Article III:4 of the GATT. Article 2.1 also requires the Members to treat like products respecting the principle of most-favoured-nation treatment. It provides for treatment no less favourable than that accorded to like products originating in any other country to be accorded. The wording of Article 2.1 also repeats in full the concept set forth in the disciplines of Article I of the GATT, namely, that any advantage granted to any product originating in any other country shall be accorded to the like product originating in the territory of all other contracting parties.

3.269 Canada points out that the fact that the expression "no less favourable" was repeated throughout the GATT Agreements was highlighted by the Panel in the case *United States – Section 337 of the Tariff Act of 1930.* The relevant passage is as follows:

> "These words are to be found throughout the General Agreement and later agreements negotiated in the GATT framework as an expression of the underlying principle of equality of treatment of imported products as compared to the treatment given either to other foreign products, under the most favoured nation standard, or to domestic products, under the national treatment standard of Article III."[414]

The use of the same wording indicates that the disciplines of Article 2.1 of the TBT Agreement are the same as those of Article III:4 of the GATT and that they are applied in the same manner. In order to address the question of whether less favourable treatment is accorded to products of Canadian origin than that accorded to like products originating in any other country, Canada considers that the Panel should examine the criteria of "the actual equality of the opportunities offered". As Canada has already stressed, the Decree affects areas that are governed by a technical regulation as defined in the TBT Agreement. There is no similar measure on PVA, cellulose or glass fibres nor on fibro-cement products. In fact, it is undeniable that the prohibitions ordered in the French technical regulation with regard to chrysotile fibre and products containing it constitute a denial of the actual equality of the opportunities for competition offered to chrysotile fibre and chrysotile-cement products on the French market. The bans do not apply to PVA, cellulose or glass fibres nor to fibro-cement products imported into France. Canada concludes that the Decree banning asbestos is incompatible with the provisions of Article 2.1 of the TBT Agreement because it discriminates against chrysotile fibre and chrysotile products, as opposed to PVA, cellulose and glass fibre and fibro-cement products.

3.270 The **European Communities** draw attention to the following points presented as an alternative, should the Panel consider that the TBT Agreement is applicable to the French measure, which they nevertheless contest.

3.271 The EC point out that Article 2.1 of the TBT Agreement may be considered as a specific application to technical regulations of Articles I and III of the GATT 1994. The sole argument put forward by Canada is the claim that a measure's compatibility with Article 2.1 of the TBT Agreement should be examined taking "into account the precedents relating to Articles I:1 and III:4 of the GATT

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[413] *United States – Section 337 of the Tariff Act of 1930*, adopted on 7 November 1989, BISD 36S/345, para.5.11. See also *United States – Gasoline*, adopted on 20 May 1996, WT/DS2/9, para.6.10, and *Canada – Import, Distribution and Sale of Certain Alcoholic Drinks by Provincial Marketing Agencies*, adopted on 18 February 1992, BISD 39S/27, para.5.6.

[414] *United States – Section 337 of the Tariff Act of 1930*, adopted on 7 November 1989, BISD 36S/345, para.5.11

1947 and the GATT 1994". As the EC show in the section relating to the application of Article III:4 of the GATT, the Decree does not discriminate between imported products and like national products.

3.272 **Canada** emphasizes that Article 2.1 of the TBT Agreement can be considered as a specific application to technical regulations of Articles I and III of the GATT 1994 and that the EC are in agreement on this point. Canada refers back to its previous arguments on the issue of the applicability of the TBT Agreement, on the one hand, and on the issue of likeness on the other. These arguments are the same as those made with respect to Article III:4 of the GATT. Canada notes that, unlike the case of Article III:4, the origin of like products is of no consequence for Article 2.1 of the TBT Agreement as this Article covers national treatment and most-favoured nation treatment. Finally, on the issue of the less favourable treatment of imported products compared to like products, Canada refers to the arguments it puts forward in relation to Article III:4 of the GATT.

(c) Article 2.2 of the TBT Agreement

3.273 **Canada** emphasizes that Article 2.2 of the TBT Agreement requires the Members of the WTO to ensure that technical regulations are not adopted with a view to or with the effect of creating unnecessary obstacles to international trade. A technical regulation creates an unnecessary obstacle to international trade if its objective is not legitimate or if the regulation is more trade-restrictive than necessary to fulfil this objective, taking account of the risks that non-fulfilment would create. In Canada's view, in order to determine whether a technical regulation is compatible with Article 2.2, the Panel must first determine if the objective that the regulation is supposed to fulfil is part of the range of legitimate objectives listed in Article 2.2. If the objective is not on this list, the regulation is incompatible with Article 2.2. If it is determined that the objective is part of the range of objectives stipulated in Article 2.2, the Panel must then determine whether the technical regulation is more trade-restrictive than is necessary.

3.274 The **European Communities** point out that a reading of Article 2.2 reveals two basic criteria enabling a WTO Member to adopt a restrictive technical regulation: (i) there must first be a legitimate objective, such as the protection of human health; and (ii) then the Member's technical regulation must not be more trade-restrictive than is necessary to fulfil this legitimate objective, taking account of the risks that non-fulfilment would create. According to the EC, the Decree meets those two conditions. The EC refer the Panel to the arguments they put forward in Section III.B and in relation to Article XX(b) of the GATT. A legal analysis relating to Article XX(b) of the GATT also applies in the context of Article 2.2 of the TBT Agreement as far as the test of necessity is concerned.

(i) Legitimate objective

3.275 **Canada** considers that, in this case, the objective claimed by France, namely, the protection of the health of workers and consumers, corresponds to the objectives identified in Article 2.2.

3.276 The **European Communities** claim that, as they emphasize in connection with Article XX(b) of the GATT, the aim of the French measure is to halt the spread of the risks associated with the use of asbestos fibres and asbestos-containing products and thus reduce the number of deaths among the French population. The Decree is therefore perfectly in keeping with policies designed to protect human health. The EC note that Canada does not dispute this.

3.277 **Canada** states that it has acknowledged that the objective sought by France when adopting the Decree, namely, the protection of human health, is one of the objectives included in Article 2.2 of the TBT Agreement. However, contrary to what the EC would like one to believe, Canada did not acquiesce in the argument that the objective is to halt the spread of the risks associated with the use of asbestos fibres and asbestos-containing products. The examples in the list of objectives set out in Article 2.2 of the TBT Agreement include protection of human health and safety. Halting the spread of the risks associated with asbestos can be a way of protecting human health. This is not, however, a

legitimate objective within the legal framework of the TBT Agreement. Inasmuch as Canada does not dispute the legitimacy of the objective, understood as being the protection of human health, the question which is submitted to the Panel for examination in this case under Article 2.2 is whether the Decree is more restrictive than is necessary to fulfil this objective, taking account of the risks non-fulfilment would create.

3.278 The **European Communities** point out that, contrary to Canada's claims, they have neither changed nor modified the objective of the Decree: the objective in banning asbestos was to stop the spread of the risk of asbestos-related diseases for the purpose of protecting human health so the objective is the same.

(ii) "For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create …" (Article 2.2, second sentence)

3.279 **Canada** maintains that the applicable test, for the purposes of determining if the technical regulation is more trade-restrictive than necessary to fulfil the objective claimed by France, consists of two different criteria. The Panel must first determine if the Decree makes it possible for the objective claimed by France to be fulfilled, in other words, if there is a rational link between the Decree and the objective. Then, to the extent that this first criterion is met, the Panel must ask itself if the trade effects of the technical regulation are necessary, taking account of the risks that the absence of this technical regulation would create. For this purpose, it is essential to consider the existence of alternative regulatory approaches, less trade-restrictive, that would make it just as possible to achieve the objective being pursued as the technical regulation being challenged. Canada maintains that the Decree banning asbestos creates an unnecessary obstacle to the international trade in chrysotile fibre and products containing it. First of all, the Decree has no rational link with the objective of protecting the health of workers and consumers sought by France. Secondly, its detrimental effects on trade are not necessary if the actual risks that would exist in the absence of a total ban are taken into account. Controlled use is an alternative likely to be less restrictive to the competition opportunities in the French market. Although a violation of Article 2.2 of the TBT Agreement exists if only one of the two criteria is not met, Canada contends that the Decree imposing the total ban on asbestos does not meet either of the two criteria. Canada adds that the Decree is not in compliance with the applicable international standards, so the EC do not benefit from the presumption in Article 2.5 of the TBT Agreement.

3.280 Canada claims that the first question before to the Panel is whether there is a rational link between the Decree and the objective of protecting the health of workers and consumers being pursued by France. In other words, does a total ban make it possible to fulfil the objective of protecting people's health? This stage of the analysis is essential in order to prevent technical regulations that only have tenuous links – or even no links at all – with the objective being pursued from finding any justification. Canada maintains that the Decree does not make it possible to fulfil the objective of protecting the health of workers and consumers, that is to say that there is no rational link between the Decree and the objective, for the following three reasons: firstly, the risks against which the Decree is supposed to protect workers and consumers are linked to uses of asbestos fibres that were already prohibited when the Decree was adopted; secondly, chrysotile fibre and modern products containing it do not present any detectable risk for health; and thirdly, the Decree replaces the undetectable risk of modern chrysotile-based products with the unknown – and perhaps greater – risk of substitute products for asbestos.

3.281 Canada states that the first difficulty in terms of the rational link is the fact that asbestos problems are derived from old uses of asbestos fibres such as the use of sprayed asbestos, which was prohibited in France in 1978. The current risks to human health are linked to exposure to asbestos dust released from brittle materials found in asbestos-treated buildings. The Decree does not achieve the protection of the population against the risks of asbestos already installed. Canada considers that

there is no rational link between the ban on hard chrysotile products and the protection of the health of workers and consumers because these products do not present any detectable risk for health. Nothing in the INSERM report links a total ban approach to any risk that might be derived from these chrysotile products. This is an essential element in determining the existence of a rational link because France has invoked this report as the only justification for its measure. INSERM has only evaluated hypothetical risks linked to past uses of asbestos, covering all varieties of fibres.[415] The concentrations of asbestos measured in the atmosphere today and on which INSERM was supposed to base its risk projections almost exclusively contain fibres released by brittle materials installed over 20 years ago. Canada maintains that the INSERM report, on which the ban is based, is therefore not relevant to the decision to adopt a policy on a ban. The only epidemiological data recorded in the report concern workers whose illnesses appeared several decades after exposure to asbestos fibres as the health effects of asbestos take 20 to 35 years on average to emerge. Moreover, the INSERM report explicitly states that almost all deaths attributable to asbestos nowadays are the result of past exposure caused by uncontrolled processing or spraying.[416] The decision to ban modern chrysotile products does not lead to reduced risks resulting from past uses nor does it even mitigate the damaging effects of brittle materials that are still to be found in certain buildings

3.282 Canada contends that the second difficulty in terms of the rational link is that INSERM has not evaluated whether the production or use of modern products containing chrysotile poses a risk for the health of workers and consumers. Such a study would undoubtedly have led INSERM to conclude that modern uses of chrysotile do not pose an actual health risk given the negligible emission of chrysotile-cement products. As Canada emphasized in its factual arguments (see Section III.B above), the health risks associated with modern chrysotile products are undetectable. Moreover, Canada notes that the EC have admitted that the practice of the controlled use of chrysotile is effective and appropriate in asbestos extraction and processing industries.[417] INSERM does not draw any conclusions on the harmless nature of the production and use of dense and non-brittle chrysotile products.[418] Nowhere is there any discussion on the specific risks related to the banned chrysotile-cement products. However, that is the necessary implication of the French statement according to which "while the principle of controlled use in the asbestos industry can be admitted, on the other hand, it is not possible to control the risk incurred in occupations related to the construction industry and in other occupations concerned".[419] (WTO translation) This statement implies, wrongly, that exposure to chrysotile-cement products is hazardous for construction industry workers. In Canada's view, the context that gave rise to the announcement and the adoption of the Decree proves that, in order to appease public opinion, the French Government used INSERM's report, which takes

[415] See Section III.B.7 above.

[416] INSERM report, p.400 and pp. 419 and 420.

[417] European Commission (G. Lohan, DG III), European justification of Decree No.96-1133 to the Canadian authorities (15 April 1997) following French Notification G/TBT/Notif.97.55, p.2. Canada notes that the French Académie nationale de médecine also recognizes that "recent important epidemiological studies, going back for 20 years or more, show that the carcinogenic or co-carcinogenic effect of asbestos (lung cancer) is no longer detected among large protected industrial populations working in the conditions prescribed by the regulatory texts. These conditions are laid down in practical leaflets published by the ministries concerned, Labour and Safety, for use by persons in occupations exposed to at least 1f/ml and in recent decrees, in 1996, concern persons working in buildings containing asbestos". (WTO translation) Académie nationale de médecine (Étienne Fournier), *Amiante et protection de la population exposée à l'inhalation de fibres d'amiante dans les bâtiments publics et privés*, Bulletin de l'Académie nationale de médecine, Vol.180, no. 4, 1996, pp. 5 and 6.

[418] Canada states that INSERM omitted to consider the many studies which conclude that modern chrysotile products are harmless. See, in particular, Spurny, K., *et al.*, *Measurement of the Fibrous Dusts in West Germany: Fiber Concentration in the Vicinity of Objects and Buildings with Asbestos-Containing-Building Materials* [Ger]. Zentralblatt Fur Bakteriologie, Mikrobiologie Und Hygiene – Series B, Umwelthygiene, Krankenhaushygiene, Arbeitshygiene, Präventive Medizin 1988; Vol. 187(2), p.136 .

[419] European Commission (G. Lohan, DG III), European justification of Decree No.96-1133 to the Canadian authorities (15 April 1997) following French Notification G/TBT/Notif.97.55, p.2.

into account the consequences of past and prohibited uses of asbestos, in order to assign risks incorrectly to modern uses of chrysotile fibre and products containing it. The Decree does not make any distinction between hard chrysotile products, for which health risks are at undetectable values, and asbestos-based brittle products, used as insulating material in the 1970s. The use of free fibres in insulating products, or products where the fibre is not encapsulated, was prohibited in view of the difficulty of controlling the dust caused by these applications. According to Canada, it is essential to note that in the modern uses of chrysotile fibre, for instance in chrysotile-cement products and chrysotile-reinforced plastics, the fibre is sealed in a matrix and cannot be released into the environment.

3.283 Canada asserts that the third difficulty in terms of the rational link between the order and the protection of health is the blind faith placed in substitute fibres for asbestos. The human health effects of most of the fibres used to replace chrysotile fibre are not known. According to Canada, the data prove that some substitutes that have been the subject of careful studies are often as, or even more, harmful than chrysotile. The total ban on chrysotile fibre and products containing it, and their replacement with substitute products, implies that substitute products are safe. However, INSERM has not been able to determine if these fibres are safe in view of the lack of epidemiological data currently available on this subject. The ban substitutes the undetectable risk of hard chrysotile products for the unknown – and perhaps greater – risk of substitute fibres. A consistent approach to risk management would have required the French Government, in the case of exposure to fibres and substitute products, to try to ensure a degree of health protection equivalent to what it intended through the total ban on chrysotile. In other words, a consistent approach would have required exposure to substitute fibres to be controlled in the same way as chrysotile. Based on the foregoing, Canada maintains that there is no rational link between the Decree and the objective of protecting public health being pursued by France. Firstly, the Decree does not address the true problem of asbestos in France: work on the sprayed asbestos products in place for at least 20 years. Secondly, the Decree ignores the scientific fact that products containing chrysotile imprisoned in a matrix are harmless. Thirdly, the Decree imposes substitute products whose risks are unknown, which in itself puts the objective being pursued by France in jeopardy.

3.284 Canada concludes that, inasmuch as the conditions of the first criterion (namely a rational link between the Decree and the objective claimed by France) have not been met, the Decree is incompatible with Article 2.2 of the TBT Agreement. Nevertheless, should the Panel conclude that there is a rational link between the Decree and the objective claimed by France, the Decree would still be incompatible with Article 2.2 of the TBT Agreement because, as Canada shows below, its effects are more trade-restrictive than necessary, taking account of the risks non-fulfilment of the objective would create. Canada asserts that an alternative solution less prejudicial to competition opportunities in the French market and with similar effects on the health of workers and consumers was available, i.e. controlled use.

3.285 Canada contends that the detrimental effects of the Decree on competition opportunities are not necessary, in view of the risks that the absence of technical regulations would create. The words "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 imply a necessity criterion. Canada notes that the two factors to be considered when examining necessity are, on the one hand, the risks that the absence of technical regulations would create and, on the other, the existence of a less trade-restrictive alternative measure that would make it possible to attain the objective being pursued just as effectively. As regards whether there are risks involved in not fulfilling the objective being pursued which could result from the absence of the technical regulations in force, the third sentence of Article 2.2 contains a non-exhaustive list of relevant factors that must be taken into consideration. In the context of this dispute, the scientific and technical information available, as well as the intended end-uses of products, in other words, chrysotile fibre and the products containing it, must be considered. By applying this criterion to the facts of this dispute, Canada maintains that the total ban on asbestos, without distinction as to fibres, completely eliminates

the French market for chrysotile fibre and products containing it, whereas the practice of controlled use of asbestos fibres, in terms of the types of fibre and their uses, allow fulfilment of the French objective of protecting the health of workers and consumers while authorizing certain safe uses of chrysotile fibre and products containing it. Accordingly, Canada claims that controlled use is an alternative that is less trade-restrictive and makes it possible to fulfil the objective claimed by France in the same way as the Decree. Consequently, if the actual risks of the modern uses of chrysotile are considered in light of the relevant criteria, specifically the scientific information and the intended end-uses, in Canada's view it becomes clear that the total ban on asbestos is not necessary, inasmuch as there is a less trade-restrictive measure that makes it possible to fulfil the objective claimed by France.

3.286 Canada states that, in the first place, there is no credible scientific information supporting a total ban on asbestos. The scientific information on which the Decree is based are included in INSERM's report, but this does not constitute a credible basis for justifying a total ban on all varieties and all uses of asbestos. INSERM's report attempts to use circumstances of high levels of exposure to a mixture of amphiboles and chrysotile in an effort to extrapolate the risks for a population that no longer experiences such exposure. Although this technique can in itself be deemed dubious, INSERM's report also raises a number of other questions when it is subjected to the criticism of peers in the scientific community. In Canada's view, INSERM's report contains conclusions that do not stand up to criticism. First, the report does not study the data on exposure actually sustained by the French population. The INSERM researchers relied on hypothetical data. Moreover, INSERM's risk assessments do not adequately make the distinction between the effects of amphiboles and the effects of chrysotile. The risk assessments presented as being linked to exposure to chrysotile are often based on parameters of exposure to amphiboles or to amphibole-chrysotile mixtures. The lack of a study of the risks posed by current exposure to chrysotile appears clearly in light of the alarmist conclusions of the report on cancer cases in France attributable to asbestos. These deaths are linked to past occupational exposure and not to current circumstances of exposure to dense products containing chrysotile. The INSERM researchers did not look at exposure to asbestos dust during incidental and/or intermittent work on structures where chrysotile-cement was used. INSERM used a linear model in its evaluation of the risk, extrapolating from cases of low exposure to chrysotile the risk involved in cases of high exposure to amphiboles or mixtures of fibres. However, as recognized by INSERM, the epidemiological data in cases of environmental exposure and exposure indoors do not indicate any detectable risk for low exposures. Finally, one of the effects of the Decree is to force the use of substitute fibres even though health risks associated with exposure to such fibres have not been addressed by INSERM.

3.287 Secondly, Canada asserts that the intended end-uses of modern products containing chrysotile fibre have not been taken into consideration in the evaluation of the human health risks. However, the intended end-uses of chrysotile, chrysotile-cement products for instance, do not present any detectable health risk. INSERM did not identify any risk linked to the modern uses of chrysotile fibre and products containing it. In assessing the risks, France has not taken into consideration the intended end-uses of modern products containing chrysotile. The known assessments of the risks linked to the modern uses of chrysotile indicate that the risks faced by an individual are so small as to be undetectable. According to Canada, the ILO confirms this as follows: "The handling of products containing asbestos in which asbestos fibres are solidly fixed in a bonding material so that dust cannot form does not present a health hazard."[420] The assessments of the risks faced by workers who come into contact with chrysotile-cement products once the material is installed indicate that the risks are undetectable.

3.288 Thirdly, Canada contends that the total ban on asbestos is the most restrictive measure from an international trade standpoint. It leads to a complete closure of the domestic market for these products. In France, in the case of asbestos, the ban has caused the entire French market for chrysotile

[420] International Labour Organization, *Safety in the Use of Asbestos*, International Labour Conference, Report VI (1), 71st session, 1985, Geneva, (first edition 1984), p.29.

fibre and products containing it to disappear. As the statistical tables in the section on French imports of chrysotile fibre from Canada show, the French market for Canadian exports has disappeared. Canada maintains that there is an alternative solution that makes it possible to fulfil the objective of protecting human health while being significantly less trade-restrictive. This alternative to the ban, i.e. controlled use, does not result in the effects previously described. Canada indicates that the practice of the controlled use of asbestos is based on recognized scientific principles and on an international consensus. Controlled use was available to France as a means of fulfilling the objective of protecting against risks associated with the uses of asbestos, without creating an unnecessary obstacle to international trade. In fact, that was the approach adopted by France until the adoption of the ban. Controlled use is an internationally endorsed regulatory approach based on scientific data applicable to an entire range of risk-related materials. The principles underlying this approach are that only products and materials that can be controlled in such a way that the associated risks are maintained at an acceptable level throughout their entire life cycle are authorized. In the case of asbestos, controlled use involves, in particular, maximum reduction of the quantity of dust released in a work environment, the adoption of specific work methods, the prohibition of amphiboles (crocidolite and amosite) and low-density brittle insulation products and the prohibition of processes or products that release dust. On the other hand, this form of regulation would allow the use of chrysotile fibre and high-density products such as chrysotile-cement. Controlled use is considerably less trade-restrictive than the ban on asbestos. The drop in Canadian chrysotile asbestos exports in 1997, the year immediately following the adoption of the Decree, clearly shows that the controlled use practices that had been implemented in France prior to the ban on asbestos did not create the same obstacles to trade as those created by the total ban on asbestos as soon as it was adopted.

3.289 Canada maintains that the total ban on asbestos, without distinction as to the types of fibre, completely eliminates the French market for chrysotile fibre, even though the practice of the controlled use of asbestos fibres, in terms of the types of fibre and their uses, allows the manufacturing of safe chrysotile products, while having the same effects on human health as the ban. The detrimental trade effects of the ban are not necessary in order to fulfil France's objectives just as effectively as the Decree. The measures based on controlled use that existed in France at the time of the announcement of the ban, would make it possible to fulfil the objective of protecting human health without creating unnecessary obstacles to trade. Canada considers that the excessive effects of the ban can only be explained by the political desire of the French Government to respond in a spectacular way to the pressure of public opinion. Canada claims that the Decree banning asbestos is incompatible with Article 2.2 of the TBT Agreement. Firstly, the Decree does not make it possible to fulfil the objective being pursued by France, that is the protection of the health of workers and consumers. Secondly, the detrimental effects of the total ban are not necessary in view of the actual risks resulting from the modern uses of chrysotile. The ban has done nothing more to protect health than the controlled use already in place.[421] The only uses allowed at the time of the Decree's adoption were the use of chrysotile fibre in dense materials, which, according to the available scientific information and considering the end-uses, did not pose – and still does not pose – detectable risks for people's health. Canada therefore concludes that the Decree is an excessive measure because

[421] Canada notes that the French Académie nationale de médecine wrote "A measure viewed so radically by public opinion as the total ban on asbestos does not in any way change the situation in a country. It does not resolve any of the problems raised by this material and may even mean neglecting the essential measures that should be taken immediately", (WTO translation), Académie nationale de médecine (Étienne Fournier), *Amiante et protection de la population exposée à l'inhalation de fibres d'amiante dans les bâtiments publics et privés*, Bulletin de l'Académie nationale de médecine, Vol.180, no.4. 1996, p.8. Also see pp.5 and 6 of the same report: "recent important epidemiological studies, going back for 20 years or more, show that the carcinogenic or co-carcinogenic effect of asbestos (lung cancer) is no longer detected among large protected industrial populations working in the conditions prescribed by the regulatory texts. These conditions are laid down in practical leaflets published by the ministries concerned, Labour and Safety, for use by persons in occupations exposed to at least 1f/ml and in recent decrees, in 1996, concern persons working in buildings containing asbestos". (WTO translation).

controlled use is a less trade-restrictive alternative that makes it possible to fulfil the objective being pursued by France.

3.290 The **European Communities** respond that the distinction made by Canada between, on the one hand, the need to determine whether the Decree permits the fulfilment of the objective cited by France ("rational link" in Canada's own words) and, on the other, whether the effects of the technical regulation are necessary, taking account of the risks that non-fulfilment would create, is artificial and at variance with the actual text of Article 2.2. of the TBT Agreement. The wording of Article 2.2 shows that the test laid down therein is in line with that used in connection with Article XX of the GATT and developed by Panel practice. In following the terms of Article 2.2 of the TBT Agreement, according to the EC, a dual examination has to be carried out: (i) determine whether the measure is the only one that allows the objective set by the Member to be attained, or whether there is a less restrictive measure whereby this objective can also be achieved; (ii) assess the risks which a failure to take the measure concerned would create, taking account, in particular, of available scientific and technical information or end-uses of products. The EC claim that, applied to the Decree, these two criteria show that the measure is compatible with Article 2.2.

3.291 The EC note that Canada repeats throughout its submission that a less restrictive measure (namely the "safe" use of asbestos) would enable the objective chosen by the French authorities to be achieved. However, the factual arguments of the EC, like their comments relating to Article XX(b) of the GATT, emphasize that "safe" use is: (i) insufficient to halt the spread of the risks linked to exposure to asbestos in the production and processing industries, even though the number of workers in those industries is limited and they are therefore, in principle, easy to supervise and monitor (this means an excess of mesotheliomas even with "safe" use); (ii) ineffective in halting the spread of the risks linked to occasional, and often unwitting, exposure to asbestos. The principle of "safe" use cannot apply where the risks affect a range of very varied occupations operating in a wide variety of situations (this means that it is genuinely impossible to ensure "safe" use among do-it-yourself enthusiasts and those exposed to para-occupational risks). For further details, the EC refer the Panel to the comments made in the factual section and those relating to Article XX(b) in their legal arguments. On that basis, the EC consider that the Panel should also conclude that the prohibition of asbestos and asbestos-containing products is the sole measure that will enable the objective set by the French authorities to be achieved.

3.292 The EC claim that failure to ban asbestos and asbestos-containing products would create risks for human health. The EC assert that, even though the burden of proof lies on Canada, the latter has done nothing to show that the replacement of the horizontal prohibition by "safe" use would not create risks to human health. In the EC's view, the risks that would be created by a failure to impose a ban are evident in the light of the available scientific information, the available technical information and the end-uses of asbestos and asbestos-containing products.

3.293 The EC maintain that the consequence of using asbestos and asbestos-containing products is to expose certain sections of the population to asbestos to a degree which scientific studies recognize as dangerous to human health. The spread of the risks linked to such exposure cannot be halted by "safe" use. In the mining and processing industries, in principle the easiest to monitor, the limits to the "safe" use of asbestos are already apparent. For example, the 1996 study of the British HSE, mentioned in the factual section, finds a significant excess of deaths due to mesothelioma among workers who began working in asbestos mines after the introduction of "safe" use. The EC note that, throughout its submission, Canada considers that asbestos inhalation is a threat only to production and processing workers and affects several thousand persons at the most. In the para-occupational and domestic context, however, hundreds of thousands of persons are exposed to asbestos (very often unwittingly) and may even be subject to exposure levels greatly in excess of the current limit values for asbestos dust. For example, as the EC indicated in Section III.B, a roofing worker using a grinder in the open air to repair corrugated roof sheeting made of asbestos-cement is exposed to a peak level of 41 f/ml, 410 times in excess of the limit value. The EC point out that a 1992 study by the Quebec

CSST shows that the risk of mesothelioma has been rising steadily in Canada since 1967, chiefly among repair and maintenance workers. This finding is even more relevant to those persons exposed to asbestos inhalation in a non-occupational context. The publication by Camus *et al.* shows a net excess of mesotheliomas in women living near chrysotile asbestos mines in Quebec, seven times higher than the level found among other women in Quebec. Canada never quotes this study.

3.294 The EC point out that, as they indicated in the factual section (see Section III.B) and in their comments on Article XX of the GATT, all these findings were taken into account in the INSERM Report. These findings are also in line with the most recent scientific studies. In the EC's view, Canada cannot discharge the burden of proof by trying to justify the "safe" use of asbestos by reference to texts which are over 15 years old and do not guarantee an adequate level of protection, given the health objectives adopted by the vast majority of countries. The EC emphasize in this connection that recent texts, not quoted by Canada, confirm the ineffectiveness of such "safe" use. This can be clearly seen in the 1998 WHO report, which states:

> "Some asbestos containing products pose particular concern and chrysotile use in those circumstances is not recommended. These uses include friable products with high exposure potential. Construction materials are of particular concern for several reasons. The construction industry work force is large and measures to control asbestos are difficult to institute. In-place building materials may also pose risk control to those carrying out alterations, maintenance and demolition. Minerals in place have the potential to deteriorate and create exposures."[422]

3.295 The EC state that the technical information indicates that "safe" use cannot halt the spread of the risks linked to exposure to asbestos, in particular where persons are unwittingly exposed (repeatedly or occasionally). The fact that "safe" use cannot halt the spread of the risk follows logically from the fact that it would be completely unrealistic to apply to the general public the extremely stringent rules applicable to a small "targeted" population (primary users). In fact, as the EC have already stated, it is impossible to implement "safe" use effectively when hundreds of thousands of persons are exposed every day in areas of activity with little supervision in terms of health, such as the construction industry, which accounts for at least 25 per cent of the cases of mesothelioma occurring in France, not to mention the millions of do-it-yourself enthusiasts unwittingly exposed to asbestos inhalation when performing everyday tasks such as cutting. As regards the specific means of ensuring the effectiveness of "safe" use, the EC point out that Canada, even though it bears the burden of proof, considers that the risk of asbestos fibres escaping during cutting or sawing of asbestos-containing products would not exist if items were supplied "pre-cut".

3.296 The EC note that Canada also refers to an ISO standard which is over 15 years old. Canada states that "… the cutting of plates or tiles for roof covering is not a source of emission if the simple techniques of standard ISO-7337 are followed". The EC note that these "simple" techniques include "the use of chains that break the pipes by the effect of pressure, low-speed saws and saws equipped with a vacuum extractor, as well as the moistening of the materials prior to any action". Use of these techniques also presupposes that do-it-yourself enthusiasts will put on a "diver's suit" before starting any operation that will bring them into contact with asbestos. In reality, these techniques are not sufficient to halt the spread of the risks. The EC emphasize that, in the real world, not all items are pre-cut. In the real world, the thousands of people who are unwittingly exposed to asbestos inhalation will not put on protective clothing to perform everyday tasks. In the EC's view, the fact that Canada is unable to demonstrate any specific or realistic methods of halting the spread of the risk linked to asbestos exposure, without a total ban on asbestos and asbestos-containing products, is due to the absence of any scientific basis. Once products are placed on the market, there is no longer any realistic means of monitoring the use of asbestos, and in particular the everyday operations (cutting, sawing, etc.) in which many persons may be engaged. The EC maintain that the "safe" use of asbestos advocated by Canada is therefore inapplicable and does not enable the legitimate objective

[422] *IPCS Environmental Health Criteria (203) on Chrysotile* WHO, Geneva, 1998, point c), p.144.

set by France to be achieved. Furthermore, the EC note that Canada states that the French Decree means "blind recourse" to substitute fibres. According to the EC, this statement reflects a misunderstanding of the French legislation. In practice, manufacturers carry out technical tests with a view to replacing asbestos products by substitute products. If these tests are inconclusive, and if the manufacturers can demonstrate that there are no substitute products with the same technical characteristics as asbestos, they can submit an application for a waiver so that they can continue to use asbestos. The Decree provides for such waivers, which are granted after a detailed assessment.

3.297 Concerning the intended end-uses of the products, the EC note that Canada maintains that the "modern" uses of chrysotile fibre are such that the fibre is bound in a matrix and cannot be released into the environment. The EC point out in this connection that Canada is claiming that this is an innovation when it is not. As the EC have already indicated, for the past forty years the production of asbestos-cement has consisted of "encapsulating" asbestos in cement (10 per cent of asbestos fibres in 90 per cent of cement). The EC emphasize that, in talking of "modern" use or of "modern" products, Canada is misleading the Panel by trying to promote a "clean" image of chrysotile asbestos; although "chrysotile asbestos" sounds better than "amphibole asbestos", chrysotile is also classified by the WHO as a "category I" product known to cause cancer in man. The Panel should know that the "encapsulation" in question by no means guarantees the harmlessness of asbestos-cement, for example. Once the use of asbestos-cement is authorized, it is no longer possible to monitor such use. A variety of operations such as cutting, sanding, crushing or sawing are bound to be applied to asbestos-cement, in the occupational, para-occupational and domestic contexts. During these operations, large numbers of carcinogenic fibres will be released in the form of dust. Consequently, the EC conclude that the "modern" use of chrysotile asbestos, to which Canada refers in its submission, is illusory and can only conceal the grave risks linked to the use of asbestos-cement, in particular by persons who are subject to unwitting, repeated or occasional exposure.

3.298 **Canada** emphasizes that, once it is acknowledged that an objective is legitimate, it must be determined whether the technical regulation constitutes a rational and necessary measure. A measure is said to be rational if it is carefully designed, based on the legitimate objective. It must be neither arbitrary nor based on irrational considerations. A measure is said to be necessary if it is not more trade-restrictive than is necessary to fulfil the legitimate objective, taking account of the risks non-fulfilment would create. The measure must therefore have a minimal impact on trade. The risks that the absence of a measure would entail must also be assessed. The foregoing is based directly on the text of Article 2.2, particularly the second sentence. In Canada's view, the application of this provision requires that the following three questions be answered: (i) does the technical regulation make it possible to "fulfil" the "legitimate objective" (rational measure); (ii) is the technical regulation "more trade-restrictive than necessary" to fulfil the legitimate objective (necessary measure); and (iii) have the alleged harmful effects ("the risks non-fulfilment would create") been assessed in light of the "available scientific and technical information" and the "intended end-uses of products"? Unlike the United States,[423] Canada considers that the obligation under Article 2.2 does not have to be interpreted in a similar way to Article 5.6 of the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement"). Article 5.6 of the SPS Agreement refers to a specific test that the United States suggests be transposed to Article 2.2 of the TBT Agreement, even though the terms of each Article are different, calling for separate approaches. To cite only one example, contrary to the footnote to which Article 5.6 of the SPS Agreement refers, Article 2.2 of the TBT Agreement does not require the demonstration of the existence of another applicable measure that is "significantly" less restrictive to trade. Canada notes that the EC subscribe to this viewpoint as they propose to interpret the criterion of necessity in Article 2.2 of the TBT Agreement in a similar way to the criterion of necessity in Article XX of the GATT 1947 and 1994.

3.299 Canada considers that the question that must be answered is whether the technical regulation embodied by the Decree has been carefully designed to fulfil France's objective? This stage of the

[423] See Section IV below.

analysis is essential in order to prevent the justification of technical regulations that only have tenuous links with the stated objective. Canada maintains that there is no rational link between the Decree and France's objective and that the total ban on asbestos does not allow this objective to be attained for three reasons: (i) the Decree does not address the real problem of asbestos in France, which is the amount of contact with friable materials containing amphiboles that have been in place for at least 20 years; (ii) the Decree ignores the indisputable scientific evidence concerning the safety of products in which chrysotile fibres are trapped in a matrix; and (iii) the Decree imposes substitute products whose risks are unknown, thereby compromising France's objective. These three points will be addressed in turn.

3.300 Regarding the first point, Canada contends that the risks associated with asbestos in France are attributable to amphibole asbestos and to sprayed-on applications, both of which are no longer used. When setting out its arguments on controlled use and workers in the servicing and maintenance sector in the factual section (Section III.B above), Canada emphasized that, in the industrialized countries, it is the friable asbestos products inherited from the past which represent by far the major potential for exposure and risk today and in the years to come. That is the situation in France, where the health problems associated with asbestos are essentially attributable to friable materials containing amphiboles (or a mixture of amphiboles and chrysotile), used in the 1950s, 1960s and 1970s in processes such as spraying and insulation. The French Académie nationale de médecine came to this conclusion earlier, in April 1996, in its report on the protection of the populations exposed to the inhalation of asbestos fibres in public and private buildings. The relevant passage reads as follows:

> "A number of epidemiologists have found that unprotected contacts with the parts of buildings containing asbestos expose, even today, too many professionals to diseases comparable to those described prior to the current regulations. This is unfortunately a simple statement of the fact that improper working conditions pose the same hazards as the working conditions of the 1950s."[424] [Translation by Canada]

3.301 According to Canada, inasmuch as the hazard already exists, France, like the other industrialized countries, cannot prevent it. France has already ordered a mandatory survey of apartment buildings containing sprayed-on asbestos. Construction workers will be able to refer to this register and take the appropriate measures. France banned spraying in 1978 and amphiboles in 1994. The Decree therefore has the effect of prohibiting chrysotile-cement and other non-friable chrysotile-based products. In Canada's view, it is obvious that the Decree does not in any way constitute a solution to France's public health problem, which is associated with amphiboles and friable products containing asbestos. Canada maintains that there is no rational link between the objective, which is to solve the health problems caused by the large quantities of friable asbestos materials in place in existing buildings, and the Decree, which is obviously not designed to fulfil this objective.

3.302 Regarding the second point, Canada states that chrysotile fibre and high-density non-friable products do not pose any detectable health risk. Nor is there a rational link between the ban on high-density products and the protection of health because these products do not pose any detectable health risk. Today, 97 per cent of chrysotile fibres are used in high-density non-friable materials. Asbestos-cement products account for 90 per cent of the world market. Brake linings represent about 7 per cent of the market. Various products, such as plastics, seals, etc. account for the remaining 3 per cent market share. These products are non-friable and only chrysotile fibres are used. In these products, the fibres are firmly bound physically and chemically to the matrix of the composite and cannot easily be released in biologically significant concentrations. Canada contends that the health risks associated with these non-friable high-density chrysotile products are undetectable. The word "undetectable" here means "below the limit of detection". This expression means that, by using the

[424] Académie nationale de médecine (Étienne Fournier), *Amiante et protection de la population exposée à l'inhalation de fibres d'amiante dans les bâtiments publics et privés*, Bulletin de l'Académie nationale de médecine, Vol.180, no.4-16,23,30 April 1996, p.7.

most recent methods and techniques and the most rigorous statistical analyses, the risk associated with conditions of exposure is so low, if there is even any risk at all, that it is "below the limit of detection". The source of the asbestos risk which the French want to stop from spreading does not come from these high-density chrysotile-based products. In Canada's view, there is no rational link between the objective of protecting human health and the Decree, whose objective is to prohibit the marketing, sale and importation of non-friable high-density chrysotile products because their health risks, if any, are undetectable.

3.303 Thirdly, Canada claims that the Decree replaced the "known" and undetectable risk of non-friable chrysotile-based products with the "unknown" risk of substitute fibres, thereby increasing the risk to human health. The absence of a rational link is even more obvious if it is considered that the Decree encourages the replacement of chrysotile by substitute fibres. As a result of the Decree, the undetectable risk associated with high-density chrysotile-based products has been replaced by the unknown risk of substitute fibres. The ban on chrysotile asbestos thus creates a false sense of security in the population, lowering the vigilance of workers and of the public who are the most likely to come into contact with the substitute products. Canada notes that the EC claim that the harmlessness or less harmful nature of substitute fibres is proven. As it emphasized in its arguments concerning substitute fibres, Canada maintains that not only does this claim not stand up to analysis, but the description given by the EC is incorrect. The EC are endeavouring in this manner to justify the irrationality of the total ban on chrysotile fibres and their ill-considered replacement by substitute fibres. According to Canada, the WHO is of the opinion that replacement must be done whenever it is possible to replace chrysotile fibres with "safe substitute materials". Canada recalls that on several occasions it has emphasized that the chrysotile substitutes used in France are not "safe" products or products whose "harmlessness" or "less harmful" nature are proven. Nor is chrysotile asbestos replaced by products which, according to the ILO, should be "harmless or less harmful". The fact that substitute products do not contain asbestos is not sufficient grounds to believe that these products are safe or less hazardous. In many cases, fibrous substitute materials are assumed to be safe by users and safety measures such as dust control and removal are not observed. Canada considers that banning a material whose risks are known, and even over-estimated, and replacing it indiscriminately with substitutes whose effects are unknown seems to be an odd choice given France's objective of protecting public health. Canada maintains that there is no rational link between the objective of protecting human health and the Decree, whose effect is to replace a product - chrysotile - whose risks are known and undetectable with substitutes - fibres or products - whose risks are unknown. The Decree does not result in increased protection of public health; it contributes rather to fostering in the population a false sense of security and potentially a greater risk to human health.

3.304 Canada concludes that, inasmuch as it has no rational link with France's objective, the Decree is inconsistent with Article 2.2 of the TBT Agreement. However, in the event that the Panel should find that there is a rational link between the Decree and France's objective, the Decree would nonetheless be inconsistent with Article 2.2 of the TBT Agreement because, as demonstrated below, its effects on trade are more restrictive than is necessary, taking account of the risks that non-fulfilment of France's objective would create. An alternative solution that is less trade-restrictive and fulfils the same objective of protecting human health was available, namely controlled use.

3.305 Canada maintains that the prejudicial effects of the Decree on trade are not necessary, taking account of the risks that the absence of a technical regulation would create. The terms of Article 2.2 of the TBT Agreement - "technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create" - suggest the application of a criterion of necessity. The two factors to be considered in examining necessity are, on the one hand, the risks that the absence of a technical regulation would create and, on the other, the existence of a less trade-restrictive alternative measure that would make it possible to fulfil the stated objective just as effectively. According to Canada, the Panel must therefore first determine what risks the absence of a Decree would create. To assess these risks, the relevant factors to take into consideration include the available scientific and technical information and the intended end-uses of

the products. In this respect, Canada is of the opinion that the protection of human health would be just as effectively ensured if the ban on chrysotile prescribed by the Decree were replaced by controlled use measures, considering the undetectable risks of the high-density chrysotile-based products which account for virtually the entire market. To determine whether the effects of the technical regulation on trade are necessary, taking account of the risks that its absence would create, Canada considers that it is essential to consider the existence of less trade-restrictive alternatives that would make it possible to fulfil the objective just as effectively as the disputed measure. In examining whether the prejudicial effects of the technical regulation are appropriate given the stated objective, the Panel must consider the existence of a less trade-restrictive alternative solution that would make it possible to fulfil the desired objective just as effectively. In Canada's view, the controlled use of asbestos is a less trade-restrictive alternative which, nonetheless, makes it possible to fulfil the objective of protecting human health.

3.306 Canada contends that the Decree is not based on scientific information. It notes that that there are two types of "asbestos" risk in France: (i) the risk of diseases that might occur among those exposed while working with modern high-density products containing chrysotile; (ii) the risk of diseases that might occur among persons working in buildings containing friable asbestos materials. The risks and diseases associated with friable materials that were put in place in France using a process – spraying – that is now banned are not affected by the Decree and are therefore not the subject of this debate. Indeed, France banned spraying, amphiboles and friable products well before the date of the Decree. The only risks and diseases concerned by the Decree are those associated with contact with modern high-density products containing chrysotile. None of the "available scientific and technical information" supports the total ban on asbestos (in fact, chrysotile asbestos) adopted by France. Canada maintains that the risk assessment used by France as a basis for the ban on chrysotile – the INSERM report – does not take into consideration the scientific information concerning products in which chrysotile fibres are solidly set in a binder in such a way that no dust can be released. Furthermore, using models derived from exposures to high doses of asbestos dust containing amphiboles, INSERM claims to make an assessment of the risks of modern applications of chrysotile. It assumed that the risk is proportional to the exposure for levels considerably lower than those that have been the subject of epidemiological study. Canada considers that such extrapolations are scientifically unfounded. According to the INSERM group of experts, this is the "most plausible uncertain" risk assessment.

3.307 Canada states that the figures obtained by INSERM based on these models are average values subject to large variations. INSERM did not consider the risks of the intermittent or discontinuous exposures that occur while working with high-density products in which chrysotile fibres are incorporated, such as asbestos-cement, the composite in which more than 90 per cent of chrysotile fibres imported into France were incorporated before the adoption of the Decree. In this application, chrysotile fibres are solidly bound to the cement in such a way that no asbestos dust is released into the ambient air. Most manufacturers now offer products pre-cut and pre-drilled in the plant. Special techniques such as pre-cutting are used to avoid any cutting operations. When cutting or drilling cannot be avoided, work methods exist which make it possible to limit the dust emissions to a level significantly lower than the safe exposure values. This is also true for the other modern chrysotile-based products in which the fibres are incorporated or encapsulated in a matrix. According to Canada, the EC have not demonstrated that chrysotile fibres encapsulated or incorporated in a cement matrix or a plastic composite pose a health risk. Canada states that it has refuted all the studies on which the EC rely in order to argue that controlled use is not effective in keeping risks to human health to an undetectable level during all stages of the life cycle of modern chrysotile-based products (extraction of chrysotile, processing, incorporation in manufactured products, distribution, sale, use and disposal). On the other hand, credible scientific information indicates that emissions of asbestos dust from non-friable high-density chrysotile-based products are minimal and represent, for those exposed, an undetectable level of risk. Canada contends that INSERM did not correctly assess the risk to human health from the manufacture or use of high-density chrysotile-based products. Such a study would

undoubtedly have prompted INSERM to conclude that modern uses of chrysotile do not pose a genuine health risk.

3.308 Canada maintains that high-density chrysotile-based products do not pose a risk to human health in light of their intended end-uses.[425] Canada also claims that France dismissed controlled use, a practice less trade-restrictive than a total ban on chrysotile, even though controlled use is equally effective in protecting human health. Canada emphasizes that the array of measures aimed at controlling the use of asbestos in place in France when the total ban on asbestos was adopted enabled the objective of protecting human health to be attained without creating an unnecessary obstacle to trade. The French legislative provisions on controlled use were quite elaborate. Several measures had been taken by the public authorities, including: (i) a ban on sprayed-on applications of asbestos for all buildings; (ii) a ban on the marketing, use and importation of all varieties of amphiboles; (iii) rigorous control of the average concentrations of asbestos fibres in the workplace (exposure limit value of 0.1 f/ml); (iv) a ban on an entire range of products containing asbestos; and (v) a mandatory survey of apartment buildings containing sprayed-on asbestos and insulation. This array of measures offered optimal protection of human health.

3.309 Canada claims that France did not have to ban asbestos completely. It merely had to continue to apply the measures already in place. In fact, the use of relatively simple methods and rules is sufficient to ensure safe use of chrysotile at each stage of its life cycle, as can be seen in the case of chrysotile-cement, which accounts for virtually all of the world market for products in which chrysotile is incorporated. Canada notes that controlled use makes it possible, to borrow the expression of the EC, to halt the spread of the risk associated with exposure to chrysotile in the production and processing sectors. The following control measures are effective in maintaining emissions of chrysotile dust below the permitted limit values: dust control equipment, regular verification of chrysotile concentrations, wet process, confinement, policy on work clothing, showers and medical examination. Similarly, during the installation and maintenance of chrysotile-cement products, controlled use affords workers a level of protection corresponding to an undetectable risk. If the methods prescribed by Standard ISO-7337 are followed, the exposure levels generated during cutting, sawing, drilling or sizing operations on chrysotile-cement products can be maintained well below values that represent a detectable risk. Canada claims that the total ban on asbestos constitutes the most restrictive possible measure from the standpoint of international trade. It has resulted in the total closure of the French market to chrysotile asbestos. In the case of high-density chrysotile-based products, controlled use is entirely practicable, effectively protects human health and has a less drastic effect on international trade. That is why controlled use is a preferable alternative to a ban in the context of Article 2.2 of the TBT Agreement. Canada states that when, in accordance with Article 2.2 of the TBT Agreement, the risks of modern uses of chrysotile are taken into consideration in light of the scientific information and the intended end-uses of the products, the total ban on asbestos is not justifiable in terms of this Article because controlled use is less trade-restrictive and makes it possible to fulfil the objective of protecting human health.

3.310 Canada maintains that the preamble to the TBT Agreement cannot be invoked to justify non-compliance of a technical regulation with Article 2.2. The preamble to the TBT Agreement cannot be used to justify the Decree. The preamble outlines the goals and rationale of a treaty. It does not confer any rights and does not impose any obligations. In the case of the preamble to the TBT Agreement, the statement that the Members can choose the measures necessary for the protection of health is explicitly limited by the obligations contained in the Agreement. Paragraph 6 of the preamble to the TBT Agreement stipulates that the principles outlined therein (notably that no country should be prevented from taking "…measures necessary for the protection of human … health") are subject to two requirements. First of all, the measures in question must not constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail nor a disguised restriction on international trade (in this connection, see also Canada's arguments in the section

[425] See Section III.B above.

dealing with Article XX(b) of the GATT). Secondly, the measures adopted must comply with the obligations contained in the TBT Agreement, notably Article 2.2. In Canada's view, it is clear that the preamble cannot be invoked to justify a technical regulation which, like the Decree, is inconsistent with Article 2.2.

3.311 With regard to the precautionary principle, to which the EC refer, Canada notes that it was recently mentioned by the Appellate Body in *Japan – Measures Affecting Agricultural Products* that the preamble and Articles 3.3 and 5.7 of the SPS Agreement refer to the precautionary principle. However, again according to the Appellate Body, the precautionary principle cannot, in itself, justify a violation of any of the obligations of the SPS Agreement. If this is true in the case of the SPS Agreement, it is even more true in the case of the TBT Agreement, which cites this principle much more vaguely. Nor can the precautionary principle be invoked to justify the attainment of a zero risk.[426]

3.312 Canada concludes that the Decree is inconsistent with Article 2.2 of the TBT Agreement. The Decree does not make it possible to fulfil France's objective, namely, better protection of human health. The prejudicial effects on trade of the total ban prescribed by the Decree are neither necessary nor justifiable. The ban has done nothing more to protect health than the controlled already in place. The only uses allowed at the time of the Decree's adoption were those in which chrysotile fibres are incorporated in high-density materials. Yet these materials, according to the available scientific information and considering their end-uses, at the time of the adoption of the Decree did not pose - and still do not pose - a detectable health risk. To summarize, the Decree is an excessive measure in view of the fact that controlled use is a less trade-restrictive alternative that enables the French objective of protecting human health to be attained. Neither the preamble to the TBT Agreement nor the precautionary principle can justify the measure taken by the French Government in breach of the obligations contained in the TBT Agreement.

3.313 The **European Communities** respond that it is important to be aware that a Member of the WTO can establish the level of health protection it deems appropriate in its territory. In this connection, the EC point out that, for example, the sixth paragraph of the preamble to the TBT Agreement clearly states that Members are free to choose the level of health protection they deem appropriate. This principle was noted by the Appellate Body, which pointed out that:

> "WTO Members have a large measure of autonomy to determine their own policies on the environment (including its relationship with trade), their environmental objectives and the environmental legislation they enact and implement. So far as concerns the WTO, that autonomy is circumscribed only by the need to respect the requirements of the *General Agreement* and the other covered agreements."[427] [italics in the original]

3.314 The EC claim that the Members of the WTO benefit from a similar "large measure of autonomy" in the field of human health protection. The question might arise whether this appropriate level is limited by the word "necessary" or by the fact that the measure must not be applied in a manner that would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade. In this respect, the EC consider it important to make a distinction between the "level" deemed appropriate by the Member and the "measure" taken by that Member to achieve the chosen level. The EC note that, in the context of Article XX(b) of the GATT, all the panels which have examined the concept of necessity have concluded that it was not the necessity of the objective pursued by the measure concerned that should be examined but whether or not it was necessary to submit the imported

[426] See the comments of Sir Leon Brittan, para.3.475 below.

[427] *United States – Gasoline*, Report of the Appellate Body, adopted on 20 May 1996, WT/DS2/AB/R, in particular pp.30 and 31 of the English text.

products to the measure contested.[428] In this connection, the Panel on *United States - Restrictions on Imports of Tuna* stated that:

> "… Article XX(b) allows each contracting party to set its own human, animal or plant life or health standards. The conditions set out in Article XX(b) which limit resort to this exception, namely that the measure taken must be 'necessary' and not 'constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade', refer to the trade measure requiring justification under Article XX(b), not however to the life or health standard chosen by the contracting party."[429]

3.315 According to the EC, it follows from the above that whereas the trade measure that makes it possible to achieve the desired objective must satisfy certain conditions, there is no restriction on the level of protection chosen by the Member. Accordingly, the EC consider that France was free to choose the level of protection it deemed appropriate in the present case, i.e. to halt the spread of the risk linked with the use of asbestos fibres and products containing such fibres.

3.316 The EC maintain that the test of "necessary" in Article 2.2 of the TBT Agreement is a formalization of the previous practice relating, in particular, to Article XX(b) of the GATT. The EC would, however, like to point out that, even though the test of necessity within the context of Article 2.2 of the TBT Agreement corresponds, in particular, to the test in Article XX(b) of the GATT, it nonetheless remains true that the burden of proof, within the context of the TBT Agreement, lies with the party which invokes a specific provision of the latter.[430] As the EC pointed out above, the Panel on *United States - Gasoline* introduced into the GATT case law concerning the test of necessity established in the GATT 1947. In particular, the Panel noted that:

> "… the term 'necessary' had been interpreted in the context of Article XX(d) by the panel in the *Section 337* case which had stated that: a contracting party cannot justify a measure inconsistent with another GATT provision as 'necessary' in terms of Article XX(d) if an alternative measure which it could reasonably be expected to employ and which is not inconsistent with other GATT provisions is available to it. By the same token, in cases where a measure consistent with other GATT provisions is not reasonably available, a contracting party is bound to use, among the measures reasonably available to it, that which entails the least degree of inconsistency with other GATT provisions."[431] [italics in the original]

3.317 The EC note that the Panel on *Thailand – Cigarettes* adopted the same reasoning when examining a measure under Article XX(b). That Panel saw no reason not to adopt the same interpretation of "necessary" under Article XX(b) as under Article XX(d), stating that:

> "The import restrictions imposed by Thailand could be considered to be 'necessary' in terms of Article XX(b) only if there were no alternative measures consistent with the General Agreement, or less inconsistent with it, which Thailand could reasonably be expected to employ to achieve its health policy objectives."[432]

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[428] *United States – Section 337 of the Tariff Act of 1930*, adopted on 7 November 1989, BISD 36S/345, para.5.26, *Thailand – Import Restrictions and Internal Taxes on Cigarettes* (hereinafter *Thailand – Cigarettes*), adopted on 7 November 1990, BISD 37S/200, para.75; *United States – Gasoline*, Appellate Body Report and Panel Report, adopted on 20 May 1996, WT/DS2/9, paras.6.22-6.24.

[429] *United States – Restrictions on Imports of Tuna*, report circulated on 3 September 1991, not adopted, BISD 39S/155, para.5.27.

[430] The EC note that this principle was underlined by the Appellate Body within the context of the SPS Agreement, (*EC Measures Concerning Meat and Meat Products (Hormones*), Report of the Appellate Body, WT/DS26/DS48/AB/R, adopted on 13 February 1998, in particular para.109.

[431] *United States – Gasoline*, Appellate Body and Panel Report, adopted on 20 May 1996, WT/DS2/9, in particular para.6.24.

[432] See, in particular, *Thailand – Cigarettes*, adopted on 7 November 1990, BISD 37S/200, para.75. The EC also note that this approach is being followed in practice. The document entitled "Streamlined

3.318 The EC consider that the concept of necessity under Article XX(b) of the GATT is similar to that in Article 2.2 of the TBT Agreement. The criterion of necessity under Article 2.2 of the TBT Agreement is also based on whether or not the measure adopted is more restrictive than necessary to fulfil a legitimate objective. In this sense, Article 2.2 echoes the test of necessity in Article XX(b) of the GATT which involves, *inter alia*, examining whether a measure consistent or less inconsistent with the GATT (and hence less restrictive) is available and could be employed to fulfil the Member's objective.

3.319 As for the second sentence of Article 2.2 of the TBT Agreement, which reads "… taking account of the risks non-fulfilment would create", the EC consider that, here again, this is an integral part of the implementation of the test of necessity under Article XX(b) of the GATT. In fact, according to the EC, a restrictive measure is "necessary" only if there are risks associated with the non-adoption of the measure in question. The purpose of this sentence is to deny Members the possibility of adopting measures, under cover of protecting human health, without having taken into account the risks associated with the use of the product banned. Such risks should be assessed, in particular, on the basis of the available scientific and technical information. Clearly, then, the degree of necessity depends on the nature of the objective, as well as on the risks its non-fulfilment would create. As the EC claimed, under the so-called "safe" use policy there continues to be a significant excess of deaths in the asbestos production and processing sector. Moreover, this policy does not provide protection for the secondary populations exposed to asbestos (carpenters, electricians, do-it-yourself enthusiasts, etc.), although the number of deaths caused by asbestos in these groups has steadily increased and now accounts for more than a quarter of deaths due to asbestos.

3.320 The EC note that France, through the INSERM report, analysed the risks associated with the use of asbestos when it adopted its Decree. Furthermore, the scientific evidence[433] predicted an increase in the annual number of deaths by mesothelioma in France up to the year 2020. It is estimated that in France the total number of deaths by mesothelioma over the whole of the period 1996-2020 will be 20,000 for men and 2,900 for women. Furthermore, the study by Peto *et al*[434], which analyses mesothelioma mortality in England and Wales during the period from 1979 to 1990, shows that about 95 per cent of all the deaths during that period involved workers belonging to the "secondary" user group. It follows that, in the present case, the risks created by non-fulfilment are mortal risks. Accordingly, as so-called "safe" use is inapplicable and ineffective[435], the EC maintain that banning asbestos and asbestos-containing products was the only measure that could be employed to achieve the level of protection deemed appropriate by France, which is to halt the spread of the risk associated with the use of this product. The EC therefore conclude that the test of necessity is the same under Article XX(b) of the GATT 1994 as under Article 2.2 of the TBT Agreement.

3.321 The EC point out, however, that the fact that the test of necessity should, in substance, be applied in the same way in each of the above-mentioned provisions does not mean that the distribution of the burden of proof is the same under each of these provisions. Within the context of Article 2.2 of the TBT Agreement, as distinct from Article XX(b) of the GATT, the burden is on the complaining party to first establish a violation. Article 2.2 of the TBT Agreement cannot be

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mechanism for reconciling the interests of contracting parties in the event of trade-damaging acts" provides, in particular, that "A measure taken by an importing contracting party should not be any more severe … than necessary to protect the human, animal or plant life or health involved, as provided in Article XX(b)" Document C/M/236, BISD 36S/67, point 1.

[433] Gilg Soit Ilg, A., *et al*., *Estimation of the Past and Future Burden of Mortality from Mesothelioma in France*, Occupational Environmental Medicine, 1998; 55:760-765.

[434] Peto, J. *et al*., *Continuing Increase in Mesothelioma Mortality in Britain*, Lancet, 1995, vol.345, p.535.

[435] Hutchings, S., *et al*., *Asbestos-Related Disease*, Occupational Health Supplement, London, Health and Safety Executive, 1996, pp.127-152.

understood as an exception to another provision of the TBT Agreement. Considering the structure and context of the TBT Agreement, the Report of the Appellate Body in the *Hormones*[436] case is particularly relevant. In fact, the complaining Member must first demonstrate the availability of a consistent or less inconsistent alternative measure that can be employed to achieve the level of protection deemed appropriate by the defending Member.[437] The EC consider that Canada has not shown that the French measure was not necessary, within the meaning of Article 2.2 of the TBT Agreement, to protect human health in accordance with the level of protection deemed appropriate by France.

3.322 **Canada** contends that, contrary to the requirements of Article 2.2 of the TBT Agreement, the Decree has no rational link with France's stated objective: it does not protect the health of French workers or of the public in general. The requirement for such a link flows naturally from the text of Article 2.2, which states that regulations shall not create "unnecessary obstacles to international trade". As the preamble to the TBT Agreement prescribes, the rational link element ensures that measures are not "applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination". Three facts supported by science demonstrate the lack of a rational link: (i) the risks posed by the high-density chrysotile products at issue in this case are undetectable; (ii) amphiboles are far more dangerous than chrysotile; and (iii) substitute fibres have not been shown to be harmless. Canada addresses each of these factual issues in turn.

3.323 Canada notes, first of all, that high-density chrysotile products do not threaten the health of French workers, but are nonetheless wrongly targeted. The Decree banning such products therefore has no rational connection with the protection of human health. According to Dr. Henderson, chrysotile-cement products pose a "negligible risk to health" because of their normal weathering, erosion or general degradation. "… there is little or no dispute among experts on this issue".[438] To illustrate the relative risk, Dr. Henderson states that: "A greater risk to health would arise from […] falling from or through the roofs".[439] At the meeting with the parties on 17 January 2000, he added that the risk of cancer and mesothelioma is consistently higher with friable products than with high-density products and that the risk associated with manufacturing high-density chrysotile-cement products was "extremely low." Canada further states that interventions on the high-density products at issue, namely chrysotile-cement exterior construction panels, roofing tiles and pipes, are rarely, if ever, required. Moreover, with the adoption of proper working procedures and the use of proper tools as recommended in international standards, such interventions pose no detectable risk to human health. According to Canada, the WHO specifically targets past uses as being problematic: "There is potential for widespread exposure of maintenance personnel to mixed asbestos fibre types due to large quantities of friable asbestos materials still in place."[440] One of the five conclusions of the WHO 1998 Report on asbestos is: "Some asbestos-containing products pose particular concerns [...] these uses include friable products with high exposure potential."[441]

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[436] *EC Measures Concerning Meat and Meat Products (Hormones*), Report of the Appellate Body, WT/DS26/DS48/AB/R, adopted on 13 February 1998, in particular paras.99-109.

[437] The EC indicate that equally relevant, by analogy, is the position of the Appellate Body in *Japan – Measures Affecting Agricultural Products*, adopted on 19 March 1999 (WT/DS76/AB/R, para.126), according to which the complaining Member must show that the contested measure is more trade-restrictive than necessary to fulfil a legitimate objective taking into account the risk which non-fulfilment would create.

[438] See Section V, reply by Dr. Henderson to question 1(b) from the Panel. [Note: in the context of this dispute, the Panel consulted four independent experts in accordance with Article 13 of the Understanding. The written replies by the experts to the questions from the Panel can be found in Section V of this report. Annex VI contains a transcription of the meeting held by the Panel on 17 January 2000 with the experts and the parties].

[439] *Id.*

[440] *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998, p.139.

[441] *Id.*, p.144.

3.324 Secondly, Canada claims that the Decree has no rational connection with the objective because it targets chrysotile, whereas amphiboles are the real danger. It does nothing either to address the serious problem posed by the enormous quantity of friable products containing amphiboles still in place. The ban merely relieves public pressure on the French Government to find a solution to the real problem. According to Canada, three of the four experts agree that a clear distinction should be drawn between the toxicity of amphiboles and chrysotile. Amphiboles may be up to 100 times more dangerous than chrysotile for the induction of mesotheliomas.[442] At the meeting of 17 January, Dr. Henderson repeated that "most if not all these mesotheliomas are a consequence of exposure to asbestos-containing materials that included a mixture of asbestos types" [sic].[443] Canada notes that a 1997 report of the French Ministry of Labour (*Ministère du Travail, Comité G2SAT*), submitted to the Panel by the EC, recognizes that, as a result of the chemical dissolution process that takes place in the lungs, chrysotile's carcinogenic activity is practically nil:

> "It has been shown that chrysotile is much more easily eliminated from the human lung than other forms (amphiboles). Moreover, it has practically no carcinogenic activity."[444] (WTO translation)

3.325 Thirdly, Canada contends that the Decree has no rational connection with the protection of human health because it imposes use of substitute fibres that are not proven to be safe. Canada notes that, at the meeting with the experts, Drs. Henderson, de Klerk and Infante agreed that, perhaps with the exception of glass fibres, which should be presumed to be carcinogens, the information on substitutes is meagre. This is confirmed in the recently published INSERM Report on substitute fibres, which "underlines some grave concerns that should rapidly be dissipated".[445] At the second substantive meeting with the parties, Canada drew to the Panel's attention the key conclusions of the INSERM report on substitute fibres. Canada notes that, in this report, INSERM admits that very little is known about their potential impact on human health:

> "Fibres on which very few toxicological data exist are today being used … on a large scale as a replacement for asbestos; the novelty of their use for such applications is accompanied by a lack of data on their potential effects on human health."[446] (WTO translation)

3.326 Canada points out that INSERM concluded that, in epidemiology, no significant excess risk of cancer has ever been detected from exposures to asbestos at the same exposure levels used to evaluate the carcinogenicity of substitutes: "No significant increase in the risk of cancer due to exposures to asbestos at levels comparable to those estimated for substitute fibres has ever been detected."[447] (WTO translation) Canada notes that, at the meeting, the experts did not deny this statement. INSERM also concluded that it was unable to demonstrate that substitute fibres are not carcinogenic:

> "Globally, it was not possible to reach a firm conclusion for any of the types of fibre or any type of cancer […]
> It must, however, be strongly emphasized that the data available do not allow the existence of a risk of cancer caused by exposure to substitute fibres to be eliminated […]
> On the basis of the epidemiological data currently available, therefore, no conclusion can thus be drawn concerning the carcinogenicity of various types of substitute fibre."[448] (WTO translation)

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[442] See Section V, replies by Dr. Musk and Dr. de Klerk to question 3 from the Panel.
[443] *Id.*, reply by Dr. Henderson to question 1(e) from the Panel.
[444] INRS, *Rapport du Groupe scientifique pour la surveillance des atmosphères de travail (G2SAT)*, 1997, p.47.
[445] INSERM, *Effets sur la santé des fibres de substitution à l'amiante*, INSERM joint report, Paris, 1999.
[446] *Id.*, p.v.
[447] *Id.*, p.411.
[448] *Id.*, pp.178-181.

3.327 Canada points out that, based on these findings, INSERM recommends that all proposed substitutes be suspected of inducing pathologies: "Any new fibre proposed as a substitute for asbestos or for any other use should *a priori* be suspected of being pathogenic."[449] (WTO translation) Canada adds that a host of other studies also show that many substitute fibres present substantial health risks. According to the United States Occupational Safety and Health Administration (OSHA), glass fibres "are reasonably anticipated to be a carcinogen".[450] The United States Environmental Protection Agency (EPA) has further concluded that refractory ceramic fibres (RCF) present a significant risk of serious harm to human beings from cancer.[451] This is consistent with the findings of the WHO's International Agency for Research on Cancer (IARC), which has classified glass wool, rock wool, slag wool, and refractory ceramic fibres as "possibly carcinogenic to humans".[452] Finally, Dr. Infante has concluded that: "on a fiber-per-fiber basis, glass fibers may be as potent or even more potent than asbestos".[453] Canada notes that, at the meeting with the experts, Dr. Infante reiterated that glass fibres should be presumed to be carcinogenic. Canada submits that there is a convergence of opinions within the scientific community that there is no solid scientifically validated evidence to support the allegation that the use of substitutes is safe. Thus, the Decree has replaced the undetectable risk of chrysotile with the unknown risks of substitute fibres. The French ban is not rationally connected with its objective of protecting human health because the risk of substitutes has not been addressed.

3.328 Canada contends that the ban is not necessary because a less trade-restrictive measure is available. Why is it so "necessary" for France to protect its citizens against the undetectable risk posed by chrysotile high-density products, but not against the risks of substitutes? Canada notes that several variations of the word "necessary" have been put forward to justify France's ban on chrysotile. In Canada's view, however, necessity, in the WTO context, is not and should not be understood as political necessity "to be seen to be doing something" in order to assuage public opinion. The French National Assembly and Senate clearly acknowledged these facts in a joint report on asbestos published in 1997:

> "The climate in society changes as a result of pressure from shaken public opinion [page 19] … [The Decree is] a decision which concerns public opinion and whose aim is to provide reassurance [page 57]."[454] (WTO translation)

3.329 Canada contends that necessity, in the WTO context – and more specifically in the context of the TBT Agreement– is a narrower concept than France and the EC suggest. A contested measure, to be in compliance with Article 2.2 of the TBT Agreement, must be "necessary to fulfil a legitimate objective", i.e. to protect human health, not to meet the French population's concerns about health. The TBT Agreement was not negotiated to allow governments to legislate to appease public opinion. It was specially negotiated to counter such recourse to technical barriers to trade in the absence of scientific evidence. Canada considers that a decision in favour of the EC would eviscerate the TBT Agreement. Under the necessity test of Article 2.2 of the Agreement, a measure will be found

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[449] *Id*., p.398.

[450] See United States Department of Labor (OSHA), *Synthetic Mineral Fibers: Hazard Description*, on line: OSHA <http://www.osha.gov/oshinfo/priorities/synthetic.html> (access date: 22 June 1999). The OSHA Report states that: "Several epidemiologic studies have demonstrated statistically significant elevations in the risk of lung cancer and other respiratory system cancers among workers employed in fibrous glass and mineral wool manufacturing facilities."

[451] See United States Department of Labor (OSHA), *Synthetic Mineral Fibers: Hazard Description*, on line: OSHA <http://www.osha.gov/oshinfo/priorities/synthetic.html> (access date: 22 June 1999) citing: EPA, Refractory Ceramic Fibres: initiation of Priority Review, Federal Register, Vol.

[452] World Health Organization, *Man-made Mineral Fibres*, IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man, 1988, 43:39-171. Lyon, France.

[453] Infante, P.F. *et al.*, *Fibrous Glass and Cancer*, Wiley-Liss, 1994.

[454] Le Déaut, J.-Y. and Revol, H., *L'amiante dans l'environnement de l'homme: ses conséquences et son avenir*, Office parlementaire d'évaluation des choix scientifiques et technologiques, *Assemblée nationale* No.329/*Sénat* No.41, 1997.

inconsistent if a less trade-restrictive means is available to reach the same policy objective. As a GATT Panel formulated the rule in respect of Article XX of the GATT, a measure will be deemed necessary only "if there were no alternative measure consistent with the General Agreement, or less inconsistent with it, which [the Party] could reasonably be expected to employ to achieve its health policy objectives". In other words, even assuming that the chosen end is legitimate, the measure must not be an excessive or over-reaching means to achieve a legitimate end. [455]

3.330 Canada claims that a ban is the most extreme and restrictive trade measure available. The Decree, as it stands, is excessive and does not meet the necessity criterion because a less trade-restrictive alternative could have properly achieved the protection of human health. France could have reached the same objective by setting up a regulatory regime under which prohibitions and authorizations of asbestos products were decided not on the basis of the existence or non-existence of substitutes, as the Decree does, but rather in the light of two guiding principles: (i) an assessment of risk made on a product-by-product and use-by-use basis; and (ii) an analysis of the non-feasibility and ineffectiveness of controlled use for each product. Canada claims that France could and should have used these two guiding principles to determine which chrysotile products are to be authorized in France, instead of the criterion of the non-availability of substitutes. If it had, the range of chrysotile products and their uses authorized in France would have been broader and international trade less restricted.

3.331 Canada contends that, first of all, the Decree is not based on a credible risk assessment and, secondly, that decisions to ban or exceptionally to authorize asbestos products under the Decree do not stem from an analysis of the feasibility and effectiveness of controlled use.

3.332 Canada considers that, if France had based its chrysotile policy on a credible product-by-product and use-by-use risk assessment, it would not have banned high-density chrysotile products. At the very least, such a risk assessment would have led the French authorities to authorize the use of a certain number of high-density chrysotile products. Canada claims that the INSERM report certainly cannot be considered a credible and sufficient risk assessment of high-density chrysotile products. The French Government used the INSERM report as the scientific basis to justify its ban on high-density chrysotile products, even though INSERM did not recommend banning them. Irrespective of the fact that the text of the report does not support the ban on high-density products, its serious deficiencies, the timing and circumstances of its adoption relative to the announcement of the French ban, and the strong criticism to which it has been subjected by members of the French and international scientific communities cast very real doubt on its credibility and its sufficiency as a scientific basis for the French ban.[456] Canada notes that critics have identified six major problems with the INSERM report:

- INSERM's risk assessment is based on hypothetical data and therefore has no real factual relation to the situation actually prevailing in France today.

- INSERM's risk assessment is often misleadingly based on data from exposure to amphiboles or mixed fibres, instead of to chrysotile fibres alone.

- The report does not make clear that, because of the long latency period for asbestos-related diseases, the estimated deaths in the 1990s and after are almost exclusively the result of occupational and para-occupational exposures in the 1950s and 1960s.

- The report did not even examine what is surely the key issue relating to the ban, namely, exposures to current chrysotile products.

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[455] *Thailand – Cigarettes*, BISD 37S/200, report adopted on 7 September 1990, para.75.
[456] See Canada's arguments in Section III.B.7 of this report.

- INSERM's extrapolations from data based on high exposure levels and exposures to friable products greatly exaggerates the risk from low exposure levels to products where chrysotile is encapsulated in a hard matrix, specifically chrysotile-cement and friction products.

- Finally, the INSERM report acknowledges that, "This problem is, however, indissociable from the choice of substitute fibre" (WTO translation) for which little information is available.[457] It was only in November 1999, almost three years after the ban on chrysotile took effect, that INSERM's report on substitutes was published, concluding that there was a lack of information on substitutes. It should also be recalled that INSERM did not recommend banning high-density chrysotile products.

3.333 Canada emphasizes that all available scientific evidence indicates that there is no detectable risk of mesothelioma or lung cancer as a result of exposure to chrysotile in the manufacture or use of friction products or in the manufacture of high-density chrysotile- cement products. The same is true for the use of high-density cement products. One of the most challenging issues in international trade law is striking the right balance between keeping markets open and allowing States to regulate in order to accomplish other legitimate goals, such as the protection of human health. In Canada's view, one manner of resolving this issue – which has been used by WTO panels – is to determine whether the formal scientific analysis on which the decision to adopt trade-restrictive measures is based constitutes a credible and sufficient justification for the measure in question. It is often unrealistic to expect a panel of trade experts to resolve a complex scientific controversy. In fact, it is not its role to do so. In this case, there is so little scientific evidence for a ban that the Panel can only reasonably conclude that France has not conducted a credible and adequate scientific evaluation to justify this extremely trade- restrictive measure. Consequently, in assessing the WTO consistency of the French ban, Canada asks that the Panel disregard the INSERM report.

3.334 Canada also points out that, at the meeting on 17 January 2000, the experts mentioned two seemingly anomalous studies. Neither overcame the great weight of contrary evidence. First, Dr. Henderson in particular relied on the Australian Mesothelioma Register (Leigh *et al*., 1999). However, this is not a controlled study but simply a set of observations. It might be expected that any large enough subset of the population (such as garage workers or schoolteachers or lumberjacks) would experience some instances of mesothelioma or lung cancer. The question that must be asked is whether the number is more than expected? The only way to know for sure is by observing controls. According to Canada, other more carefully conducted studies suggest that Leigh's data do not show excess risk. An examination by electron-microscopy of lung tissue in 221 definite or probable cases of mesothelioma in the Register and of 339 age-and-sex-matched controls (Rogers *et al*. 1991) suggest that the mesothelioma cases in the Register cannot be attributed to chrysotile exposure. Dr. Henderson puts a lot of emphasis on the Australian Mesothelioma Register to justify the non-feasibility of controlled use at all stages of the lifecycle of asbestos-cement products. But, in addition to criticism by Dr. McDonald regarding the use of such data, Canada stresses that the Australian experience is unique and that it is not prudent to draw general conclusions applicable elsewhere. Crocidolite amphiboles were used massively until the end of the 1970s in Australia, while amosite was used until the mid-1980s. Many houses were built with asbestos-cement products containing mainly amphiboles. Leigh *et al.* write that:

> "From about 1940 to the late 1960s all three types of asbestos were used in [the asbestos-cement manufacturing industry], crocidolite then being phased out. Amosite was used until mid 1980s. Much of this industry output remains in service today in the form of 'fibro' houses and water and sewage piping. By 1954 Australia was number four in the Western world in gross consumption of asbestos-cement products, after USA, UK and France, and clearly first on a per capita basis. After World War II to 1954, 70,000 asbestos-cement houses were built in the State of New South Wales alone (52% of all

[457] INSERM report, p.428.

houses built). In Australia as a whole, until the 1960's, 25% of all new housing was in asbestos-cement."

3.335 Secondly, Canada maintains that the apparently high risk of lung cancer in the Charleston cohort, where exposure was predominantly to chrysotile, has only been observed in two other textile plants where substantial amounts of amphibole fibres were used. The "textiles mystery", as it has been called by Dr. McDonald (1998), is anomalous and has yet to be explained. However, it is evident that it is limited to the textile process. Perhaps the numerous very long and fine fibrils produced in carding or the use of carcinogenic mineral oil spray for dust control and facilitation of weaving are responsible. These factors are peculiar to the textile industry and have no relevance whatsoever to friction or high-density cement products. In Canada's view, it is evident that the French ban is not supported by credible and sufficient scientific evidence.

3.336 Canada contends that a balanced assessment of high-density chrysotile products would have forced the French authorities to conclude that this type of product is not dangerous for the public. Canada notes that, according to the experts appointed by the Panel, the risk to human health associated with the various uses of chrysotile throughout its life cycle is "overwhelmingly a workplace issue".[458] The INSERM report on asbestos also supports the view that the asbestos issue concerns occupational and para-occupational exposures.[459] Chrysotile-cement products do not pose a health risk from normal weathering, erosion or general degradation, and "there is no dispute among experts on this issue" [sic].[460] The removal of chrysotile-cement products does not pose any danger either, except in Dr. Infante's view. Nor do these products endanger the general public via environmental exposure. As for the French do-it-yourself enthusiast, he will rarely, if ever, come into contact with a chrysotile-cement pipe, an exterior construction panel on a commercial building or brake linings, let alone saw or puncture one of these. Canada notes that, as Dr. Henderson confirmed, a do-it-yourself enthusiast therefore runs very little risk. The experts agree that one must turn to cumulative exposure to assess the risk.[461] It can readily be understood that the cumulative exposure of do-it-yourself enthusiasts is inconsequential because, for the few who may be exposed, this is probably nothing more than a once-in-a-lifetime exposure to chrysotile from high-density products. Canada concludes that banning high-density chrysotile products allegedly because they subject the general public to risk is not supported by a balanced, product-by-product, use-by-use risk assessment.

3.337 Canada points out that a balanced risk assessment of high-density chrysotile products would have led the French authorities to conclude that these products are not dangerous to workers for two reasons. Firstly, most workers are not in contact with high-density chrysotile products and, when they are, their exposure is intermittent and therefore the cumulative exposure is very low. Secondly, controlled use is both feasible and effective. The term "worker" encompasses quite a diverse group of people. The Panel, in its questions to the experts, grouped workers in the following categories (see Question 1): (i) miners and millers; (ii) workers in the manufacturing industry (friction materials and chrysotile-cement products); (iii) employees of the textile industry; (iv) workers in the construction industry; (v) workers in the renovation, maintenance and heat insulation industry; and finally (vi) workers in the asbestos removal industry. Canada points out that it is defending high-density chrysotile products, not asbestos textiles. Therefore whether or not these workers are at risk is irrelevant to this proceeding. Regarding miners and millers, there has been no mining or milling activity in France since 1965. Canada also contends that these workers are not at risk.[462] Workers manufacturing high-density chrysotile products likewise are not at risk. Article 2.2 of the TBT

[458] See Section V, reply by Dr. Henderson to question 1(b) from the Panel.

[459] INSERM Report: "the vast majority of these deaths can indisputably be explained by occupational or para-occupational exposure" (WTO translation) (pp.419 and 420).

[460] See Section V, reply by Dr. Henderson to question 1(d) from the Panel.

[461] See Dr. Henderson's comments, Section V.C.1(i), citing *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998. See also the EC's comments on the replies by the experts, Section V.D.2.

[462] See in particular paras.3.155 *et seq.*

Agreement specifically points to the analysis of the risks that "related processing technology" entails. Canada concurs with the EC and the experts that, with controlled use, processing technologies used to manufacture high-density products pose no threat to human health.[463]

3.338 According to Canada, no epidemiological studies show that workers in the high-density chrysotile products manufacturing industry incur excess risks of lung cancer or mesothelioma. As Dr. Thomas concluded for an asbestos-cement factory, "the population of the chrysotile-cement factory studied are not at any excess risk in terms of total mortality".[464] Studies of the friction products manufacturing industry show no chrysotile-related increase in lung cancer risk for persons exposed to the equivalent of up to 9 f/ml for 40 years. Workers in the maintenance, renovation, asbestos removal and heat insulation sectors, as well as electricians, are likely to be in contact with in-place friable asbestos and amphiboles, not primarily high-density chrysotile products. In Canada's view, banning high-density chrysotile products is not necessary to protect these workers against the risks of amphiboles and friable products. Authorizing high-density chrysotile products in France does not increase the level of risk for these workers. The WHO specifically identifies the threat of friable asbestos and amphiboles for maintenance personnel.[465] Dr. Henderson is of the view that, for these workers, mesotheliomas are almost invariably associated with amphiboles:

> "… for data on mesotheliomas among electricians, carpenters, plumbers, insulation workers and so forth (it is acknowledged that most if not all these mesotheliomas are a consequence of exposure to asbestos-containing materials that included a mixture of asbestos types, including chrysotile and one or more of the amphiboles) ..."[466]

3.339 Canada maintains that the ban on high-density chrysotile products is not necessary to protect workers in the maintenance, renovation, asbestos removal and heat insulation sectors, and electricians. Banning high-density chrysotile products on the grounds that such products increase the risks for this category of workers is inconsistent with a balanced product-by-product, use-by-use risk assessment. Some workers and do-it-yourself enthusiasts may encounter high-density chrysotile products intermittently, for example, some construction workers who might occasionally intervene, depending on the nature of their work, on cement pipes, cement external wall panels or cement roof tiles; or perhaps mechanics who handle brake linings; or a do-it-yourself enthusiast who is occasionally exposed when working on his home. Canada considers that, in most cases, infrequent exposures lead to such low cumulative exposures that, even without the use of proper tools and procedures, the experts have agreed that the health of workers is not in danger. In the other cases, application of controlled use, including procedures and the use of tools prescribed by international standards, reduces the risk to an undetectable level.

3.340 Canada asserts that the French ban is not based on evidence that controlled use in unfeasible and ineffective. The regulatory system established by the Decree does not determine bans and authorizations for asbestos products in the light of a product-by-product examination of the feasibility and efficacy of controlled use. Canada notes that, if this were the case, France would have authorized high-density chrysotile products for which it has been established that controlled use is applicable and effective, for example, asbestos-cement pipes and brake pads and linings. Before commenting on controlled use as applied to work on asbestos-cement pipes and brake linings, Canada wishes to return to the meeting of 17 January 2000 with the experts and then describe briefly the concept of controlled use.

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[463] European Commission (G. Lohan, DG III), European justification of Decree No.96-1133 to the Canadian authorities (15 April 1997) following French Notification G/TBT/Notif.97.55.

[464] Thomas, H.F., Benjamin, I.T., Elwood, P.C. and Sweetnam, P.M., *Further Follow-up Study of Workers From an Asbestos-cement Factory* (1982) 39:3 British Journal of Industrial Medicine, 273, p.275.

[465] *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998, p.139.

[466] See Section V, reply by Dr. Henderson to question 1(e) from the Panel.

3.341 Canada claims that controlled use is an approach that is not specific to the asbestos industry. It is a general method of risk management for all products or technologies which, in the absence of controls or regulations, might involve risks. Moreover, the experts confirmed this when they specifically recommended the controlled use of substitute fibres. The experts also recommended applying the principles of controlled use as a way of dealing with the sensitive issue of amphiboles and friable products already in place. Canada notes that Dr. Musk referred to the principles of controlled use as a way of dealing with the problem of asbestos in place, in particular friable products and products containing amphiboles. The implementation of controls, the issue of permits and best work practices have already been advocated by Dr. Musk. Canada also notes that Dr. Infante refers to the principles of controlled use in the context of use of substitute fibres. He suggested that best work practices (use of low-speed cutting tools and wearing a mask) should be used to reduce the levels of exposure. This also forms part of controlled use as applied to the chrysotile industry. He also referred to United States standards for the control of nuisance dusts such as glass fibre. Dr. Infante also declares at the same time, paradoxically, that controlled use is unfeasible for chrysotile products because workers are not sufficiently informed or do not use the recommended equipment. If controlled use is applicable and effective for substitutes, amphiboles and friable material already in place, Canada wonders why it would not be applicable and effective for high-density chrysotile products.

3.342 Canada notes that, during the meeting with the experts, the question of whether it could be expected that regulations on controlled use would be respected was raised. In Canada's view, official decisions should definitely not be taken on the basis of a hypothesis that the law will not be observed. Dr. Infante nevertheless commented that controlled use was not feasible in the United States due to the high number of breaches of the two United States standards on exposure to asbestos established by the OSHA. Canada wishes to point out in this respect that, of the 3,349 breaches of the two standards recorded during the period 1998-1999, only 16 concerned exceeding the United States exposure standard of 0.1 f/ml. Even more significantly, these 16 breaches were exclusively related to exposure to friable materials already existing within buildings. They bear no relation to the products concerned by this case.

3.343 Canada maintains that controlled use can be summarized by the three major recommendations in ILO Convention 162. Firstly, exposure should be brought down to levels that do not involve any health risk. Low levels of exposure allow asbestos-related diseases to be eliminated. Secondly, use of crocidolite should be banned. In general, scientific studies show that exposure to chrysotile is much less dangerous than exposure to amphiboles. Thirdly, friable asbestos materials such as sprayed and insulating materials should be banned. Asbestos-related diseases appear in the secondary production industries, when installing insulation containing asbestos and in building work involving friable asbestos materials. The fixing of an exposure limit in the workplace is only one aspect of protecting the health of workers. The means used to ensure observance of the exposure limit are of course an important part of the effort. These means include dust collection, monitoring, employing best work practices and, if necessary, using protective breathing equipment. Proper monitoring of exposure limits in workplaces is an essential criterion for correct application. Lastly, other aspects of protection in the workplace specifically concern secondary users, for example, building workers, servicing and maintenance workers, who work with asbestos-cement, or mechanics who handle brake linings. Controlled use mainly involves reducing the number of situations in which fibres are released (for example, by pre-cutting of asbestos-cement pipes) and eliminating unprotected work on high-density products.

3.344 Canada points out that the means employed for controlled use effectively reduce exposures, which then fall within the exposure limits, as recognized by the WHO;

> "Exposure is dependent upon such factors as the extent of control, the nature of the material being manipulated and work practices […]

> Levels dropped considerably between the 1930's and the late 1970's and have continued to decline substantially to the present day, owing to the introduction of controls."[467]

3.345 Canada notes that the WHO goes further and states that even partial application of controlled use methods, techniques or procedures is effective because it brings exposure levels down below 0.5 fs/ml. If personal protective equipment is used, the exposure levels drop even lower:

> "Data from industries where control technologies have been applied demonstrated the feasibility of controlling exposure levels generally below 0.5 f/ml. Personal protective equipment can further reduce individual exposure where engineering controls and work practices prove insufficient."[468]

3.346 Canada notes that the WHO also indicates that controls eliminate fibre suspended in the air when it becomes necessary to work on high-density chrysotile products, as may occasionally be the case for certain workers in the construction industry.[469]

3.347 Canada adds that, according to the OSHA as well, controlled use is effective:

> "There is substantial information available concerning both health effects and current exposure levels, and the potential for risk reduction is great using control methods already in use in some workplaces where mineral fibers or asbestos are manufactured or used."[470]

3.348 Canada draws attention to the study by J. Peto, which shows the effectiveness of regulations, one aspect of controlled use. The 1995 study shows that only 5 per cent of the cases of mesothelioma recorded were in jobs subject to regulation.[471] Taking into account the latency period, the British regulation of the asbestos industry in the 1960s, even though it allowed high levels of exposure and the use of friable materials and amphiboles, already constituted an effective way of limiting the risks of using asbestos. J. Peto underlines the greater effectiveness of the regulations in the 1980s by highlighting the marked decrease in exposure levels. For example, the 1995 regulations in France, i.e. before the adoption of the Decree, sufficed to protect the population against risks related to high-density chrysotile products. Canada points out that it stressed, and the experts agreed, that for primary users, namely, workers involved in the mining and processing of chrysotile products such as asbestos-cement and friction materials, occupational exposure levels are low because of controlled use and, consequently, the risk that these workers will contract an asbestos-related disease is undetectable. Canada acknowledges that it is aware of the EC's objective and the experts' concerns regarding controlled use. It is not so much the risk during mining of chrysotile and manufacturing that are the cause of concern, but the risks linked to occupational exposure of secondary users. Canada declares that, in order to show that the EC's objection to controlled use among secondary users is excessive, it will comment on both products, namely, asbestos-cement pipes and friction materials.

3.349 Canada asserts that no-one can seriously contest that controlled use is as effective as a ban for the protection of human health against risks caused by working with asbestos-cement water pipes buried in the ground. Asbestos-cement pipes are almost never cut during their installation. They are delivered on-site ready to use and it is not necessary to carry out any work likely to produce dust. Prefabrication of elements subsequently assembled on the spot thus makes it possible to eliminate exposure of the workers to chrysotile fibres. If the pipes have to be cut, the use of hand tools or tools with vacuum dust extractors allows the risks to be eliminated. Workers use hand tools or low-speed mechanical tools, which create large dust particles or chips, rather than machines that work through

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[467] *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998, p.137.
[468] *Id*., p.144.
[469] *Id*., p.29.
[470] See United States Department of Labor (OSHA), *Synthetic Mineral Fibers: Hazard Description*, on line: OSHA <http://www.osha.gov/oshinfo/priorities/synthetic.html> (access date: 22 June 1999).
[471] Peto, J. *et al*., *Continuing Increase in Mesothelioma Mortality in Britain*, Lancet, 1995, vol.345, cited in *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998, p.123.

abrasion. High-speed mechanical tools are equipped with an effective and specially designed vacuum dust extractor. According to the OSHA, the application of control measures leads to average levels of exposure of 0.00253 f/ml for those working with asbestos-cement pipes.[472] Canada adds that the risk of asbestos-related disease is based on the hypothesis of persistent exposure. There are no data on cumulative "lifetime" levels for persons exposed intermittently. Workers using asbestos-cement pipes are, however, exposed intermittently. In Canada's view, the EC will readily acknowledge that few handymen have to work with asbestos-cement pipes. Workers usually install asbestos-cement pipes by heavy machinery and not manually. Buried in the ground, asbestos-cement pipes are quite safe. They can also be taken out of the ground mechanically. Canada asserts that controlled use is also feasible and effective for mechanics working on brake linings. They are in contact with the brake linings intermittently so their cumulative exposure to chrysotile is very low. In addition, simple methods such as moistening and vacuum dust extractors make it possible to reduce exposure to levels at which the risk is undetectable, as already indicated in studies cited by Canada and discussed with the experts.

3.350 Regarding the next objection that, according to some theoretical models not empirically verified, workers in general are subject to risks even if cumulative exposure is within the limits laid down under controlled use policies, Canada responds that the lower the exposure, the lower the risk. The question is to what extent levels of exposure to a substance can be lowered in order to achieve a significant and measurable reduction in the risk for workers? Canada notes that the most recent data published, as well as the latest retrospective reviews on the relationship between exposure and the effect of chrysotile asbestos are revealing: when levels of exposure to around 40 f/ml over 20 years (or 20 f/ml over 40 years) are reached, the excess risk of lung cancer related to chrysotile asbestos, although it still exists, has become undetectable. If a safety factor is introduced by imposing a level that is ten times lower, for example, 2 f/ml over 40 years, it is obvious that the risk, although it still exists, remains undetectable. Canada points out that Drs. de Klerk and Musk agree that current epidemiological data does not show an excess health risk at low levels of exposure to chrysotile, lower than the exposure limits under controlled use. Dr. Henderson acknowledges that "no increase in risk of mesothelioma has been identified at very low-level exposures". A review of eight studies of cohorts exposed to chrysotile by Browne and Gibbs led the authors to conclude that "there exist levels of exposure below which risks are for practical purposes zero".[473]

3.351 Canada maintains that, if France had based its asbestos regulations on a serious examination of the feasibility and effectiveness of controlled use product-by-product, it would – at the very least – have authorized asbestos-cement pipes and friction materials. But this is not the case: the French Decree bans asbestos-cement pipes and friction materials, two products which handymen and non-specialized workers never or only exceptionally use and for which controlled use is feasible and effective. The Decree is therefore not based on any serious examination of the feasibility and effectiveness of controlled use product-by-product, which means that it does not meet the necessity criterion in Article 2.2. According to Canada, France could have regulated the application and use of asbestos through non-discriminatory technical regulations dealing *inter alia* with monitoring the average concentrations of asbestos fibres in the workplace, which France in fact does for the exemptions allowed. In addition, France could have regulated the manufacture of high-density materials by eliminating work likely to release dust, just as the construction industry gives workers proper training on how to handle these materials. The effect or the purpose of such measures would not have been to create unnecessary obstacles to international trade and at the same time would have enabled the objective of protecting health to be attained.

[472] See OSHA, on line OSHA <http://www.osha.slc.gov (access date: 22 June 1999), Tables 5 and 6.

[473] Browne, K., and Gibbs, G., *Chrysotile Asbestos – Thresholds of Risk*, in Chiotany, K., Hosoda, Y., Aizawa, Y., eds. Advances in the Prevention of Occupational Respiratory Disease, Elsevier, Amsterdam, 1998.

3.352 To conclude on Article 2.2 of the TBT Agreement, Canada points out that its examination shows that the French ban on chrysotile asbestos does not enhance the protection of human health. The objective sought by France is not achieved by a ban. There is no rational link between the French ban on chrysotile and France's objective. Moreover, within the meaning of Article 2.2 of the TBT Agreement, the French measure is not necessary in regard to the objective sought. The ban does not address the real health problem associated with asbestos: the friable products and the amphiboles already in place. It is a bold step for the ban to replace chrysotile by the risk of substitute fibres. Furthermore, the ban, by covering high-density chrysotile products, does nothing to raise the level of protection of human health. The French Decree is an excessive measure "more trade-restrictive than necessary" to achieve France's objective because the objective could be achieved by a measure that is less trade-restrictive and which Canada has presented: a regulatory system that is, first of all, really based on a rigorous examination of the risks product-by-product and use-by-use and then by an examination of the feasibility and effectiveness of controlled use product-by-product.

3.353 The **European Communities** wish to recall that any Member of the WTO has the right to establish the level of health protection it deems appropriate in its territory. The EC note that, within the context of Article XX(b) of the GATT, all the Panels which have examined the concept of necessity have concluded that it was not the necessity of the objective pursued by the measure concerned that should be examined but whether or not it was necessary to submit the imported products to the measure contested in order to achieve the chosen level of protection (e.g. *United States - Section 337*, *Thailand - Cigarettes* and *United States - Gasoline* Panel reports). It follows that, whereas the trade measures that make it possible to achieve the desired objective must satisfy certain conditions, there is no restriction on the level of protection chosen by the Member. Accordingly, the EC consider that France was free to choose the level of protection it deemed appropriate in the present case, i.e. to halt the spread of the risk linked with the use of asbestos fibres and products containing such fibres. The EC again point out that, even though the test of necessity within the context of Article 2.2 of the TBT Agreement corresponds, in particular, to the test in Article XX(b) of the GATT, it nonetheless remains true that the burden of proof within the context of the TBT Agreement lies with the party which invokes a specific provision of the Agreement to establish the inconsistency. The EC indicate that the arguments it develops on the necessity criterion are also applicable in the context of Article XX(b) of the GATT.

3.354 The EC maintain that the necessity criterion under Article 2.2 of the TBT Agreement involves, *inter alia*, examining whether a less restrictive measure is available to a Member and could be employed to fulfil that Member's legitimate objective. The EC note in this respect that, in their written and oral replies, the scientific experts all agreed that banning the use of all types of asbestos, including high-density asbestos-containing cement products, to which Canada attempts to limit the scope of this dispute, was in fact the only real option available to France to achieve its legitimate objective of protecting human health. This is because all types of asbestos are classified as proven human carcinogens and because the so-called "controlled use" advocated by Canada is in practice unfeasible and unrealistic. The EC note that Dr. Henderson gave a number of reasons why it is unrealistic and impossible to apply such a use in practice and cited examples of concrete cases in which he personally observed the absence of any kind of "controlled use". Dr. Infante also explained that in the United States several hundreds of violations continue to arise, whether in the manufacturing of asbestos-containing cement products or in subsequent downstream situations, despite the controls exercised and the fines applied by the United States authorities. Dr. de Klerk, when discussing this issue, said that "at best it is imprudent" to wish to continue exporting asbestos, for example to least developed or developing countries, because it is impossible for them to apply such a controlled use.

3.355 The EC also recall that, since the beginning of this dispute, Canada has been avoiding a precise definition of what it means by the term "controlled use". As a last attempt to confuse the legal

debate, in its comments on the replies of the experts[474], Canada finally defined the way it understands the concept of "controlled use". But that description of "controlled use" has never been explained in such detail until now, none of the experts chosen by the Panel have ever heard of it before, and they have explicitly stated that they know of no international standard or recommendation suggesting that such a use will substantially reduce or eliminate the risks of asbestos-related diseases. In addition, all the experts found that the conditions of use mentioned by Canada in its comments are impossible to apply in practice in a way that will enable the level of protection chosen by France to be attained. According to the EC, Dr. Henderson and the other experts agreed with the EC's argument that the problem France faces because of the existing asbestos in place and the risks associated with its removal do not in any way justify the continued use of asbestos and the perpetuation of the serious risks to human health through the further introduction of asbestos into the environment. France, like other countries, has been trying to deal in the best way possible with the problems for human health posed by the asbestos in place and it took measures for this purpose a long time ago. But experience and science have shown that these measures cannot eliminate the risks to human health. In the EC's view, there is no provision in the TBT Agreement nor in the WTO Agreements that could oblige France to continue using chrysotile asbestos, due to the difficulties it (like other countries) faces in eliminating the risks from past mistakes when the use of chrysotile asbestos was allowed.

3.356 As for the second sentence of Article 2.2 of the TBT Agreement ("taking account of the risks non-fulfilment would create"), the EC consider that, here again, this is an integral part of the implementation of the test of necessity under Article XX(b) of the GATT. In fact, a restrictive measure is "necessary" only if there are risks associated with the non-adoption of the measure in question. The purpose of this sentence is to deny Members the possibility of adopting measures, under cover of protecting human health, without having taken into account the risks associated with the use of the product that is banned. Such risks should be assessed, in particular, on the basis of the available scientific and technical information. The EC comment that they have shown, and all the experts have agreed, that under the so-called "safe use" policy there continues to be a significant excess of deaths in the asbestos production and processing sector. Moreover, this policy does not offer any meaningful and realistic protection, in particular for the secondary or downstream users exposed to asbestos (carpenters, electricians, do-it-yourself enthusiasts, etc.) because they cannot be aware of the risks in all situations and the risks frequently become apparent many years after exposure. The EC point out that they have also asserted (and all the experts have agreed) that there exist several safer alternative products that can replace nearly all the uses of asbestos. Indeed, all the scientists agreed with Dr. Infante and Dr. Henderson that the available scientific evidence shows that none of the substitute non-fibrous or fibrous products is dangerous to human health or as dangerous as asbestos, including chrysotile asbestos. Dr. Infante also stated that it is unreasonable to continue using chrysotile asbestos simply because there exist some doubts about some fibrous products.

3.357 The EC also wish to respond to Canada's claim, completely unjustified in their view, that the French ban on asbestos was taken for reasons of "political necessity", not out of real concern to protect human health. This is plainly wrong and contradicts all the scientific evidence coming from so many countries that already banned asbestos before France and from so many international institutions such as the WHO, the IARC, the ILO, etc., which all recommend that asbestos be banned and replaced. The EC ask whether Canada can really argue that all these countries and all these international institutions have done so for reasons of political necessity? Certainly not in the EC's view.

(d) Article 2.4 of the TBT Agreement

3.358 **Canada** maintains that Article 2.4 lays down the principle that, where technical regulations are required and relevant international standards exist, Members shall use them, or the relevant parts of them, as a basis for their technical regulations if they are effective and appropriate for the

[474] See Section V.D.1, comments by Canada concerning question 5(a) from the Panel.

fulfilment of the objective being pursued. Under Article 2.4, it is up to the Panel to determine: (i) whether a technical regulation on chrysotile is required; (ii) whether there are international standards concerning chrysotile; (iii) whether the international standards are an effective and appropriate means for the fulfilment of the objective pursued; and (iv) whether the Decree is based on international standards. Canada recognizes that it is important for governments to take action to manage the risks associated with the use of asbestos fibre. Therefore, Canada does not dispute the fact that action is required to manage the risks associated with asbestos fibres and their uses. However, in this case, it is the excessive nature of the French action that is being challenged. Such action must be based on existing international standards that recognize the controlled use of asbestos, which, in practice, eliminates any health risk, i.e. the objective pursued by France. Canada submits that, in the case of chrysotile fibre, a regulation and not a ban is required pursuant to Article 2.4. Canada points out that it in fact implements and encourages the regulation of the "safe" or "controlled" use of chrysotile fibre, the required and approved form of action. Prior to the adoption of the Decree, France practised controlled use. Canada has already emphasized that a set of measures existed prior to the adoption of the Decree and guaranteed the protection of people's health in France.

3.359 Canada claims that international standards, within the meaning of Article 2 of Annex 1 to the TBT Agreement, exist for the controlled use of chrysotile fibre. Convention 162 and Recommendation 172 of the International Labour Organization concerning safety in the use of asbestos by workers constitute such international standards.[475] They set forth rules and guidelines for the use of asbestos, in particular chrysotile fibre, as well as processes and production methods for products containing it. The ILO Code of Practice on Safety in the Use of Asbestos – endorsed by Convention 162 and Recommendation 172 - constitutes another international standard.[476] The Code contains standards and practical instructions aimed at preventing the risks faced by workers using chrysotile. These standards govern all the stages of exposure to asbestos by proposing safe procedures and methods; from the extraction of the fibre to the transportation of products containing it, from the manufacturing of products containing fibre to their maintenance. Standards for the use of chrysotile-cement materials are included in the Code for chrysotile-cement products – Guidelines for On-Site Work of the International Organization for Standardization (International Standard ISO-7337).[477]

3.360 Canada contends that existing international standards are effective and appropriate for fulfilling the objectives of protecting human health. International standards such as those in

[475] ILO, *Convention concerning Safety in the Use of Asbestos* (Convention 162), adopted on 24 June 1986, International Labour Conference, Geneva; ILO, *Recommendation concerning Safety in the Use of Asbestos* (Recommendation 172), adopted on 24 June 1986, International Labour Conference, Geneva.

[476] *ILO, Code of Practice on Safety in the Use of Asbestos*, International Labour Organization, Geneva, 1984.

[477] Canada notes that, in the area of public works, chrysotile-cement pipes are used in the construction of piping systems. These pipes are machined into varied lengths that can meet the specifications of buyers and are equipped with couplers that can ensure the linkage between two pipes without the need for cutting or grinding. In the event that the cutting or grinding of chrysotile-cement pipes nonetheless turns out to be inevitable, there are simple techniques, described by standard ISO-7337 that can guarantee the safety of workers on sites. Standard ISO-7337 was designed to be applied at the time of the cutting or grinding of any hard chrysotile-cement product. For example, the cutting of plates or tiles for roof covering, is not a source of emission if the simple techniques of standard ISO-7337 are followed. These techniques consist, in particular, of the use of chains that break the pipes by the effect of pressure, low-speed saws and saws equipped with a vacuum dust extractor, as well as the moistening of the materials prior to any action. The cutting or grinding of a cement pipe, whether or not it contains chrysotile, can also release silica in the air. The International Agency for Research on Cancer (IARC) rates silica among group 1 carcinogens (proven for humans), like asbestos. A worker who cuts any cement pipe therefore has an interest in following the instructions recommended in standard ISO-7337. See also the studies Baujon, Authier & Thomazo, *Détermination de concentrations de fibres d'amiante dans l'atmosphère au voisinage de construction en amiante ciment,* (October 1993*),* and *Détermination de concentrations de fibres d'amiante dans l'atmosphère lors de la pose sur chantier de plaques ondulées et d'ardoises en amiante-ciment,* (July 1993), *Laboratoire d'hygiène et de contrôle des fibres minérales*, Paris.

Convention 162, Recommendation 172, the ILO Code of Practice and standard ISO-7337 provide for controlled and safe use of asbestos. The wording of these standards indicates very clearly that asbestos fibres should only be replaced if it is established that this is necessary to protect the health of workers and if it is technically feasible. However, replacement of chrysotile asbestos fibre in modern materials or products, where it is sealed in a matrix and cannot be released into the environment, is not necessary to ensure the protection of workers' health because these products do not pose any detectable risks against which workers would need to be protected. Canada states that it has already clearly shown the absence of a detectable health risk linked to the controlled use of chrysotile fibre, including its incorporation in safe modern materials. As the measures set forth in the international standards described above are, with respect to controlled use, both effective and appropriate to protect people's health from the risks posed by exposure to chrysotile fibre, the total ban on the modern uses of chrysotile was not necessary.

3.361 Canada asserts that the Decree is not in compliance with international standards because it imposes a total ban on chrysotile fibre rather than providing for the controlled and safe use of this fibre and of its uses. Canada contends that a ban is not necessary to protect people's health and, consequently, is not in compliance with the relevant international standards. International standards impose an approach that is quite different from the complete ban without distinction as to the type of fibre or its use. International standards impose an approach whereby regulation of asbestos must take into account the type of fibre, the products in which a type of fibre is incorporated and the intended uses of each product. Convention 162 and Recommendation 172 provide for the banning of crocidolite[478] and materials containing brittle sprayed asbestos[479], as well as the elimination of certain other uses (work processes), if the national authority deems these measures to be necessary for the protection of workers,[480] but only if the substitute products have undergone a thorough scientific evaluation of their effects on health.[481] According to Canada, the EC have recognized that controlled use would ensure adequate protection of the health of workers in the chrysotile industry (extraction, manufacturing of chrysotile-cement, for example).[482] Canada considers that, given this recognition of the effectiveness of the principles of controlled use upon which international standards are based, the EC must prove that the international standards are ineffective and inappropriate in order to comply with Article 2.4. Canada submits that the burden of proof rests with the EC. Canada also maintains that the Decree is not necessary pursuant to Convention 162 or Recommendation 172 because, according to the EC themselves, there are only certain specific categories of workers, on projects involving brittle materials containing asbestos, that are at risk. The Decree does not resolve the problem that these workers face. Canada also indicates that the EC cannot claim that Convention 162

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[478] ILO, *Convention concerning Safety in the Use of Asbestos* (Convention 162), adopted on 24 June 1986, International Labour Conference, Geneva, Article 11.

[479] *Id.*, Article 12.

[480] Article 10 of *Convention 162* reads as follows:

"Where necessary to protect the health of workers and technically practicable, national laws or regulations shall provide for one or more of the following measures:

(a) replacement of asbestos or of certain types of asbestos or products containing asbestos by other materials or products or the use of alternative technology, scientifically evaluated by the competent authority as harmless or less harmful, whenever this is possible*;*

(b) total or partial prohibition of the use of asbestos or of certain types of asbestos or products containing asbestos in certain work processes."

[481] Paragraph 12 of *Recommendation* 172 reads as follows:

"12. (1) The competent authority, wherever necessary for the protection of the workers, should require the replacement of asbestos by substitute materials, wherever possible. (2) Before being accepted for use in any process, all potential substitute materials should be thoroughly evaluated for their possible harmful effects on health. The health of workers exposed to such materials should be continuously supervised, if judged necessary."

[482] European Commission, Directorate General III (Industry), Office A, *Industrial Policy* to the Canadian authorities as further information for Notification G/TBT/Notif.97.55 made by France to the WTO Committee on Technical Barriers to Trade on 21 February 1997.

or Recommendation 172 are ineffective or inappropriate when the Decree does not offer the same objective safety warranty with respect to substitute products. In fact, the Decree takes for granted that any product replacing asbestos is safer than chrysotile, whereas Convention 162 and Recommendation 172 require that the replacement be carried out only if it has been "scientifically" and "thoroughly" evaluated that each substitute product proposed is safer. In providing that no asbestos shall be used in the manufacture and processing of materials, products and devices, without distinction as to the variety of fibre or its use, the Decree is the most restrictive type of technical regulation that can exist. The international community has nevertheless developed standards that are less trade-restrictive. These standards enable people's health to be protected in an effective and appropriate manner. France has chosen to ignore these international standards and opted for a total ban. In view of the foregoing, the Decree banning asbestos violates the provisions of Article 2.4 of the TBT Agreement.

3.362 The **European Communities** contend that, for the purposes of the TBT Agreement, the term "standards" has the precise meaning it is given in Annex 1 to the Agreement. In this case, however, the international texts referred to by Canada (the ILO, WHO, ISO texts) do not meet the definition concerned. In any event, the EC consider that the French authorities used the texts referred to by Canada in its submission "as a basis" for their Decree, within the meaning of Article 2.4 of the TBT Agreement.

3.363 The EC point out that, as already stated, the object and purpose of the TBT Agreement, as derived from its preamble, its background and the actual wording of several of its provisions, are to monitor the adoption and application of "standards" and "technical regulations" which cover the detailed characteristics of products or their methods of production. The object and specific purpose of the Agreement are bound to have an impact on the meaning to be given to the term "standards" mentioned in Article 2.4 of the TBT Agreement. This impact is moreover recognized by the Agreement itself, whose Article 1.1 and 1.2 are particularly explicit. As Annex 1 contains a definition of "standard", according to the EC, the drafters of the TBT Agreement must have wished to use a specific definition of "standard" for the purposes of the Agreement's application. This specific definition appears in Annex 1 and it follows from this definition that the TBT Agreement encourages the use of international standards, but solely those which can provide rules, guidelines or characteristics for products or related processes and production methods. But in this case, the EC note that the international texts referred to by Canada do not satisfy the definition contained in Annex 1 to the TBT Agreement and cannot therefore be used "as a basis" for technical regulations. Neither the ILO and WHO documents nor the ISO standards can be considered as laying down the characteristics of asbestos fibres or an ordered set of rules for the manufacture of this product. Even less can they be considered as laying down the characteristics of asbestos-containing products or an orderly set of rules for the manufacture of those products. These are texts that certainly do not satisfy the definition of "standard" within the meaning of the TBT Agreement.

3.364 In the alternative, the EC maintain that, even if the Panel were to consider that the texts cited by Canada in its submission are "standards" within the meaning of the TBT Agreement, it has to be recognized that these texts were used "as a basis" for the adoption of the Decree. The phrase "as a basis for" could be compared with the term "on the basis of" used in the SPS Agreement, a term for which the Appellate Body (Hormones) indicated: "... we disagree with the Panel's interpretation that 'based on' means the same thing as 'conform to'."[483] "A thing is commonly said to be 'based on' another thing when the former 'stands' or is 'founded' or 'built' upon or 'is supported by' the latter."[484] If this definition is followed, the EC conclude that the international texts quoted, or sometimes not quoted, by Canada serve "as a basis" for the Decree.

3.365 The EC indicate that, as early as 1986, ILO Convention 162 stated:

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[483] *EC Measures concerning Meat and Meat Products (Hormones)*, report of the Appellate Body, WT/DS26/AB/R and WT/DS48/AB/R, adopted on 13 February 1998, para.166.

[484] *Id.*, para.163.

> "Where necessary to protect the health of workers and technically practicable, national laws or regulations shall provide for one or more of the following measures:
>
> (a) replacement of asbestos or of certain types of asbestos or products containing asbestos by other materials or products or the use of alternative technology, scientifically evaluated by the competent authority as harmless or less harmful, whenever this is possible.
>
> (b) total or partial prohibition of the use of asbestos or of certain types of asbestos or products containing asbestos in certain work processes."[485]

3.366 Similarly, ILO Recommendation 172 also indicated in 1986 that:

> "… asbestos should be used only when its risks can be prevented or controlled; otherwise, it should be replaced, when technically feasible, by other materials or the use of alternative technologies, scientifically evaluated as harmless or less harmful."[486]

3.367 The EC note that, more recently, a WHO report specifically dealing with chrysotile was even more categorical. The summary of its conclusions and recommendations states:

> "Exposure to chrysotile asbestos poses increased risks for asbestosis, lung cancer and mesothelioma in a dose dependent manner. No threshold has been identified for carcinogenic risks. […] Where safer substitute materials are available for chrysotile, they should be considered for use. […] Some asbestos containing products pose particular concern and chrysotile use in those circumstances is not recommended. These uses include friable products with high exposure potential. Construction materials are of particular concern for several reasons. The construction industry work force is large and measures to control asbestos are difficult to institute. In-place building materials may also pose risk control to those doing alterations, maintenance and demolition. Minerals in place have the potential to deteriorate and create exposures."[487]

3.368 The EC conclude from these texts that: (i) the banning or replacement of asbestos fibres or asbestos-containing products may be decided in cases where this is necessary to protect the health of workers and is technically feasible; (ii) where substitute materials are considered safer, they must be used to replace asbestos; (iii) control of the use of asbestos, including chrysotile, in the construction industry is difficult to introduce. According to the EC, this conclusion by the WHO contradicts Canada's statements that the "safe" or "modern" use of asbestos would do away with any risk connected with its use. The Decree is completely in line with these conclusions. The EC add that Article 2.4 of the TBT Agreement also provides that international "standards" must be ignored when they are "ineffective or inappropriate". Such is clearly the case and the ISO standard provides a perfect illustration of this point. At the time it was published in 1984, this standard represented a major step forward in relation to the arrangements prior to that date, but it does not guarantee sufficient levels of protection in the light of the health objective adopted by the vast majority of countries, and by France in particular. In the light of the foregoing, the EC therefore maintain that the Decree is compatible with Article 2.4 of the TBT Agreement.

3.369 **Canada** asserts that Article 2.4 of the TBT Agreement sets out the principle that, where technical regulations are required and relevant international standards exist, Members shall use them, or the relevant parts of them, as a basis for their technical regulations when such international standards are an effective and appropriate means for the fulfilment of the objective pursued. This

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[485] ILO, *Convention concerning Safety in the Use of Asbestos* (Convention 162), adopted on 24 June 1986, International Labour Conference, Geneva. ILO, *Recommendation concerning Safety in the Use of Asbestos* (Recommendation 172), adopted on 24 June 1986, International Labour Conference, Geneva.

[486] *Recommendation concerning Safety in the Use of Asbestos* (Recommendation 172), adopted on 24 June 1986, International Labour Conference, Geneva.

[487] *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998, p.144.

means that, in this case, the Panel must determine: (i) whether a technical regulation concerning chrysotile is required; (ii) whether there are relevant international standards concerning chrysotile; if so, (iii) whether the international standards are effective and appropriate for the fulfilment of the objective pursued; and (iv) whether the Decree is based on these international standards.

3.370 Canada acknowledges that it is important for governments to take action to manage the risks posed by asbestos. However, in the case of chrysotile fibre, this action cannot legally take the form of a ban. A regulation concerning the "controlled" use of chrysotile fibre and products containing it is the required and appropriate form of action. Canada contends that there are relevant international standards concerning controlled use of chrysotile fibre. These are to be found in Convention 162 and Recommendation 172 of the ILO, the ILO Code of Practice on Safety in the Use of Asbestos, and Standard ISO-7337 – chrysotile-cement products – Guidelines for on-site work practices. Canada rejects the EC's claim that these are not standards within the meaning of Annex 1 to the TBT Agreement. The ILO and ISO documents fully meet the criteria of the definition in Annex 1 to the TBT Agreement. They are documents approved by recognized bodies that provide "process and production methods" for chrysotile-based products. Canada notes that the EC have not, however, disputed the relevance of these international standards. The ordinary meaning of the word "relevant" is: "bearing on or pertinent to the matter in hand". The standards cited deal with the same product: asbestos. Furthermore, they have an identical objective, namely, the safe use of asbestos. These international standards are relevant because they relate to the use of chrysotile asbestos in a safe and controlled manner.

3.371 Canada contends that international standards such as those contained in Convention 162, Recommendation 172, the ILO Code of Practice and Standard ISO-7337 prescribe a safe and controlled use of asbestos. According to Convention 162, the use of substitute products is encouraged only "Where necessary to protect the health of workers and technically practicable […] by other materials or products or the use of alternative technology, scientifically evaluated by the competent authority as harmless or less harmful …"[488] According to this standard, chrysotile fibre should not be replaced in high-density products because it is trapped in a matrix from which it cannot escape. Furthermore, Canada has also stressed that controlled use of high-density chrysotile-based products presents, at most, an undetectable risk to human health. As the measures prescribed by these standards are both effective and appropriate to protect human health against the risks posed by exposure to chrysotile, a total ban on chrysotile, and consequently on modern uses of chrysotile, is not necessary. According to Canada, the EC have not provided evidence that it is necessary, in this case, to set aside these international standards on the grounds that they are ineffective or inappropriate. In order to avoid rendering Article 2.4 ineffective, an interpretation consistent with the precepts of the international law of treaties requires that, in order to set aside a relevant international standard, a Member must provide evidence of a "fundamental" problem and not a simple allegation that the relevant standards are not appropriate.

3.372 Canada points out that Article 2.4 of the TBT Agreement requires that Members use relevant international standards or their relevant parts as a basis for their technical regulations. According to the ordinary meaning of the words, this means that a technical regulation must be based on international standards or relevant parts thereof. In other words, a technical regulation must take what is set out in the international standards as its basic principle or starting point. The technical regulation adopted by a Member does not have to be identical to the international standards, but when they are relevant, the technical regulation must use them as a foundation or logical starting point. Canada contends that the international standards concerning asbestos are relevant. The international standards do not call for a complete ban without distinction as to the type of fibre or its use. They propose rather an approach whereby the asbestos regulations must take into account the type of fibre, the products in which a type of fibre is incorporated, and the intended uses of each product. The

[488] ILO, *Convention concerning Safety in the Use of Asbestos* (Convention 162), adopted on 24 June 1986, International Labour Conference, Geneva.

international standards thus propose a less trade-restrictive approach while at the same time stressing the protection of human health in an effective and appropriate manner. France has chosen to ignore these international standards, preferring instead a total ban. What is more, the French technical regulation deviates so much from the international standards that their basic principles are no longer recognizable. Canada points out that the EC have offered no explanation of the reasons that might have justified France's total rejection of these standards as the logical starting point for its regulations on asbestos. Given the foregoing, the Decree banning asbestos is inconsistent with the provisions of Article 2.4 of the TBT Agreement.

3.373 The **European Communities** contend that the texts cited by Canada do not fall within the scope of the TBT Agreement and are therefore not relevant under Article 2.4 thereof because they do not correspond to the definition of "standard" in Annex 1 to the Agreement. In fact, the terms of the ILO, ISO and WHO texts, in their particular context, do not lay down guidelines or characteristics for products or related production processes and methods, nor is that their object and purpose. At best, they can be treated as assessments of the risks created by asbestos and asbestos-containing products rather than as establishing international technical standards or conformity assessment procedures. The EC point out, for example, that the Constitution of the ILO (preamble) specifically provides for "the protection of the worker against sickness, disease and injury arising out of his employment". As for the Philadelphia Declaration (Article III-g) concerning the aims and objectives of the ILO, it provides for "adequate protection for the life and health of workers in all occupations". The ISO texts are conceived in the same spirit. Similarly, Article 3 of ILO Convention 162 of 1986 states that "National laws or regulations shall prescribe the measures to be taken for the prevention and control of, and protection of workers against, health hazards due to occupational exposure to asbestos." According to point 1(i) of the scope and definitions of ILO Recommendation 172 of 1986, "The provisions of the Asbestos Convention, 1986, and of this Recommendation should be applied to all activities involving a risk of exposure of workers to asbestos in the course of work." Thus, the EC consider that the ILO and ISO texts are not relevant standards within the meaning of Article 2.4 of the TBT Agreement.

3.374 The EC, after responding to the question of whether or not a standard was relevant, emphasizes that Article 2.4 raises the question of whether the standard is effective or appropriate. This Article prescribes in particular that "…Members shall use [these international standards] ... except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems". Before considering the case at issue, the EC would like to spell out the circumstances in which a standard might be considered ineffective or inappropriate within the meaning of this provision. The EC consider that the level of protection deemed appropriate by the Member could be a factor in making international standards ineffective or inappropriate. Within the context of the TBT Agreement, a Member is free to choose the level of protection it deems appropriate. An international standard is only effective or appropriate if it enables the Member to achieve the legitimate objective it has set itself. Advances in scientific knowledge can also lead to the application of obsolete standards being ruled out. A systematic comparison of the WTO Agreement (in this specific case the TBT Agreement) with the NAFTA Agreement - a GATT Article XXIV agreement negotiated at the same time as the WTO Agreements – reveals that, on the subject of technical barriers to trade, the NAFTA Agreement provides as follows:

> "1. Each Party shall use, as a basis for its standards-related measures, relevant international standards or international standards whose completion is imminent, except where such standards would be an ineffective or inappropriate means to fulfil its legitimate objectives, for example because of fundamental climatic, geographical, technological or infrastructural factors, scientific justification or the level of protection that the Party considers appropriate.
>
> 2. A Party's standards-related measure that conforms to an international standard shall be presumed to be consistent with Article 904(3) and (4).

> 3. Paragraph 1 shall not be construed to prevent a Party, in pursuing its legitimate objectives, from adopting, maintaining or applying any standards-related measure that results in a higher level of protection than would be achieved if such measure were based on an international standard."

3.375 The EC therefore consider that scientific reasons or the level of protection deemed appropriate by the Member are factors that could render an international standard ineffective or inappropriate within the meaning of Article 2.4 of the TBT Agreement. In the present case, the EC consider that the standards cited by Canada do not make it possible to achieve the level of protection deemed appropriate by France insofar as: (i) there can be no doubt that chrysotile asbestos is a proven carcinogen; (ii) there is no exposure limit (threshold) for chrysotile asbestos and asbestos-containing products; (iii) so-called "safe" use is not applicable in all circumstances nor to every type of person who may come in contact with asbestos or asbestos-containing products and, moreover, does not eliminate every risk; and (iv) there are substitute products that are safe, or safer, than chrysotile asbestos.

3.376 The EC consider that, in the circumstances, it is clear that an international standard which permitted the use of asbestos or asbestos-containing products or which established an exposure limit or recommended "safe" use would be ineffective or inappropriate for achieving the level of protection deemed appropriate by France. France has chosen, as the level of protection deemed appropriate, to halt the spread of the risk associated with the use of asbestos. These risks mainly concern "secondary" users. The ISO standard and the ILO texts do not make it possible to achieve the legitimate objective pursued by France, inasmuch as they apply only to a limited number of "workers", in the occupational sense of the term. According to the EC, in the present case, the only texts that might be of some interest are those of the WHO and the IARC. They may be defined as assessments of the risks posed by asbestos and asbestos-containing products. France is complying fully with the WHO rules and has chosen to make no further use of asbestos and to replace such products with substitutes. Moreover, the ban provides for waivers that make it possible to take into account certain specific situations in which the use of asbestos remains necessary because there is no substitute that would ensure equivalent performance while being less of a threat to health. Accordingly, in the light of the above, the EC consider that the Decree is compatible with Article 2.4 of the TBT Agreement.

3.377 **Canada** reaffirms its arguments concerning Article 2.4 of the TBT Agreement, namely: (i) effective and appropriate international standards on asbestos exist; and (ii) the Decree is not based on international standards. According to Canada, the EC's position, which asserts that the standards recommend the replacement of all types of asbestos by less harmful or harmless materials, is the result of a summary and simplistic examination. The texts cited by Canada as international standards come from the ILO and the ISO. Canada points out that it did not mention, for example, *Environmental Health Criteria for Chrysotile Asbestos (203)* of the WHO as a standard within the meaning of Article 2.4 of the TBT Agreement because it does not see how this text could be considered a standard when the WHO itself presents it as a risk assessment. Furthermore, contrary to what the EC suggests, the WHO recommendations are not to cease using chrysotile asbestos and to replace it with substitute products. Rather, the WHO suggests that consideration be given to replacing chrysotile by harmless substitute products where such materials are available. Canada refers the Panel to the arguments already put forward concerning Article 2.4 and adds some comments relating to the two issues: on the one hand, the effectiveness and appropriateness of the international standards and, on the other, the question of whether these standards were used as a basis for the Decree.

3.378 Canada contends that the international standards are effective and appropriate. Article 3.1 of Convention 162 of the ILO provides that "National laws or regulations shall prescribe the measures to be taken for the prevention and control of and protection of workers against health hazards due to occupational exposure to asbestos". The purpose of the ILO Code of Practice is similar. The object of international standard ISO 7337 is to provide "guiding principles for the tools and methods to be used on site so as to keep dust emissions as low as possible […]". In Canada's view, the

international standards must be appropriate because their purpose and the objective of protecting human health put forward by France are one and the same. Canada notes that the EC give two reasons to justify the inappropriateness and ineffectiveness of the standards, namely: (i) scientific grounds; and (ii) the level of protection deemed appropriate by France. The EC obfuscate on this point. They reject the standards of the ILO and the International Labour Office on the pretext that they recommend controlled use, a means of protection that is unacceptable to France, which now only cites the WHO. Canada points out that, in their first written submission, the EC did not reject the ILO standards but claimed that they recommended a ban on asbestos and its replacement by less harmful substitute fibres. Canada can only explain this sudden change in position by implicit recognition that the standards mentioned by Canada do not recommend a ban and the replacement of all types of asbestos and all their uses. Regarding the reasons for ineffectiveness and inappropriateness, namely, the scientific grounds, it is unthinkable to claim that progress in scientific knowledge leads to disregard for international standards. These standards recommend taking effective and appropriate measures to protect human health against the risk of exposure to chrysotile. To disregard an international standard, it is necessary to provide evidence of a fundamental situation that makes the standard ineffective or inappropriate. According to Canada, the EC have not shown that recent scientific discoveries have made the international standards cited by Canada obsolete, standards which, moreover, reflect the WHO's recommendations in its recent assessment of the risks of chrysotile asbestos.

3.379 As far as the second reason for ineffectiveness and inappropriateness is concerned, namely, the non-fulfilment of the level of protection deemed appropriate by France, Canada does not contest a Member's freedom, within the framework of the TBT Agreement, to choose the level of protection it deems appropriate, but nevertheless considers that the international standards are effective and appropriate because they enable France to achieve its objective, namely, to protect human health. Canada notes that the EC hold the contrary position for the following four reasons: (i) chrysotile is a proven carcinogen; (ii) there is no exposure limit (threshold) for chrysotile; (iii) safe use is not feasible in all circumstances and for all persons and does not eliminate all the risks; and (iv) there are substitute products which are safe, or safer, than chrysotile. Under such circumstances, the EC point out that the only texts that are effective and appropriate are those which advocate ceasing to use asbestos, banning it and replacing it with substitute products. Canada, for its part, considers that the international standards make it possible to achieve the level of protection of human health deemed appropriate by France for four reasons: (i) chrysotile is less harmful than amphiboles; (ii) the understanding of certain mechanisms by which the fibres cause certain diseases makes plausible the existence of a threshold of exposure below which no cancer can develop; (iii) controlled use is possible; and (iv) the risks associated with substitute fibres are not known.

3.380 Canada maintains that there is a broad consensus among the scientific community that chrysotile asbestos is less harmful than amphibole asbestos. The WHO draws a distinction between chrysotile and amphiboles as far as the risks to human health are concerned. Three of the four experts consulted by the Panel recognize that chrysotile asbestos is less dangerous. The international standards, as well as the national regulations in a number of countries, take into account the difference in the harmfulness of different types of asbestos by laying down higher exposure limits for chrysotile than for amphiboles. Canada recalls that it has already explained that the difference in harmfulness can be explained by the different chemical compositions, physical properties and biopersistence of amphiboles and chrysotile.[489] The question of controlled use has already been examined. Canada asserts that controlled use is feasible and effective and gives workers and do-it-yourself enthusiasts adequate protection. The control measures have proved their effectiveness in the mining and processing sectors. According to Canada, studies show that it is possible to produce chrysotile fibre and manufacture asbestos-cement or friction materials in places where exposure levels are strictly

[489] See Canada's arguments in Section III.B, as well as the comments on the replies by the experts, especially those concerning question 3 from the Panel.

controlled and kept below safe levels, where workers are not exposed to any increased risk of disease due to exposure to chrysotile.

3.381 With regard to secondary users, in Canada's view this is a false problem. Threats to the health of secondary users are due to friable materials, in particular sprayed asbestos already *in situ*. As Canada has already pointed out, this debate does not concern friable materials, but high-density products (water pipes, roof tiles, cladding, guttering, friction linings), in other words, products in which the fibres are encapsulated and cannot be released into the ambient air. The recommended methods of installation eliminate the need to cut or drill these products on building sites because they are delivered in a number of pre-cut and pre-drilled sizes according to the buyer's specifications. If such operations are necessary, the risks can be reduced to undetectable levels by using proper hand tools or tools equipped with vacuum dust extractors. By using appropriate tools and practices (moistening, for example), the emission of fibres during intermittent work can be kept at levels below those deemed safe. In Canada's view, the effect of intermittent exposure on the health of workers naturally depends on protective measures, but also on the intensity and duration of the exposure. It is in fact cumulative exposure that determines the risk. For those working with chrysotile intermittently, cumulative exposure levels are usually low, precisely because the work is intermittent. This is even more true for do-it-yourself enthusiasts, who work even less with high-density products than construction workers. Canada points out that these considerations come from Dr. Henderson's reply to question 5(e) by the Panel: " … the risks from occasional or infrequent interventions on chrysotile-only products (e.g. by home 'handymen') – although not quantifiable because of absence of data – must be very small for lung cancer and mesothelioma, and non-existent for asbestosis".

3.382 Canada rejects the EC's claim that the substitutes most commonly used are "substances which have given no cause for concern after decades of massive use […]".[490] The most recent data available on the dimensions of substitute fibres[491], their biopersistence and the reactions of the human organism to exposure to them do not enable any definitive comparison with chrysotile fibre to be made. This is also the opinion of the European Commission's Scientific Committee on Toxicity, Ecotoxicity and Environment: " … the conclusion that specific substitute materials pose a substantially lower risk to human health, particularly public health, than the current use of chrysotile, is not well founded …"[492] In Canada's view, the Panel should be circumspect concerning the opinions of the experts on substitute fibres. Those who have adopted a position on this subject based themselves on a very small number of scientific data. According to INSERM's report on substitute fibres:

> "Taking into account the current uncertainties regarding the effects on humans of exposure to substitute fibres for asbestos, it is important to ensure that the levels of exposure among users of products containing substitute fibres for asbestos are as low as possible."[493] (WTO translation)

3.383 For the same reasons, Canada believes that the international standards enable France to give the population the protection it considers appropriate in the health sphere.

3.384 Canada also considers that the effective and appropriate international standards have not been used "as a basis" for the adoption of the French Decree. Canada refers the Panel to the arguments in Section III.B above and the replies to the questions by the Panel (see Annex II to this report) concerning the meaning of the obligation to use the international standards or their relevant parts "as a

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[490] See Section III.B.6 above.

[491] Glass fibre, cellulose fibre, para-aramid fibre, and PVA fibre.

[492] Opinion on a study commissioned by Directorate General III (Industry) of the European Commission on *Recent Assessments of the Hazards and Risks posed by Asbestos and Substitute Fibres, and Recent Regulation on Fibres World-Wide* (Environmental Resources Management, Oxford (opinion expressed on 9 February 1998).

[493] INSERM, *Effets sur la santé des fibres de substitution à l'amiante*, INSERM joint report, Paris, 1999, p.426.

basis" for a technical regulation. Neither the ILO nor the International Labour Office recommends replacing all types of asbestos for all applications. Convention 162 only advocates the use of substitute fibres "Where necessary to protect the health of workers and technically practicable […] by other materials or products, or the use of alternative technology […] scientifically assessed by the competent authority as harmless or less harmful …". Article 5 of the ILO Code of Practice on Safety in the Use of Asbestos is in the same vein. Canada asserts that France did not proceed in the manner called for in the standards. It did not assess the risks for each product, each use and each application. If it had done so, it would have realized that chrysotile fibre does not have to be replaced in asbestos-cement products, which alone account for almost all applications of chrysotile. Dr. de Klerk points out that: "Asbestos-cement products containing only chrysotile pose no measurable threat to health."[494]

3.385 Canada notes that in the *Environmental Health Criteria for Chrysotile Asbestos (203)*, considered by the EC to be a standard within the meaning of the TBT Agreement, the WHO recommends that chrysotile asbestos should only be replaced by safer substitute materials where this is possible. In France, however, the products replacing chrysotile are not safer. As the INSERM report on substitute fibres states:

> "On the basis of the epidemiological data currently available, no conclusions can be drawn concerning the carcinogenicity of the various types of substitute fibre."[495] (WTO translation)

3.386 Canada contends that, to date, no comparative scientific study has established beyond any doubt that substitute products are harmless or less harmful than chrysotile asbestos. Some recent studies even show that certain fibrous substitutes (for example, PVA fibres and cellulose fibres) have a higher degree of biopersistence than chrysotile.[496] Canada also maintains that many scientific studies, which it mentioned during the meeting with the experts on 17 January 2000, show that, at the low levels of exposure currently prevalent in the chrysotile products industry, it is not possible to measure an increased risk for human health. International standards on asbestos do not call for a total ban without drawing distinctions that take into account the type of fibre or the use. The standards propose an approach under which asbestos regulations must take account of the type of fibre, the products in which the fibre is incorporated, and the uses of the product. The international standards thus propose a less trade-restrictive approach while at the same time laying emphasis on the effective and appropriate protection of human health. France has ignored these international standards and has banned asbestos. Moreover, the technical regulation it has adopted is so far from the international standards that their bases can no longer be perceived. According to Canada, the EC has not provided any valid explanation to justify rejecting the standards as the starting point for French regulations on asbestos. For the foregoing reasons, Canada asks the Panel to find that the Decree is inconsistent with the provisions of Article 2.4 of the TBT Agreement.

3.387 The **European Communities** contend that the texts cited by Canada to suggest that there exist international standards that could have been used as a basis by France are not relevant under Article 2.4 of the TBT Agreement because these texts do not correspond to the definition of a "standard" in Annex 1 to the TBT Agreement. In fact, the terms of the ILO and ISO texts mentioned by Canada do not lay down any guidelines or characteristics for products or related process and production methods nor is that their object and purpose. At best, they can be seen as assessments of the risks caused by asbestos and asbestos-containing products rather than as establishing international technical standards or conformity assessment procedures. They also aim at providing a minimum level of protection for workers, not the substantial reduction or elimination of the risks, which is the level of protection chosen by France. Thus, the EC consider that the ILO and ISO texts are not

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[494] *Effects on Health of Asbestos-cement Products: A Review of the Literature*, p.1.

[495] INSERM, *Effets sur la santé des fibres de substitution à l'amiante*, INSERM joint report, Paris, 1999, p.181.

[496] Canada's comments on the replies by the experts to question 6(b) from the Panel.

relevant standards within the meaning of Article 2.4 of the TBT Agreement and therefore are not applicable in this case. Accordingly, in the light of the foregoing, the EC consider that the Decree is compatible with Article 2.4 of the TBT Agreement.

(e) Article 2.8 of the TBT Agreement

3.388 **Canada** maintains that the Decree is based on provisions relating to products in terms of their design or their descriptive characteristics, whereas it would have been appropriate to base it on their performance. Based on this fact, the Decree is incompatible with Article 2.8 of the TBT Agreement, which provides that a Member shall regulate products "Wherever appropriate ... in terms of performance…". Regulating chrysotile fibre "in terms of performance" requires an analysis of the intended uses of this fibre. Canada maintains that the appropriateness criterion in Article 2.8 has been met to a large extent in this case inasmuch as the potential risks of chrysotile fibre make regulating it "in terms of performance" necessary, even essential. International standards address the uses of chrysotile in terms of the risks that they present. These international standards provide for technical regulation of chrysotile based on its performance. Until the adoption of the Decree, France regulated asbestos in terms of the risks that each of its uses entailed. For a long time, the technical regulation of chrysotile, in France, was therefore based on the performance of this product. According to Canada, France has not offered any justification to show that, henceforth, it would no longer be "appropriate" to follow this approach. Examination of the "wherever appropriate" criterion for regulating a product "in terms of performance" rather than "descriptive characteristics" must be done on a case-by-case basis. In this case, chrysotile fibres have no usefulness or commercial value as such. They are only used as inputs in a limited range of finished products. Chrysotile fibres only present an actual risk in certain conditions of past use, whereas hard modern products that contain these fibres do not present any detectable risk. It therefore appears quite appropriate to regulate chrysotile in terms of its performance rather than its descriptive characteristics.

3.389 Canada maintains that it is utterly inappropriate and contrary to the objectives of the TBT Agreement to consider that a product must be banned because it is potentially hazardous *per se* because many products would fall into this category, at least in part. In the particular case of products containing fibres, the potential risks depend on the type of fibre used, on the way in which it is incorporated in a product and the precautionary measures that are taken at the time of manufacturing, handling and using the product. If the purpose of Article 2.8 is to have technical regulations based on "performance", it is because the potential risk of a product is generally in fact closely linked to its use. Bagged chrysotile exported by Canada is an inert product as long as it is not handled or used for particular purposes. It is these uses that can be the source of some risk. Modern products where chrysotile fibre is imprisoned do not pose any detectable risk for health. Article 2.8 requires, wherever appropriate, that a Member comply with this fact when drawing up its technical regulations. Canada maintains that, with respect to chrysotile fibre, only a regulatory approach based on an analysis of the risks, use-by-use, product-by-product, is in keeping with Article 2.8 of the TBT Agreement or, more generally, with the objectives of this Agreement. Until the adoption of the Decree, France recommended this approach, and rightly so, as it regulated uses (e.g. spraying) or specific products containing asbestos (e.g.: toys), taking account of the hazards inherent in some of these applications. Based on the foregoing, Canada concludes that, inasmuch as the Decree was not based on performance even though it was utterly appropriate to do so, France has violated Article 2.8 of the TBT Agreement.

3.390 The **European Communities** contend that it is important to note that Article 2.8 applies to a sub-category of "technical regulations" i.e. "technical regulations based on product requirements". In this instance, it is clear that the Decree is not "based on" requirements relating to asbestos or asbestos-containing products. Article 2.8 is therefore inapplicable in this instance. According to the EC, the purpose of the provision is to ensure that technical rules that aim to ensure a given quality or minimum performance are, as far as possible, technically neutral and do not therefore prescribe a

particular process or technology but simply set objectives to be achieved. This is perfectly clear from the English text of Article 2.8 of the TBT Agreement.

3.391 The EC contend that the ban on asbestos, even if it were considered to be a technical rule, is not a technical rule that falls within the scope of this provision. In any event, Article 2.8 of the TBT Agreement means that, wherever appropriate, the technical regulation shall be based on the performance of the product in question (i.e. based on requirements connected with the performance of the product, for example, "the product must be safe, watertight and non-flammable"), and not based on the design or descriptive characteristics of the product (i.e. not specify in detail how these requirements of safety, watertightness and non-flammability are to be attained). However, asbestos and asbestos-containing products present a major risk to human health, and in particular to the health of persons who are exposed repeatedly, occasionally or unwittingly. With the exception of the waivers granted when there is no substitute product less harmful to health or safer, there is no possible "use" of the product. Only a prohibition is capable of halting the spread of the risk. The EC consider that, under such conditions, a technical regulation that aims to prohibit the "use" of a product cannot set out the circumstances or conditions in which asbestos or asbestos-containing products are to be used. Consequently, the Decree is compatible with Article 2.8 of the TBT Agreement.

3.392 **Canada** maintains that the Decree is inconsistent with Article 2.8 of the TBT Agreement because the Decree's requirements relating to chrysotile asbestos and products containing it were based on the design or descriptive characteristics of these products, whereas it would have been appropriate to base them on performance. Indeed, the Decree prohibits a product because it contains chrysotile asbestos. This ban is a product requirement. The scope of the ban (whether it affects a product or not) depends on its design or a descriptive characteristic (the product does or does not contain chrysotile asbestos). According to Canada, the EC interpret Article 2.8 incorrectly. This Article does not apply only to a sub-category of technical regulations that are "technical regulations based on product requirements". Nor does it have the limited goal of ensuring that technical regulations aimed at ensuring minimum product performance or quality are neutral. Contrary to what the EC maintain, Canada contends that there are possible uses of chrysotile asbestos that do not involve a detectable risk to human health and can be subject to controlled-use measures. The EC wrongly claim that only a ban is capable of halting the spread of the asbestos risk.

3.393 Canada contends that the EC, in their reply to a question from Brazil,[497] acknowledged the relevance of a regulatory approach based on product performance and, implicitly, their obligation, pursuant to Article 2.8 of the TBT Agreement, to regulate chrysotile asbestos and asbestos-containing products based on their performance. Canada notes that the EC write that the assessment of the risk must be specific to each product and that the national risk management decisions that result differ depending on each product in question. With respect to chrysotile fibre, only a regulatory approach based on an assessment of the risk on a use-by-use, product-by-product basis is compatible with Article 2.8 of the TBT Agreement and, more generally, with the objectives of the TBT Agreement. Moreover, prior to the adoption of the Decree, France advocated this approach because it regulated chrysotile asbestos based on uses (for example, spraying) or based on the hazards inherent in applications of specific products containing it (for example, toys). Canada claims that, inasmuch as it did not base the Decree on the performance of chrysotile asbestos and products containing it when it would have been possible to do so, France violated Article 2.8 of the TBT Agreement.

2. General Agreement on Tariffs and Trade (GATT)

(a) Applicability of Article III and/or Article XI of the GATT

3.394 **Canada** maintains that the Decree is incompatible with Articles XI:1 and III:4 of the GATT. The Decree should be examined in the light of these two Articles because it comprises two distinct

[497] See Annex II to this report, section B.6, para.344.

aspects: on the one hand, it prohibits imports and, on the other, it contains discriminatory internal regulations. The wording of the Decree clearly shows these two aspects. With regard to the first aspect, the Decree prohibits the import of all varieties of asbestos fibres and any product containing them. According to Canada, this aspect is subject to Article XI:1 of the GATT. With regard to the second aspect, the Decree affects domestic market use of all varieties of asbestos fibres and all products containing them. Canada considers that this point is subject to Article III:4 of the GATT. Just as two specific aspects of the same measure can be examined in the light of two different agreements, similarly, two specific aspects of the same measure can be examined in the light of two different articles of the same agreement; in this case, Article XI:1 and Article III:4 of the GATT.[498] Specifically, Canada maintains that the first aspect of the Decree, which aims to prohibit the import of all varieties of asbestos fibres and any product containing them, is incompatible with Article XI:1. The second aspect of the Decree, which aims to prohibit, in particular, the domestic marketing and transfer on any basis of all varieties of asbestos fibres and any product containing them, is, according to Canada, incompatible with Article III:4 of the GATT.

3.395 The **European Communities** claim that the Decree has to be seen as an "internal regulation" providing wholly identical treatment for "like" domestic and imported products within the meaning of Article III:4 of the GATT, and must therefore be considered fully compatible with that Article. The EC note that Canada maintains that the measure contested is contrary to both Articles III:4 and XI:1 of the GATT. However, either the measure is an "internal regulation", in which case it falls under Article III:4, or it concerns only the importation of products, in which case it must be judged in the light of Article XI:1. In the present case, the Decree only establishes a single measure that applies in a non-discriminatory manner to asbestos and covers both domestic and imported products.

3.396 The EC contend that Canada wrongly maintains that the Decree comprises two separate measures: one relating to the use of asbestos and asbestos-containing products on the domestic market (falling under Article III:4) and the other relating to imports of asbestos and asbestos-containing products (falling under Article XI:1). Such a distinction fails to take account of the relationship between Article III:4 and Article XI:1 and, according to well-established GATT practice, a single measure that applies both to domestic and to imported products is necessarily covered as a whole by Article III:4 of the GATT if it is imposed on an imported product at the time or place of importation.

3.397 The EC point out that the Decree prohibits the manufacture, processing, possession for sale, offer, importation and exportation, domestic marketing, or transfer under any title of all varieties of asbestos fibres or any product containing them. The Decree also provides for an exemption from the ban on asbestos and asbestos-containing products when there are no substitute products capable of performing a function equivalent to that of asbestos and of guaranteeing both the technical safety of use and a lower risk to workers' health. This is a measure prohibiting the use (in any form whatsoever) of asbestos and asbestos-containing products, "which applies" both to domestic asbestos and asbestos-containing products and to imported asbestos and asbestos-containing products at the time of importation. In other words, the import ban is merely the logical corollary of the general prohibition on the use of asbestos and asbestos-containing products. The fact that the Decree applies at the border (by banning imports) so as to enforce the French measure prohibiting the use of asbestos does not render Article III:4 inapplicable.

3.398 The EC note that, in a different case, a Panel held that: "The fact that Section 337 is used as a means for the enforcement of United States patent law at the border does not provide an escape from the applicability of Article III:4".[499] Similarly, the Panel Report on *Canada - Import, Distribution and Sale of Certain Alcoholic Drinks by Provincial Marketing Agencies* raised the question of whether the

[498] *European Communities – Regime for the Importation, Sale, and Distribution of Bananas*, Report of the Appellate Body, adopted on 25 September 1997, WT/DS27/AB/R, para.221.

[499] *United States – Section 337 of the Tariff Act of 1930*, adopted on 7 November 1989, BISD 36S/345, para.5.10.

measure contested (in that instance, minimum prices) fell under Article X:1 or Article III:4. It noted that, according to the Interpretative Note Ad Article III, a regulation is subject to the provisions of Article III if it "applies to an imported product and to the like domestic product" even if it is "enforced, in the case of the imported product, at the time or point of importation".[500] Even if the word "import" were deleted from the Decree, this would not alter the position as regards imported asbestos and asbestos-containing products in any way. Their use, in whatever form, would still be prohibited on French territory. The import ban is simply designed to make the prohibition of their use more effective in terms of inspection. For the same reason, in the case of domestic products, the Decree prohibits not only their sale, but also their manufacture. The aim, then, is to halt the spread of asbestos as far upstream as possible.

3.399 The EC contend that Article III:4 must be assessed in the light of the Interpretative Note relating to it. The Panel Report on *United States - Restrictions on Imports of Tuna* is especially instructive for the purposes of the present case. In this case, the United States Marine Mammals Protection Act involved two measures. The first was a regulation governing the fishing practices of national tuna fishermen. Secondly, it also imposed an import ban on tuna or tuna-based products where the commercial fishing techniques used had the incidental effect of killing or severely injuring a greater number of marine mammals than the norms set by the United States. The Panel Report stated in general terms that:

> "This suggests that Article III covers only measures affecting products as such. Furthermore, the text of the Note Ad Article III refers to a measure 'which applies to an imported *product* and the like domestic *product* and is collected or enforced, in the case of the imported *product*, at the time or point of importation'. This suggests that this Note covers only measures applied to imported products that are of the same nature as those applied to the domestic products, such as a prohibition on importation of a product which enforces at the border an internal sales prohibition applied to both imported and like domestic products." [501] [italics in the original]

3.400 The EC indicate that, in this case, the Panel was unable to make use of the Note Ad Article III because the internal measure governing the fishing practices of United States tuna fishermen did not cover a particular product, unlike the import measure. The situation regarding the Decree is radically different and consequently warrants examination solely in the light of Article III:4 of the GATT. The thesis that Articles III and XI cannot both apply to any one measure is apparently confirmed by the rulings of Panels which, when examining a measure, always pose the question whether it falls under Article III or Article XI.[502] The EC note that Canada appears to share this view too, as it argued in the *Hormones* case that: "... in the alternative, the EC import prohibition infringed GATT Article XI, but noted that this claim should only be considered by the Panel if it decided that Article III of GATT did not apply in this case".[503] Besides, it would be totally illogical if one and the same measure were permitted under Article III and prohibited under Article XI, in other words if a measure prohibiting the use of a product on national territory could not be enforced at the border.

3.401 **Canada** maintains that the Decree is inconsistent both with Articles XI:1 and III:4 of the GATT because it involves two separate aspects. As Canada has asserted, the terms of the text make it clear that, on the one hand, the Decree prohibits imports of asbestos or of asbestos-containing products and, on the other hand, regulates the domestic market. Canada notes that the EC do not

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[500] *Canada – Importation, Distribution and Sale of Certain Alcoholic Drinks by Provincial Marketing Agencies*, BISD 39S/27, para.5.28.

[501] *United States – Restrictions on Imports of Tuna*, circulated on 3 September 1991, not adopted, BISD 39S/155, paras.5.8-5.16.

[502] See, for example *Canada – Importation, Distribution and Sale of Certain Alcoholic Drinks by Provincial Marketing Agencies*, adopted on 18 February 1992, BISD 39S/27, para.5.6. See also *United States – Restrictions on Imports of Tuna*, pp.193 *et seq.*.

[503] *EC Measures Concerning Meat and Meat Products (Hormones)*, report of the Panel, adopted on 13 February 1998, WT/DS48/R/CAN, para.4.354.

recognize the dual aspect of the French measure, but claim that the import ban is intended simply to render more effective, in terms of control, the ban on use. According to Canada, the EC's reasoning is tendentious in that it is incomplete. Canada notes that, in an effort to demonstrate that the measure is solely an internal measure, the EC claim that removing the "importation" aspect from the text of the measure would not in any way affect the scope of the internal provisions. Canada fully agrees with this reasoning because it is precisely what Canada asserts. However, this is only half of the Canadian reasoning.

3.402 Canada asserts that the corollary of this reasoning highlights the dual aspect of the Decree. Using the same logic as that applied by the EC, Canada can in return claim that if the "internal measure" aspect is removed from the reading of the text of the Decree, this does not change in any way the scope and effectiveness of the ban on the import of asbestos into France. That is why the measure must be examined under both Article III:4 and Article XI:1 of the GATT. Canada notes the argument of the EC and of the United States relating to the Interpretative Note Ad Article III (measures imposed "at the time or point of importation"). However, the Interpretative Note is not applicable because the import ban is not an internal measure imposed, for administrative reasons, at the border. Also, the Interpretative Note Ad Article III only applies, as indeed the EC maintain, if the measure applies "to an imported product and to the like domestic product".[504] Yet, it is clear to Canada that the aspect of the measure in question, namely the explicit import ban, is not applicable to the domestic product because the domestic product is obviously not "imported". The import ban is therefore aimed specifically at something that is not covered by the internal measure. Canada contends that the Decree has a dual aspect involving Articles III:4 and XI:1 of the GATT.

3.403 The **European Communities** assert that the Decree must be examined as an internal measure falling exclusively under Article III:4 of the GATT. When a domestic measure applies to both domestic and imported products, Article III must apply. Therefore, the contested measure may be examined as a single measure with identical implications for both domestic products and imports. Article III then rules out the application of Article XI, inasmuch as these two Articles cannot be applied cumulatively to one and the same measure. This interpretation follows both from a textual analysis of the Interpretative Note Ad Article III and from previous practice under the GATT. It also follows from an analysis, by analogy, of other legal systems.

3.404 The EC recall that, as already indicated, the Interpretative Note Ad Article III has been interpreted by the Panel in *United States - Restrictions on Imports of Tuna* as follows:

> "This suggests that this Note [Ad Article III] covers only measures applied to imported products that are of the same nature as those applied to the domestic products, such as a prohibition on importation of a product which enforces at the border an internal sales prohibition applied to both imported and like domestic products."[505]

In so doing, the Panel recognized that, even if a measure is applied to imported products, the fact that that same measure is also applied to domestic products makes Article III applicable. This in itself rules out any possibility of cumulative application together with Article XI of the GATT.

3.405 The EC indicate that the Panel in *United States - Measures Affecting Alcoholic and Malt Beverages* noted that:

> "…the issue is not whether the practices in the various states affect the right of importation as such, in that they clearly apply to both domestic (out-of-state) and imported wines; rather, the issue is whether

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[504] *Canada – Importation, Distribution and Sale of Certain Alcoholic Drinks by Provincial Marketing Agencies*, adopted on 18 February 1992, BISD 39S/27, para.5.28.

[505] *United States – Restrictions on Imports of Tuna*, circulated on 3 September 1991, not adopted, BISD 39S/155, para.5.11.

> the listing and delisting practices accord less favourable treatment - in terms of competitive opportunities – to imported wine than that accorded to the like domestic product. Consequently, the Panel decided to analyze the state listing and delisting practices as internal measures under Article III:4."[506]

This latter Panel shows that a domestic measure can affect the right to import as such without, for all that, falling under Article XI.

3.406 The EC claim that some legal systems, for example, that of the EC, take the same approach. Thus, with regard to the fiscal measures applicable between Member States, the Court of Justice of the EC makes a distinction between, on the one hand, measures that apply to a product only when imported, which fall under Article 12 of the EC Treaty (Elimination of customs duties or charges having equivalent effect), and, on the other, measures that apply to both imported and domestic products, which fall under Article 95 of the EC Treaty[507] (Internal taxation). The text of Article 95 of the EC Treaty could, as a Panel has already indicated[508], be compared to the text of Article III of the GATT. It follows from the above that a measure which applies to both domestic products and imported products must be examined in relation to Article III, insofar as such measure is identical in nature for both domestic products and imports. From a systematic interpretation it also follows that such a measure cannot be examined simultaneously from the standpoint of both Article III and Article XI of the GATT.[509] According to the EC, the students of legal theory have come to the same conclusion:

> "This line [between Articles XI and III] may sometimes be hard to draw. The notes to Article III provide that measures applied to domestic products, which are applied to imported products at the time of importation, are to be analyzed under Article III. Thus, if an import were barred because it failed to meet a national product standard, the permissibility of the action would be examined under Article III, not as an import ban under Article XI."[510]

3.407 The EC assert that, in the case of the French measure on asbestos, the domestic measure and the border measure cover the same products (asbestos and asbestos-containing products) and are of the same nature. The Decree prohibits the importation of asbestos and asbestos-containing products from third countries and, at the domestic level, prohibits the production, processing, possession for sale, offer, exportation and transfer of these products. The practical application of the Decree leads to the same measure - that is, the general ban on asbestos and asbestos-containing products - being applied to all products, irrespective of their origin. As one and the same measure is applied to domestic products and imported products - in the case of the latter at the border - the Communities conclude that only Article III:4 of the GATT is applicable in this case, which rules out the application of Article XI. With regard to the Canadian argument that France does not manufacture asbestos or manufactures it only in extremely limited quantities, the EC wish to point out that asbestos was

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[506] *United States – Measures Affecting Alcoholic and Malt Beverag*es, adopted on 19 June 1992, BISD 39S/206, in particular para.5.63.

[507] See, for example, the judgement of the Court of Justice of the European Communities, 11 June 1992, cases C-149/91 and C-150/91, Sanders Adour/*Directeur des Services Fiscaux des Pyrénées-Atlantiques*, Rep. 1992, p.I-3899, and in particular paras.15 and 19.

[508] *Korea – Taxes on Alcoholic Beverages*, adopted on 17 February 1999, WT/DS75/DS84/R, report of the Panel, in particular point 10.81.

[509] In this connection, the EC note that the non-cumulative application of Articles 12 and 95 of the EC Treaty (see above) has been forcefully recalled by the European Court of Justice, which has stated that:

> "It is settled law … that the provisions relating to charges having equivalent effect and those relating to discriminatory internal taxation cannot be applied together, so that under the system of the Treaty the same imposition cannot belong to both categories at the same time".

[510] Jackson, J.H., Davey, W.J., Sykes, A.O., *Legal Problems of International Economic Relations*, West Publishing Co., 1995, p.502.

produced in France in the past. The potential for production remains, insofar as asbestos in its natural form is present on French territory.

3.408 **Canada** asserts that the Decree should be considered as falling under both Article XI and Article III of the GATT. The Decree's provisions banning imports of asbestos are incompatible with Article XI:1 and the Decree's provisions banning the sale of asbestos and other transactions on the French market are incompatible with Article III:4. In this connection, Canada points out that the report in *United States – Restrictions on Imports of Tuna*, cited by the EC several times to underpin its thesis of systematic interpretation, was not adopted by the Contracting Parties. Canada indicates that, if the Panel considers that the Decree cannot be examined under the two Articles, it should be considered as a measure affecting imports and incompatible with Article XI:1. If the Panel considers that the Decree cannot be examined under the two Articles and cannot be considered as a measure affecting imports, it should be considered as a measure affecting sales and other transactions on the French market and thus incompatible with Article III:4.

3.409 The **European Communities** contend that the Decree constitutes a single measure that applies to both domestic and imported products alike. As one and the same measure is applied to both domestic products and imported products – in the case of imports at the border - the EC conclude that only the arguments of Canada relating to Article III:4 of the GATT are relevant in this case. According to the EC, this interpretation rules out the cumulative application of Articles III and XI of the GATT, as the Note Ad Article III provides and previous GATT Panel reports have clearly established (see, for example, the first Panel report in the *Tuna/Dolphin* case). Indeed, the Decree prohibits the importation of all types of asbestos and products containing asbestos from all third countries and, at the domestic level, prohibits the production, processing, possession for sale, offer, exportation and transfer of these products. The practical application of the Decree thus leads to the same result, namely, a general ban on asbestos and products containing asbestos applicable to all products irrespective of their origin. The EC claim that, in order to establish a violation of Article III:4 of the GATT, the complaining party has the burden of showing that there is *de jure* or *de facto* discrimination in the treatment of imported compared to like domestic products.

(b) Article III:4 of the GATT

(i) Application of Article III:4 of the GATT

3.410 **Canada** maintains that, in adopting the Decree banning asbestos, France violates the national treatment disciplines in Article III:4 of the GATT 1994. The effect of the French measure is to favour the French fibre industry and that of substitute products such as chrysotile fibre and chrysotile-cement products, which is prohibited under Article III:4 of the GATT 1994. According to case law under the GATT 1947 and the GATT 1994, examination of the applicability of Article III:4 to a measure taken by a Member and, if need be, of its compatibility with the disciplines of Article III:4, has two separate facets. The first is to determine whether the measure constitutes a law, a regulation or a requirement affecting the sale, offering for sale, purchase, transportation, distribution or use of an imported product on the domestic market. Canada asserts that the Decree banning asbestos is a regulation affecting these activities. The second facet is to determine whether the products from the territory of a Member imported into the territory of another Member are subject to treatment less favourable than that accorded to like products of national origin in respect of all laws, regulations or requirements affecting, *inter alia*, their supply, offering for sale, or sale. With respect to the second facet, Canada draws attention to the following three points: (i) products like Canadian chrysotile fibre and chrysotile-cement exist; (ii) these like products are of French origin; and (iii) they benefit from treatment more favourable than that accorded to imported Canadian chrysotile fibre and chrysotile-cement products. Canada notes that, in this case, France recognized in specific terms in the Decree banning asbestos that chrysotile fibre and the products containing it are like the substitute fibres and materials, products or devices containing the latter.

3.411 Canada maintains that the likeness of these products is confirmed by application of the criteria established in the case law, i.e. end-use of the product, consumers' tastes and habits, the physical properties, the nature and quality of the product, as well as tariff classification. According to these criteria, the substitute fibres are like chrysotile fibre and fibro-cement products are like chrysotile-cement products. Furthermore, a substitute fibre manufacturing industry and a sizeable industry for the manufacture of fibro-cement products exist in France. The prohibition of a number of operations – including domestic marketing, sale and transfer on any basis – relating to chrysotile fibre and products containing it unequivocally constitutes treatment less favourable than that accorded to like French substitute fibres and products that are not subject to any prohibition regulations of the same type.

3.412 Canada contends that the Decree constitutes a regulation affecting the sale, placing on the market or purchase of chrysotile fibre and chrysotile-cement products in France. According to Canada, Article III:4 applies to "all laws, regulations and requirements". Article III:4 applies to the Decree, which is a regulation of the French Government. Pursuant to the terms of Article III:4, a measure must affect "the internal sale, offering for sale, purchase, transportation, distribution or use …" on the domestic market. The Decree specifically aims to prohibit the manufacture, processing, sale, domestic marketing, possession for sale, offer or transfer on any basis of all varieties of asbestos fibres and products containing them. In Canada's view, the Decree undoubtedly constitutes a regulation directly affecting the sale, release for sale or purchase of chrysotile fibre and products containing it. The Decree applies to France's domestic market pursuant to the terms of Article III:4. In prohibiting the sale, release for sale or purchase, the Decree changes the conditions of competition, in the domestic market, between substitute fibres and products containing them of French origin and chrysotile fibre and products containing it originating in Canada. Canada concludes that the conditions regarding the applicability of Article III:4 of the GATT have been met.

3.413 The **European Communities** assert that the Decree has to be examined as an "internal regulation" that provides perfectly identical treatment for "like" domestic and imported products within the meaning of Article III:4 of the GATT and it must therefore be considered fully compatible with that Article.

(ii) The concept of "like products"

3.414 **Canada** claims that, in the case of the Decree, the question of determining whether the treatment accorded is less favourable for the imported product than for the like product of national origin presupposes the examination of the following three points: (i) the existence of products like Canadian chrysotile fibre and chrysotile products; (ii) the French origin of those like products; and (iii) less favourable treatment accorded to chrysotile-cement products and to imported chrysotile fibre than that accorded to like French products. According to the report by the Working Party on *Border Tax Adjustments*, likeness of products shall be assessed on a "case-by-case" basis considering, in particular, end-use of the product, consumers' tastes and habits and the properties, nature and quality of the product.[511] The Appellate Body describes the Working Party report on *Border Tax Adjustments* as setting out "the basic approach for interpreting 'like or similar products', generally, in the various provisions of the GATT 1947".[512] Tariff classification was added as a supplementary element to the

[511] Working Party Report *Border Tax Adjustments*, BISD 18S/97, para. 18: "... the interpretation of the term should be examined on a case-by-case basis. This would allow a fair assessment in each case of the different elements that constitute a 'similar' product. Some criteria were suggested for determining, on a case-by-case basis, whether a product is 'similar': the product's end-uses in a given market, consumers' tastes and habits, which change from country to country, the product's properties, nature and quality." This Report was adopted by the contracting parties in 1970 and has been taken up many times since, notably by the Appellate Body in *Japan – Taxes on Alcoholic Beverages*, adopted on 1 November 1996, WT/DS8/AB/R; WT/DS10/AB/R; WT/DS11/AB/R, pp.18 *et seq*.

[512] *Japan – Taxes on Alcoholic Beverages*, Report of the Appellate Body, adopted on 1 November 1996, WT/DS8/AB/R; WT/DS10/AB/R; WT/DS11/AB/R), p.22.

above-mentioned criteria.[513] Analysis of the likeness of products is therefore based on criteria such as (i) end-use of the product; (ii) consumers' tastes and habits; (iii) the properties, nature and quality of the product; and (iv) the tariff classification.[514] Precedents under the GATT 1947 and the GATT 1994 do not require that all the criteria apply for the purpose of analysing the likeness of products.[515] For example, in the report *Japan – Customs Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages*, it was determined that various types of alcohol were like products because they constituted a well-defined and single product at the end-use stage.[516]

3.415 Canada maintains that the term "like" does not mean identical. It is rather a matter of showing that fibres and products that are substitutes for chrysotile fibre and chrysotile- cement products are similar in many ways and, according to the Decree they are not covered by the national treatment rule under Article III:4.[517] More than 150 substitute fibres for chrysotile fibre exist. In the products in which they are incorporated, they attempt to replicate the properties of chrysotile fibre. The most common are the aramid fibres, PVA fibres, cellulose fibres, glass fibres, ceramic fibres, rock wool, and wollastonite. Virtually all the chrysotile fibre of Canadian origin imported into France before the Decree took effect was intended for the manufacture of chrysotile-cement products. Canada uses the example of chrysotile fibre and chrysotile-cement in order to show the similarity of chrysotile fibre and substitute fibres and of products containing chrysotile and those containing substitute fibres. Chrysotile fibre and PVA, cellulose and glass fibres are used interchangeably, the first in the manufacture of chrysotile-cement, the three others in manufacturing fibro-cement.[518] Chrysotile-cement and fibro-cement are used in the manufacture of products such as pipes, pipe fittings (casings, bends, sealing joints), corrugated sheets, insulation and soundproofing board, exterior siding and roofing shingles, floor tiles, slabs, gutters, chimney cowls and sinks.

3.416 Canada asserts that the guiding principle underlying the examination of the question of similarity is to proceed on a case-by-case basis, i.e. taking into account the particular circumstances of each situation. However, in this instance, France undertook to ban chrysotile asbestos for all possible

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[513] *EEC – Measures on Animal Feed Proteins*, adopted on 14 March 1978, BISD 25S/49, para. 4.2; *Japan – Customs Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages*, adopted on 10 November 1987, BISD 34S/83, para. 5.6; *United States – Gasoline*, Appellate Body Report and Panel Report, adopted on 20 May 1996, WT/DS2/9, paras.6.8 and 6.9.

[514] *United States – Gasoline*, Appellate Body Report and Panel Report, adopted on 20 May 1996, WT/DS2/9, paras.6.8 and 6.9.

[515] Canada notes that, on the contrary, in the Report *Japan – Customs Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages*, it is recalled that products may be deemed like products according to the criterion of end-use only: "Past GATT practice has clearly established that 'like' products in terms of Article III:2 are not confined to identical products but cover also other products, for instance if they serve substantially identical end-uses ..." Report adopted on 10 November 1987, BISD 34S/83. See also *United States – Taxes on Petroleum and Certain Imported Substances*, adopted on 17 June 1987, BISD 34S/136, para.5.1.1.

[516] *Japan – Customs Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages*, adopted on 10 November 1987, BISD 34S/83, para.5.6: "The Panel agreed in this respect with the arguments submitted to it not only by the European Communities but also by other important producing countries of wines and distilled spirits that gin, vodka, whisky, grape brandy, other fruit brandy, certain 'classic' liqueurs, still wine and sparkling wine, respectively, were recognized not only by governments for purposes of tariff and statistical nomenclature, but also by consumers to constitute 'each in its end-use... a well defined and single product intended for drinking'." See also *Spain – Tariff Treatment of Unroasted Coffee*, adopted on 11 June 1981, BISD 28S/102, p.112, para.4.7.

[517] Canada notes that this interpretation is consistent with the precedent of the GATT 1947, in particular the aforementioned Panel Report on *Japan – Customs Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages*. It was clearly established therein that "like" products under Article III:2 are not limited to identical products […]. (para. 5.5(d)). The Panel judged in this case, that gin, vodka, whisky, brandy, wine and sparkling wine constituted like products for the purposes of Article III.

[518] For the purposes of Canada's argument with regard to Article III:4 of the GATT and Article 2.1 of the TBT Agreement, the term "fibro-cement" means a mix of cement to which PVA, cellulose fibre or fibreglass is added. The term fibro-cement includes "glass cement".

uses and to replace it with like substitute fibres capable of performing an equivalent function. The Decree indicates that products like chrysotile fibre, chrysotile-cement products, as well as all other products using chrysotile fibre, exist. This observation ensues from the terms of the Decree, which require substitute products to perform an "equivalent function" and offer the same "technical guarantees" as chrysotile-based products. Under Article 2 of the Decree, the ban does not apply to certain products that contain chrysotile fibre when, to ensure an equivalent function, "no substitute for that fibre is available which, on the one hand, in the present state of scientific knowledge, poses a lesser occupational health risk than chrysotile fibre to workers handling those materials, products or devices; [and] on the other, provides all technical guarantees of safety corresponding to the ultimate purpose of the use thereof." In France, chrysotile fibre has been replaced in all products in which it was used, with the exception of four uses. According to Canada, the replacement of chrysotile fibre in all cases in which there exists a substitute fibre capable of performing an equivalent function presupposes that the chrysotile fibre and the substitute fibre are nearly perfectly alike.[519] For example, the replacement of chrysotile fibre in fibro-cement products implies an admission that the substitute fibres have like characteristics. Finally, to satisfy the requirement under the Decree that a substitute fibre must provide all technical guarantees of safety appropriate to the end-use, it is essential that the end-uses of the products manufactured using chrysotile fibre be the same. According to the precedents, products are like products if their end-uses are the same.

3.417 Canada claims that the application of the criteria from case law confirms that PVA, cellulose and glass fibres and chrysotile fibre, on the one hand, and fibro-cement products and chrysotile-cement products, on the other, are like products.

3.418 As far as end-use is concerned, given the nature of chrysotile fibre - a raw mineral resource - Canada maintains that, in accordance with the case-by-case approach, special importance must be attached to the end-use criterion for the product when examining whether chrysotile fibre is like the substitute fibres. Chrysotile fibre has no use in its raw form; it serves as an input in the production of chrysotile materials. The most widespread end-use of chrysotile fibre is chrysotile-cement. Around 90 per cent of Canadian chrysotile fibre previously imported into France was used for this purpose. Like chrysotile fibre, PVA fibre, cellulose fibre and glass fibre are used in the manufacture of fibro-cement. After they have been incorporated in the cement, chrysotile fibre, on the one hand, and PVA, cellulose and glass fibres, on the other, are used for the manufacture of chrysotile-cement products and fibro-cement products respectively. These products constitute, "at the end-use stage", "a well-defined and single product" intended for the same purposes: whether a chrysotile-cement or a fibro-cement product.[520] The Decree points to the existence of substitute fibres for chrysotile fibre that perform an "equivalent" end function and provide "all technical guarantees of safety to the ultimate purpose of the use thereof".[521] Canada maintains that the conclusion that chrysotile fibre and PVA, cellulose and glass fibres are "like products" under Article III:4 of the GATT is derived from applying the sole criterion of end-use of the product.

3.419 Canada claims that the fact that chrysotile-cement products and fibro-cement products have the same end-uses is proof that they are "like products". Chrysotile-cement and fibro-cement boards are used for insulation and soundproofing. Sheeting, shingles and tiles are used for cladding exteriors,

[519] Canada notes that only four products made of chrysotile fibre have no equivalent and are therefore exempt from the ban until 2000 or 2002.

[520] See *Japan – Customs Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages*, adopted on 10 November 1987, BISD 34S/83, para.5.6: "The Panel agreed in this respect with the arguments submitted to it not only by the European Communities but also by other important producing countries of wines and distilled spirits that gin, vodka, whisky, grape brandy, other fruit brandy, certain 'classic' liqueurs, still wine and sparkling wine, respectively, were recognized not only by governments for purposes of tariff and statistical nomenclature, but also by consumers to constitute 'each in its end-use... a well defined and single product intended for drinking'."

[521] Article 2 of the Decree and the Decrees of 16 December 1996, 17 March 1998 and 24 December 1996 on exemptions from the ban.

roofs and floors. Pipes and pipe fixtures are used for pipeline systems or, for industrial purposes, in the transportation of liquids. Chrysotile-cement and fibro-cement products are like products because they are manufactured using either chrysotile-cement or fibro-cement without distinction, because they are finished products the end-use of which is identical and because the Decree recognizes that the technical guarantees with regard to "end-use" are identical. In Canada's view, the Decree concludes that there are substitute products for chrysotile-cement products that perform an "equivalent" function and provide "all technical guarantees of safety appropriate to the use" of chrysotile-cement products.

3.420 With regard to the properties, quality and nature of the product, Canada contends that the nature of chrysotile fibre (natural mineral fibre), PVA fibre (synthetic organic fibre), cellulose fibre (natural organic fibre) and glass fibre (man-made mineral fibre) is the same inasmuch as fibres are involved, be they organic or mineral, man-made or natural. Substitute fibres for chrysotile fibre are used to replicate the qualities of chrysotile fibre in view of the end-use. Chrysotile-cement or fibro-cement manufacturers use them for identical purposes, which points to the likeness of the properties, nature and quality of chrysotile, PVA, cellulose and glass fibres. In addition, PVA, cellulose and glass fibres, just like chrysotile fibres, give composites both strength and resistance. Their chemical resistance and their quality as a binder and reinforcing agent are useful in the manufacture of chrysotile-cement and fibro-cement.[522] In Canada's view, the likeness of the manufacturing processes for chrysotile-cement and fibro-cement shows the likeness between the properties and the nature of the fibres in question.

3.421 Canada states that chrysotile-cement products, like fibro-cement products, are known for their greater durability than cement products not containing fibre. They are also known for their chemical resistance, their insulating properties, both for heat and soundproofing, and their lightness. Chrysotile-cement and fibro-cement, whether they contain a percentage of chrysotile fibre or other like fibres, are manufactured using the same technical process. Indeed, the Hatschek process and the Mazza process – its derivative for pipe production – are used in the manufacture of chrysotile-cement and fibro-cements.[523] The likeness of the manufacturing processes indicates a convergence as regards the properties, quality and nature of the products. According to Canada, the Decree recognizes that, except in four cases, like asbestos-based products exist which offer "the same technical guarantees".[524] Fibro-cement products have replaced chrysotile-cement products. By offering the same technical guarantees as chrysotile-cement products, fibro-cement products undoubtedly have the same properties, are of the same quality and the same nature. Given that chrysotile-cement products and fibro-cement products have the same intrinsic qualities, that they are manufactured using the same technical process and that the Decree recognizes that they offer the same technical guarantees, for Canada, the obvious conclusion is that chrysotile-cement products and fibro-cement products are "like products".

3.422 Canada asserts that, according to the consumers' tastes and habits criterion, chrysotile fibre and PVA, cellulose and glass fibres, which are inputs in chrysotile-cement products and fibro-cement products, are "like products". Chrysotile fibre, PVA fibre, cellulose fibre and glass fibre are not products of mass consumption. These products are used by a limited number of economic agents, in particular the manufacturers of chrysotile-cement and fibro-cement products, who incorporate these fibres into their products. In so doing, these manufacturers are the consumers of chrysotile fibre for the purposes of the consumers' tastes and habits criterion. According to Canada, the drop in chrysotile asbestos imports intended for chrysotile-cement products in 1996 and 1997 is a result of the Decree and not of a sudden change in consumers' tastes and habits. To change the preferences of French consumers, the Decree on the banning of asbestos was necessary. The impact of the Decree does not reflect consumers' tastes and habits. Businesses manufacturing chrysotile-cement products have converted to substitute fibres or have closed down. The Decree forced these conversions or

[522] Cossette, M., *Substitutes for Asbestos*, December 1998, pp.1-3.
[523] *Id.*, p.23.
[524] Article 2 of the Decree.

closures. Canada maintains that, in determining the likeness of products, it is inappropriate to consider the criterion of the habits of manufacturers who were forced to convert to fibro-cements.[525]

3.423 Canada contends that chrysotile-cement products and fibro-cement products are both industrial products and it is almost impossible to distinguish between them based on their external appearance. Thus, in the eyes of the consumer, chrysotile-cement products and fibro-cement products are like products in all aspects, unless a data sheet is available showing which fibre makes up their composition. From the point of view of the tastes and habits of French consumers, chrysotile-cement products and fibro-cement products are interchangeable. The ban on the import of chrysotile-cement products did not cause a fall in the imports of fibro-cement products. Since the Decree took effect, the import of chrysotile-cement products has simply been replaced by the import of fibro-cement products. If products like asbestos-cement products had not been available, imports into France of fibro-cement products, which include asbestos-cement products, would have dropped immediately after the import of chrysotile-cement products was prohibited. According to Canada, the fact that it is impossible to distinguish between chrysotile-cement products and fibro-cement products based on their external appearance and their interchangeability are elements which indicate that consumers perceive these products as "like products".

3.424 Concerning tariff classification, according to the World Customs Organization, chrysotile-cement products and fibro-cement products are so similar that the 107 six- or eight-digit codes given to chrysotile-cement products in the Harmonized System are identical to the 107 codes given to fibro-cement products. Chrysotile-cement and fibro-cement products are in Heading 68.11 of the Harmonized System, i.e. the category relating to "Articles of asbestos-cement, of cellulose fibro-cement or the like". The World Customs Organization defines Heading 68.11 as follows:

> Chapter 68 – Articles of stone, plaster, cement, asbestos, mica or similar materials
> Heading 68.11 – Articles of asbestos-cement, cellulose fibro-cement or the like[526]
>
> | | | |
> |---|---|---|
> | 6811.10 | - | Corrugated sheets |
> | 6811.20 | - | Other sheets, panels, tiles and similar articles |
> | 6811.30 | - | Tubes, pipe and tube or pipe fittings |
> | 6811.90 | - | Other articles |

3.425 Canada indicates that this category includes fibro-cements made of cellulose, synthetic polymer (i.e. PVA) or glass fibres. As proof that chrysotile-cement and fibro-cement are like products, tiles, for example, made of chrysotile -cement, cellulose-cement or the like are given the same code, i.e. 6811.2011. Chrysotile fibre and PVA, cellulose and glass fibres, on the one hand, and chrysotile-cement products and fibro-cement products, on the other, are "like products" for the

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[525] *Japan – Customs Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages*, adopted on 10 November 1987, BISD 34S/83, para.5.7. Canada notes that, in this report, the Panel underlined that the effect of a tax measure, in this case, should not serve to "determine" consumers' tastes and habits and thus differentiate otherwise like products.

[526] *World Customs Organization*, Category 68.11, which states that**:** "This heading covers hardened articles consisting essentially of an intimate mixture of fibres (for example, asbestos, cellulose and other vegetable fibres, synthetic polymer, glass or metallic fibres) and cement or other hydraulic binders, the fibres acting as strengthening agents. These articles may also contain asphalt, tar, etc. These products are generally manufactured by pressing together thin layers of a mixture of fibres, cement and water or by moulding (possibly under pressure), by pressing or by extruding. The heading includes all sizes and thicknesses, obtained as described above, and also articles made by cutting these sheets or by pressing, moulding or bending them before they have set, e.g. roofing, facing or partition sheets and tiles; sheets for making furniture; window sills; sign-plates; letters and numbers; barrier bars, corrugated sheets; reservoirs, troughs, basins, sinks; tubing joints; packing washers and joints; panels imitating carving; ridge tiles, gutters, window frames; flower-pots; ventilation or other tubing, cable conduits; chimney cowls, etc. All these articles may be coloured in the mass, varnished, printed, enamelled, decorated, drilled, filed, planed, smoothed, polished or otherwise worked; they may also be reinforced with metal, etc."

purpose of Article III:4 of the GATT. This conclusion derives from the application of criteria such as the end-use of the products, consumers' tastes and habits, the properties, quality and nature of the products and their tariff classification. Each of the four criteria taken separately leads to the same conclusion.

3.426 The **European Communities** consider that asbestos and asbestos-containing products, on the one hand, and substitute products, on the other, are not "like" products within the meaning of Article III:4 of the GATT. According to established GATT practice[527], four specific criteria can be used to assess whether products are "like products": (i) their properties, nature and quality; (ii) their tariff classification; (iii) their end-use; and (iv) consumers' tastes and habits. The Panel Report on *United States - Gasoline*[528] held that "those criteria were also applicable to the examination of like products under Article III:4". On the issue as to what criteria should be applied in considering what are "like products", the Appellate Body report on *Japan - Taxes on Alcoholic Beverages* stated that:

> "No one approach to exercising judgement will be appropriate for all cases. The criteria in *Border Tax Adjustments* should be examined, but there can be no one precise and absolute definition of what is 'like'. The concept of 'likeness' is a relative one that evokes the image of an accordion. The accordion of 'likeness' stretches and squeezes in different places as different provisions of the *WTO Agreement* are applied. The width of the accordion in any one of those places must be determined by the particular provision in which the term 'like' is encountered as well as by the context and the circumstances that prevail in any given case to which that provision may apply."[529] [italics in the original]

3.427 The EC consider that Canada is confusing the concept of "like products" contained in Article III:4 of the GATT with that of "directly competitive and substitutable products" contained in Article III:2 of the GATT, read in conjunction with the relevant Interpretative Note. However, the two concepts are radically different. This can be seen by examining the texts in question. Article III:2 contains a concept that is not explicitly contained in Article III:4. The Panel report on *EEC - Measures on Animal Feed Proteins* noted that "the General Agreement made a distinction between 'like products' and 'directly competitive and substitutable products'."[530] Moreover, the Appellate Body has held that:

> "If imported and domestic products are not 'like products' for the narrow purposes of Article III:2, first sentence, then they are not subject to the strictures of that sentence and there is no inconsistency with the requirements of that sentence. However, depending on their nature, and depending on the competitive conditions in the relevant market, those same products may well be among the broader category of 'directly competitive or substitutable products' that fall within the domain of Article III:2, second sentence."[531]

3.428 The EC point out that, in the case at issue, although certain fibrous products (p-aramids, PVA, cellulose) and non-fibrous products (plastic, ductile iron) are indeed "substitutable" for chrysotile asbestos and products containing it, they are nevertheless not like products. Asbestos has unique physical characteristics and properties that make it difficult to replace for certain industrial purposes, especially in the chemical, petrochemical, aeronautical and nuclear industries. Amphibole asbestos is in fact the only product that is truly a like product to chrysotile asbestos. And it is precisely because

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[527] Report of the Working Party on *Border Tax Adjustments*, BISD 18S/97, para.18. Cited in particular by the Appellate Body in the Report on *Japan – Customs Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages*, adopted on 10 November 1987, BISD 34S/83, pp.22-26.

[528] *United States – Gasoline*, Appellate Body Report and Panel Report, adopted on 20 May 1996, WT/DS2/9, paras.6.8 *et seq*.

[529] *Japan – Taxes on Alcoholic Beverages*, Report of the Appellate Body, adopted on 1 November 1996, WT/DS8/AB/R; WT/DS10/AB/R; WT/DS11/AB/R, p.24.

[530] *EEC - Measures on Animal Feed Proteins*, adopted on 14 March 1978, BISD 25S/49, para.4.3.

[531] *Japan – Taxes on Alcoholic Beverages*, Report of the Appellate Body, adopted on 1 November 1996, WT/DS8/AB/R; WT/DS10/AB/R; WT/DS11/AB/R, p.28.

asbestos is uniquely suited for certain industrial uses that the Decree envisages some exceptions to the general prohibition.

3.429 The EC consider that, in this case, three criteria are pertinent when assessing the similarity of products pursuant to Article III:4. These criteria are the products' properties, nature and quality, tariff classification and end-use. As far as the tastes and habits of consumers are concerned, the EC consider that, while this criterion may be relevant in certain cases (everyday consumer goods), it is not relevant in the case of asbestos and asbestos-containing products. The Panel Report on *United States - Gasoline* also made use of the first three criteria, but ignored the tastes and habits of consumers.

3.430 The EC claim that the properties, nature and qualities of the products are different, both for asbestos fibres and substitute products and products containing asbestos and substitute products. As the EC have explained in their factual arguments, asbestos fibres have a very particular fibrous texture. They consist of bundles of small fibrils, stuck to each other. The fibrils separate very easily lengthways under the effect of machining, shock, vibration, friction (or simply draughts if it is a friable material) to form a cloud of very fine dust, often invisible to the naked eye, which can settle anywhere and penetrate very deep into the lungs. Asbestos fibres are minute in diameter (less than 1 micron) so there may be high concentrations in the air. According to the EC, the properties of asbestos fibres serve to underline their uniqueness. Although they pose a danger to health, their unique characteristics incontestably make them a mineral with exceptional physical and chemical properties. They do not burn, are remarkably resistant to various kinds of chemical attack and show high mechanical resistance to traction. No other product, natural or synthetic, exhibits all of the properties that asbestos fibres possess, for the simple reason that no substitute product has the same characteristics as these fibres. The explanatory notes to the Harmonized System ("HS") acknowledge the special nature of asbestos fibres, stating that:

> "Asbestos is a natural mineral substance produced by the decomposition of certain rocks. It has a very characteristic fibrous texture; it is sometimes silky in appearance and the colour varies greatly, being usually white, but sometimes grey, greenish, blue or dark brown …"[532]

3.431 The EC indicate that the characteristics of asbestos fibres make them particularly dangerous to health as they increase the risk of cancer. It is the diameter of a fibre that determines how long it will remain in suspension in the air. Consequently, the smaller the diameter, the higher the risk of cancer. In addition, the greater the fibrillation, the higher the risk of inhalation, again increasing the risk of cancer. Since 1977, the WHO has recognized the existence of a link between the characteristics of asbestos fibres and their danger to health by classing them (including chrysotile fibres) in "category I" of proven carcinogens. By contrast, none of the substitute products for chrysotile asbestos is classified as carcinogenic for man. Substitute fibres possess different characteristics from chrysotile: they are much bigger in diameter than asbestos fibres, up to 40 microns thick. Substitute fibres also show a more limited fibrillation capacity. Moreover, many substitute products are not fibrous in texture (for example, plastic, ductile iron or plaster). The EC point out in this connection that Canada mentions only fibrous substitute products (cellulose, p-aramid, PVA), making no reference at all to non-fibrous products. Yet non-fibrous products are very easily and commonly used instead of asbestos-cement, which used to account for 90 per cent of the chrysotile used in France. The EC conclude that the very nature, composition, physical properties and proven effects on human health of chrysotile make it radically different to substitute products, whether fibrous or non-fibrous. For this reason, in 1986 the ILO[533] – followed by the WHO in 1996[534]

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[532] Explanatory notes of the World Customs Organization, Harmonized System, note under heading HS 25.24 "Asbestos".

[533] *ILO, Convention concerning Safety in the Use of Asbestos (Convention 162)*, adopted on 24 June 1986, International Labour Conference, Geneva.

[534] Press release dated 26 July 1996.

and 1998[535] – recommended replacing asbestos by less harmful materials or technologies wherever possible.

3.432 Regarding asbestos-containing products and substitute products, the EC point out that asbestos fibres possess such special characteristics that they necessarily have an impact on the properties of the product in which they are incorporated, making that product extremely dangerous to health too. If one compares a PVC pipe with a chrysotile-cement pipe, for instance, it is impossible to say that the products are of the same nature. One is made of cement (with asbestos added), whereas the other is made of plastic. The EC note that if one compares a slab of chrysotile-cement used as a roof covering with a tile or slate, it is evident once again that the products are completely different in kind. They do not have the same properties or qualities either. Here again, in the EC's view, it is impossible to speak of "similarity" between asbestos-containing products and substitute products. The EC note that Canada is not wrong when it refers to "convergence" and "resemblance" in terms of the properties, quality and nature of the products concerned. But the fact remains that "convergence" and "resemblance" certainly do not mean "likeness" within the meaning of Article III:4 of the GATT. The EC claims that this lack of "similarity" between asbestos-containing products and substitute products is also confirmed by the fact that, as the materials obtained after replacing asbestos have different physical and mechanical properties from the material which contained asbestos, each substitution operation requires, on the part of manufacturers, careful checks on the properties of the new material and sometimes a complete redefinition of the field of application of the product. This is especially true in the case of gaskets and plaited sealing twine.

3.433 The EC assert that the tariff classifications are different, both for asbestos fibres and substitute products and for asbestos-containing products and substitute products. Canada does not deal with the question of tariff classification for asbestos fibres. It should be recalled that the explanatory notes to the Harmonized System ("HS") recognize the special nature of asbestos fibres by stating that "Asbestos … has a very characteristic fibrous texture …"[536] Given the differences due to the properties, nature and quality of asbestos fibres, the Harmonized System takes the logical step of classifying them under a single tariff heading: HS 25.24. This heading includes chrysotile asbestos fibre. The only other products covered by the same heading are the other varieties of asbestos fibres such as amphibole asbestos fibres. Substitute fibres, on the other hand, all fall under different tariff headings. The EC consider that, in the light of the tariff classification criterion, therefore, there can be no likeness between asbestos fibres and substitute fibres. In the second case – asbestos-containing products and substitute products – the EC point out that many substitute products come under a different tariff heading from asbestos-containing products. For example, rock wool and glass wool fall under heading HS 68.06, which does not cover asbestos-containing products. Some asbestos-containing products, on the other hand, fall under a specific tariff heading such as HS 68.12, which covers in particular clothing, cords, yarn and thread, and gaskets containing asbestos. This heading does not cover any products that do not contain asbestos. As for articles of chrysotile-cement (HS 68.11), the EC must point out that they can be replaced by many other products that fall under different tariff headings. For example: (i) articles of plaster come under tariff heading HS 68.09; (ii) articles of cement are under tariff heading HS 68.10; and (iii) plastic pipes come under tariff heading HS 39.17. By the criterion of tariff classification, the EC conclude that there can be no similarity between asbestos-containing products and products not containing asbestos.

3.434 The EC claim that the end-uses are different. Canada takes the line that the concepts of "like products" and "competitive or substitutable products" are equivalent and that the criterion of end-use is the key to determining what are "like products" within the meaning of Article III:4 of the GATT. However, the two concepts are radically different. Although end-use is the key criterion for

[535] *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, 1998, Geneva.

[536] Explanatory notes of the World Customs Organization, Harmonized System, note under heading HS 25.24 "Asbestos".

determining whether two products are directly competitive or substitutable[537], this is not true for "likeness" within the meaning of Article III:4, which is essentially "technical" in nature. The EC note that this was pointed out in the clearest terms in the Panel Report on *Japan - Taxes on Alcoholic Beverages*.

> "In the view of the Panel, the wording of the term 'directly competitive or substitutable' does not suggest at all that physical resemblance is required in order to establish whether two products fall under this category. This impression, in the Panel's view, was further supported by the words 'where competition exists' of the Interpretative Note; competition can and does exist among products that do not necessarily share the same physical characteristics. In the Panel's view, the decisive criterion in order to determine whether two products are directly competitive or substitutable is whether they have common end-uses, *inter alia*, as shown by elasticity of substitution. The wording of the term 'like products' however, suggests that commonality of end-uses is a necessary but not a sufficient criterion to define likeness. In the view of the Panel, the term 'like products' suggests that for two products to fall under this category they must share, apart from commonality of end-uses, essentially the same physical characteristics."[538]

In other words, the end-use is not in itself conclusive in deciding whether products are "like" within the meaning of Article III:4 of the GATT.

3.435 The EC argue further that, even where products may have some end-uses in common, that is not sufficient grounds to class them as "like products", if each of them also has many other end-uses. As the EC has already asserted above that asbestos and asbestos-containing products are different in terms of their properties, nature, quality and tariff classifications, the criterion of end-use cannot, by itself, invalidate the conclusion that such products are not "like" products within the meaning of Article III:4 of the GATT. In any event, substitute products can be used for many other purposes than the uses to which asbestos fibres or asbestos-containing products can be put, and vice-versa. For the EC, every asbestos-free substitute product necessarily has many uses that asbestos-containing products do not have. In conclusion, the Decree is compatible with Article III:4 of the GATT 1994 inasmuch as: (i) there is no protection of domestic industry; (ii) there is no discriminatory treatment of imported products compared with domestic products *de jure* or *de facto*; and (iii) there is no likeness within the meaning of Article III:4 of the GATT between asbestos and asbestos-containing products, on the one hand, and their substitute products on the other.

3.436 **Canada** contends that case law in the GATT and the WTO indicate that the concept of "like product" in Article III:2 must be interpreted narrowly. This narrow interpretation does not, however, apply to Article III:4, where the concept of likeness must be interpreted more broadly, given the purpose and context of Article III:4. Consequently, Article III:4 encompasses a broader range of like products than Article III:2, first sentence. Canada also refers to its response to question 34 of the Panel (see Annex III).

3.437 Canada indicates that, for the purposes of Article III:4 of the GATT, it does not invoke the argument of likeness with respect to non-fibrous substitutes (e.g. PVC, ductile iron). Nor does Canada extend the argument of likeness to non-fibrous products used as substitutes for chrysotile-cement products. The argument of likeness put forward by Canada is limited to glass fibre, cellulose fibre, and PVA fibre, even though the range of substitute fibres is broader, as well as to fibro-cement products incorporating these types of fibre. Canada does not consider that, in order to demonstrate the violation of Article III:4 of the GATT and Article 2.1 of the TBT Agreement, it is incumbent upon it to cite all the products like to chrysotile or to chrysotile-cement products. For there to be a violation,

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[537] *Japan – Taxes on Alcoholic Beverages*, Report of the Appellate Body, adopted on 1 November 1996, WT/DS8/AB/R; WT/DS10/AB/R; WT/DS11/AB/R, p.29.

[538] *Japan – Taxes on Alcoholic Beverages*, Report of the Panel, adopted on 1 November 1996, WT/DS8/R; WT/DS10/R; WT/DS11/R, p.113. The EC note that the Appellate Body did not contradict the Panel on this point, see the aforementioned Report of the Appellate Body, p.26.

it simply suffices to demonstrate that, for an imported product or a series of given products, there are like products that enjoy more favourable treatment. According to Article III:4, these like products must be of national origin. Canada notes that the EC go to a great deal of trouble to assert that PVC and ductile iron are not like products to chrysotile fibre and chrysotile-cement products. However, this analysis, although interesting, is completely irrelevant for determining whether glass fibre, cellulose fibre, PVA fibre, as well as fibro-cement products incorporating these types of fibre, are products like to chrysotile fibre and chrysotile-cement products.

3.438 Canada points out that, of the four criteria that can be used to determine the likeness of products, it takes into account end-use and tariff classification, as well as the product's properties, nature and quality. These criteria show that the products in question are like products. Canada also agrees with the EC that consumer tastes and habits are not relevant in this case.

3.439 Concerning the end-use criterion, Canada emphasizes that chrysotile fibre and chrysotile-cement products are like products to PVA, cellulose and glass fibres, and to fibro-cement products incorporating them. Canada reiterates the importance of an analysis of likeness on a "case-by-case" basis, i.e. based on the circumstances. In this case, because these products are inputs that cannot be used in their raw state, particular importance must be accorded to the end-use criterion in these circumstances. Canada notes that the EC appear to claim that the end-use criterion can be decisive only for determining whether two goods are directly competitive or substitutable according to Article III:2, first sentence. This question might be relevant if Article III:2 was being addressed, but this is not the case. Canada recognizes that end-use is a "decisive criterion" for determining the "substitutability"[539] or directly competitive nature of two products. In Canada's view, however, end-use is not the only relevant factor with respect to "substitutability", as the EC suggest. End-use can be equally important with respect to likeness, as the Panel dealing with Article III:2 in *Japan - Taxes on Alcoholic Beverage*s, asserts: "In the Panel's view, the wording makes it clear that the appropriate test to define whether two products are 'like' or 'directly competitive or substitutable' is the marketplace."[540] The market determines the end-use of a product. Canada notes that the EC maintain that substitutability and likeness are two radically different concepts. Canada takes the opposite view, like the Appellate Body in *Korea - Taxes on Alcoholic Beverages*, namely, that likeness is only a sub-set of substitutability and that like products are by definition substitutable.[541] In any event, the jurisprudential distinction between substitutability and likeness in Article III:2 is not necessary because in this case it is a question of Article III:4. The concept of substitutability is inevitably implicit in Article III:4 whenever products are deemed to be like products according to the broader criterion of likeness in Article III:4.

3.440 Canada indicates that the tariff classification of chrysotile-cement products is exactly the same for 107 separate products in the Harmonized System (HS). Heading 68.11 of the HS contains "Articles of Asbestos-Cement, of Cellulose Fibro-cement or the Like". The HS describes the products contained in heading 68.11 as follows: "This heading covers hardened articles consisting essentially of an intimate mixture of fibres (for example, asbestos, cellulose or other vegetable fibres, synthetic polymers [PVA] or glass fibres)."[542] All of the like products cited are found together, under 107 customs codes with six or eight common digits. For example, shingles made of chrysotile-cement, cellulose-cement, PVA-cement and glass-cement fall under code 6811.2011. Canada indicates that, despite these facts, the EC continue to argue, less than convincingly, that "By the criterion of tariff classification, therefore, there is no similarity between asbestos-containing products and products not containing asbestos." Canada is surprised that the EC simply reject the argument of

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[539] *Japan – Taxes on Alcoholic Beverages*, Report of the Panel, adopted on 1 November 1996, WT/DS8/R; WT/DS10/R; WT/DS11/R, para.6.22.

[540] *Id.*

[541] *Korea - Taxes on Alcoholic Beverages*, Report of the Appellate Body, adopted on 17 February 1999, WT/DS75/AB/R, WT/DS84/AB/R, para.118.

[542] Source: World Customs Organization.

likeness for the products cited by Canada merely by demonstrating that products which are not cited by Canada (PVC, ductile iron, rock wool, etc.) are not like products for the purposes of Article III:4. Such an approach is unfounded. Canada considers that the fact that glass wool or rock wool products do not fall under the same heading as chrysotile-cement products in no way changes the fact that chrysotile-cement products are found in exactly the same heading as articles containing PVA fibre, glass fibre and cellulose fibre.

3.441 Canada reaffirms its arguments regarding the properties, nature and qualities of the products in question and calls on the Panel not to lend too much weight to the distinctive physical properties of asbestos, put forward by the EC, i.e. that asbestos fibre is silky, and white, grey, green, blue or brown in colour. Canada notes that the EC are also endeavouring to reject the argument of likeness advanced by Canada by stating that the "lower" pathogenicity of substitute fibres makes it impossible to conclude that they are like products. As Canada has already asserted, the inadequate state of scientific knowledge about substitute fibres makes it impossible to conclude that they are less carcinogenic than chrysotile fibres. In any event, the fact that a product has a greater or lesser impact on health is not a criterion that makes it impossible to conclude that they are like products. In this respect, wine and vodka are like products, even if their effects on health are different.[543]

3.442 The **European Communities** emphasized that it follows clearly from a textual analysis of Article III:4 that the "like products" provision therein does not cover "directly competitive or substitutable" products. In fact, whereas Article III:2, second sentence, read in the light of the corresponding Interpretative Note, provides for an examination of directly competitive or substitutable products, Article III:4 mentions only the consideration of "like domestic products". This difference in the texts is not a matter of chance. If the authors of Article III:4 had intended to include an analysis of directly competitive or substitutable products, it would have had to appear in the text of Article III:4 or in an Interpretative Note, as was done in Article III:2, second sentence. Any other interpretation would result in giving a provision of the GATT a meaning that the signatories to the Agreement did not intend. The EC recall in this connection that the Appellate Body considered that "directly competitive or substitutable products" were a "broader" category than "like products".[544]

3.443 The EC, having already developed this point, only wish to point out that, at the first meeting of the Panel with the parties, Canada stated that "the Panel in *Japan - Alcoholic Beverages* stated that all similar products are, by definition, directly substitutable".[545] In the EC's view, however, the passage from the Panel Report mentioned by Canada needs to be cited in full. In fact, the Panel in *Japan - Taxes on Alcoholic Beverages* stated that:

> "In the view of the Panel, like products should be viewed as a subset of directly competitive or substitutable products. The wording ('like products' as opposed to 'directly competitive or substitutable products') confirmed this point, in the sense that all like products are, by definition, directly competitive or substitutable products, whereas all directly competitive or substitutable products are not necessarily like products."[546]

3.444 The EC also note that a Panel has already concluded that the concept of "like products" in the context of Article III:4 does not cover directly competitive or substitutable products. Thus, in the case of *EEC – Measures on Animal Feed Proteins*, the Panel observed that:

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[543] *Japan - Customs Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages Imported*, BISD 34S/83, adopted on 10 November 1987.

[544] *Japan – Taxes on Alcoholic Beverages*, Report of the Appellate Body, adopted on 1 November 1996, WT/DS8/AB/R; WT/DS10/AB/R; WT/DS11/AB/R, p.28.

[545] Canada's oral submission, 1 June 1999, para.290, See also para. 3.439 above.

[546] *Japan – Taxes on Alcoholic Beverages*, Report of the Panel, adopted on 1 November 1996, WT/DS8/R; WT/DS10/R; WT/DS11/R, para.6.22.

> "Having regard to its own conclusion with respect to 'like products', the Panel was satisfied that animal, fish and synthetic proteins could not be considered as 'like products' for the purpose of Article III:4. Since the obligations under Article III:4 relate to 'like products', the Panel concluded that the non-application of the EEC measures to these products was not inconsistent with the EEC obligations under the Article."[547]

The EC point out that, for a better understanding of this conclusion, it should be noted that the same Panel also pointed out that: " … vegetable proteins and skimmed milk powder were technically substitutable in terms of their final use and that the effects of the EEC measures were to make skimmed milk powder competitive with these vegetable proteins".[548] The EC maintain that, despite Canada's unfounded assertions to the contrary, it follows from these two paragraphs that Article III:4 does not cover directly competitive or substitutable products.

3.445 The EC thus confirm the arguments they have already put forward, namely that, even if they can be considered to be competitive or substitutable products, substitutes for asbestos fibres and asbestos-containing products are not "like products" within the meaning of Article III:4 of the GATT 1994. Substitute products, by definition, are only substitutable for other products. In the present case, the substitute products are only substitutable for asbestos fibres and products containing them to a very limited extent. In fact, in view of the multiple uses of asbestos, there is no single natural or synthetic product that alone could replace asbestos generally in all the products or materials that contain it. Thus, there is no substitute for asbestos, only alternative solutions that rely on substitutes which vary depending on the intended application and are sometimes used in combination in order to obtain a material or product that performs an equivalent function.

3.446 The EC claim that the nature/quality/properties criterion is clearly important for assessing likeness within the meaning of Article III:4 of the GATT. This follows from the practice of previous panels, which have always used the physical characteristics for the purpose of determining "likeness" within the meaning of Article III:4, but this is not the case for the other criteria. Thus: (i) the Panel on *Measures Affecting Alcoholic and Malt Beverages*[549] used neither tariff classification, nor end-use, nor consumers' tastes and habits for determining the "likeness" of the products within the meaning of Article III:4; (ii) the Panel on *EEC - Measures on Animal Feed Proteins*[550] used neither end-use nor consumers' tastes and habits for determining the "likeness" of the products within the meaning of Article III:4; (iii) the Panel on *United States - Gasoline*[551] did not use consumers' tastes and habits for the purpose of determining the "likeness" of the products within the meaning of Article III:4. The EC note, on the other hand, that all these Panels used the nature/quality/property criterion for examining likeness within the meaning of Article III:4 of the GATT, which underlines the importance of this criterion within the context of this provision. The EC add that, among these differences in the nature, properties and quality of the products, the health risk posed by the product must necessarily be taken into account. A dangerous product should be regarded as being different in nature and quality from a harmless or less dangerous product. The EC also emphasize that, even if the criterion of consumers' tastes and habits might seem to have little relevance to the present case insofar as the products concerned are not consumer goods, it might nevertheless be useful to analyse the consumer's perception of these products. There can be little doubt that informed users would not choose asbestos or asbestos-containing products after the competent international organizations had decided that asbestos was a proven carcinogen.

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[547] *EEC - Measures on Animal Feed Proteins*, adopted on 14 March 1978, BISD 25S/49, para.4.11.

[548] *Id.*, para.4.3.

[549] *Measures Affecting Alcoholic and Malt Beverages*, adopted on 19 June 1992, BISD 39S/206, paras 5.73-5.75.

[550] *EEC - Measures on Animal Feed Proteins*, adopted on 14 March 1978, BISD 25S/49, para.4.2.

[551] *United States – Gasoline*, Appellate Body Report and Panel Report, adopted on 20 May 1996, WT/DS2/9, para.6.9.

3.447 The EC assert that the criteria of likeness, in particular the nature/quality/properties criterion, mean that the substitute products are not "like" products with respect to asbestos and asbestos-containing products. Asbestos fibres are by definition "fibrous" products. It follows logically that, given this marked difference in physical characteristics, no non-fibrous substitute product could be considered a product "like" to asbestos fibres. As for "fibrous" substitutes, they cannot be considered "like" either within the meaning of Article III:4 because the morphology of asbestos fibres is different to that of "fibrous" substitutes. The fibres that must be taken into account in making a metrological assessment of a working environment have been defined by the WHO in accordance with the following dimensional parameters: (i) more than 5 microns in length; (ii) less than 3 microns in diameter; (iii) ratio of length to diameter greater than 3 microns [3:1]. Chrysotile fibres are 0.1 to 1 micron in diameter and separate lengthways into even finer crystalline fibrils (0.020 micron). The EC indicate that substitute fibres, on the other hand, have a different morphology. Thus, the polyvinyl alcohol and para-aramid fibres used to replace asbestos are 2 to 8 mm in length (i.e. 2,000 to 8,000 microns) and from 10 to 16 microns in diameter. Cellulose fibres, which are from 12 to 40 microns in diameter, can give rise to finer particles (fluff), which are said to irritate the respiratory pathways. These fibres are more than 10 microns in diameter, which physically prevents them from penetrating into the pulmonary alveoli. In addition, the EC stresses the analogy with the case *United States - Measures Affecting Alcoholic and Malt Beverages*.[552] If a beer containing the same substance (alcohol) is not "like" to another beer simply because it contains a different quantity of alcohol, then *a fortiori* a product containing a different type of fibre cannot be considered to be "like" a product containing asbestos. The EC also mention the case of *EEC - Measures on Animal Feed Proteins*, in which the Panel noted that "the varying protein contents and the different vegetable, animal and synthetic origins of the protein products before the Panel" were sufficient to conclude that "these various protein products could not be considered as 'like products' within the meaning of Articles I and III".[553] Similarly, the different origin of the fibres present in the substitute products containing them prevents these products from being considered "like" to products containing asbestos.

3.448 The EC note that Canada itself points out, in relation to the quality of fibrous substitutes, that they are often "of lower quality in terms of their physical, chemical and mechanical resistance". The EC also emphasize that asbestos fibres have certain characteristics that differentiate them from other fibres. Thus, asbestos fibres do not have the same physical characteristics as the substitute fibres, despite Canada's assertions to the contrary. Furthermore, within the context of this nature/quality/properties criterion, the EC maintain that, being hazardous, asbestos and asbestos-containing products cannot be considered as "like" to other products. In fact, asbestos is a hazardous product classified as such by the competent international bodies (a category I carcinogen) whose use can put the lives of thousands at risk. Its hazardous nature has a marked impact on the consumer's perception of the product. Thus, in 1989, the Supreme Court of Canada recognized that the risks associated with the use of asbestos were already a matter of common knowledge in 1973. In particular, it observed that:

> "It seems clear from the journals, newspapers, magazines and manuals which are discussed in detail in the courts below that asbestos-related health risks had spread well beyond the boundaries of industry knowledge and were in wide public circulation. […] Quite apart from the many studies and reports on asbestos-related health hazards published in various medical and scientific journals prior to the issuance of the policy, there were numerous articles published in newspapers across Canada and in the United States dealing with asbestos-related health hazards […] some of the articles in question were not published in obscure publications. These were prominent articles in the New York Times, the Wall Street Journal, the New Yorker magazine, the Washington Post and others. […] Did all of this lend a

[552] *United States - Measures Affecting Alcoholic and Malt Beverages*, adopted on 19 June 1992, BISD 39S/206.

[553] *EEC - Measures on Animal Feed Proteins*, adopted on 14 March 1978, BISD 25S/49, para.4.2.

> 'public character' and 'notoriety', within the meaning of Article 2486 C.C., to the asbestos-related health risks that existed in 1970 and 1973? In my respectful opinion, it did."[554]

3.449 The EC contend that not only North American consumers, but also European consumers, are perfectly well aware of the carcinogenicity of asbestos. Consumers may therefore take a different view of asbestos and asbestos-containing products, on the one hand, and the substitute products, on the other. This difference in perception reinforces the lack of similarity between these products. In these circumstances, it must be concluded that asbestos and asbestos-containing products are not "like" the substitute products within the meaning of Article III:4, in particular because the nature/quality/properties of these products are different from those of asbestos and asbestos-containing products, as is the consumer's perception of them, due to the health risks associated with the characteristics of asbestos. To conclude, the EC wish to draw attention to the paradox inherent in the observations made by Canada. Thus, Canada developed, at considerable length, arguments according to which amphibole fibres are very different to chrysotile fibres. The Canadian arguments related in particular to their physical characteristics. The EC consider that, resituated within the present context, Canada's arguments concerning a hypothetical similarity between asbestos and asbestos-containing products, on the one hand, and the substitute products, on the other, are even more surprising.

3.450 **Canada** emphasizes that, in their second written submission, the EC stated that the tastes and habits of consumers are relevant in order to determine whether products are like products.[555] However, in their first written submission, the EC do not identify the tastes and habits of consumers as a relevant criterion for the purposes of examining the similarity of asbestos products because they are not products in everyday use.[556] In their second written submission, the EC consider that the hazardous nature of asbestos has an effect on the way in which consumers perceive the product. According to the EC, the fact that consumers, rightly or wrongly, perceive chrysotile pipes as different to PVA, cellulose or glass fibre pipes from the risk standpoint supports the hypothesis that chrysotile-cement and fibro-cement are not like products. Canada states that such a hypothesis does not stand up to examination. Consumers' perception of the health risks of chrysotile and of substitute fibres is not an element that should be taken into account when determining the likeness of chrysotile fibres and substitute fibres. Moreover, it is not appropriate to consider the criterion of the tastes and habits of manufacturers of fibro-cement – the consumers whose tastes and habits count in this case – when determining the likeness of chrysotile fibres and PVA, cellulose or glass fibres. Canada agrees with the practice of the Panel in the three cases cited by the EC in paragraph 3.446 and asks the Panel not to take account of consumers' tastes and habits in order to determine the likeness of the products in this case.

3.451 Canada claims that, contrary to the EC's argument, the different origins of substitute fibres (artificial minerals, natural, organic, synthetic organic or natural organic minerals) do not prevent them being considered like products. The higher cost of substitute fibres in comparison with chrysotile fibres, and the fact they have a number of uses in addition to replacing chrysotile fibre, do not run contrary to the likeness of substitute fibres and chrysotile fibres within the meaning of Article III:4 of the GATT. The criterion of the nature, quality and properties of the product imply that chrysotile fibre and chrysotile-cement, on the one hand, and substitute fibres and fibro-cement, on the other, have qualities in common. Canada notes that, in their reply to question 9 of Canada (see Annex II), the EC recognize the relevance of the chemical composition of the fibres for determining likeness and relate it to the criterion of the nature, quality and properties of the products. Asbestos fibres have the same characteristics as substitute fibres. Even if the length, diameter and

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[554] Canadian Indemnity Company vs. Canadian Johns-Manville Company, Limited, 7 December 1989; 13 September 1990, spec. Part V, available on the Website of the Supreme Court of Canada: www.droit.umontreal.ca/doc/csc.scc/fr/index.html.

[555] See paras. 3.442-3.449 above.

[556] See para. 3.429 above.

width/diameter ratio have an effect on pathogenicity (one of the three "Ds"), in Canada's view this does not mean that fibres with different dimensions are necessarily not like fibres. Canada notes that, in paragraph 3.447, the EC state that fibrous substitute products cannot be considered as like products within the meaning of Article III:4 because the morphology of asbestos fibres is not the same as that of "fibrous" substitute products. The EC therefore maintain that substitute fibres for asbestos used in fibro-cement are too large to penetrate the lungs and cannot be taken into account when making a metrological assessment of a work environment according to the dimensional parameters set by the WHO. In Canada's view, the EC's conclusion is contradicted by the *Notice concerning chrysotile asbestos and possible substitute products*. This Notice clearly states that the characteristics of the fibres suggest that substitute fibres (PVA, p-aramids and cellulose) of the critical size and shape reach human pulmonary alveoli.[557] The dimensional parameters set by the WHO do not constitute the criterion of the nature, quality and properties according to which the likeness of fibrous products is determined. They help to identify fibres likely to reach far into the lungs. That is all. A fibre is a fibre, irrespective of its dimensions. Canada points out that the potential risks or harmlessness of chrysotile fibres is not an element to be taken into account in order to determine whether chrysotile fibres can be considered as "like" products to other fibres. Even if the toxicity of chrysotile is not the same as that of amphiboles, the chrysotile fibre is a "like" product to amphibole fibres. Likewise, some substitute fibres are like to chrysotile fibre because of their nature, quality and properties, irrespective of any differences in their toxicity potential. There is no contradiction between distinguishing two types of fibres at the scientific level and in relation to their pathogenicity, on the one hand, and applying the criteria utilized in the WTO and the GATT to determine whether products are like products. An examination of likeness in connection with the GATT and the WTO is different to an analysis of pathogenicity. The toxicity of a product is not recognized as a criterion when examining likeness.

3.452 The **European Communities** contend that Article III:4 does not cover "directly competitive or substitutable products". In fact, whereas Article III:2, second sentence, read in the light of the corresponding Note, provides for an examination of directly competitive or substitutable products, Article III:4 mentions only the consideration of "like domestic products". This difference in the texts is not a matter of chance. If the authors of Article III:4 had intended to include an analysis of directly competitive or substitutable products, it would have had to appear in the text of Article III:4 or in an Interpretative Note, as was done in Article III:2, second sentence. In the EC's view, any other interpretation would result in giving a meaning to a provision of the GATT which the signatories to the Agreement had not intended and would, therefore, not be supported by the generally accepted principles of treaty interpretation. The GATT case law relies essentially on the physical characteristics of products, i.e. the nature, quality and properties criterion, when assessing "likeness" within the meaning of Article III:4 of the GATT. In this case, the substitute products for asbestos can be non-fibrous or fibrous, although the vast majority is non-fibrous. The EC note that Canada accepts that non-fibrous substitute products are not "like" products in this case. In view of the multiple uses of asbestos, there is no single natural or synthetic product that alone could replace asbestos generally in all of its applications and for all the products or materials that contain it. Thus, there is no single substitute for asbestos, only alternative solutions which rely on substitutes that vary depending on the intended application and are sometimes used in combination in order to obtain a material or product that performs an equivalent function. For example, cellulose has been used for many years in a large number of applications, including as a partial substitute for chrysotile. The EC conclude that this very large category of substitute products with numerous potential uses, including as a substitute for asbestos, cannot be considered "like" within the meaning of the case law developed under the GATT.

3.453 The EC point out that, among these differences in the nature, properties and quality of the products, the health risk posed by the product in question must necessarily be taken into account. In fact, a dangerous product should be regarded as being different in nature and quality from a harmless

[557] See Section V of this report, the comments by Canada on the replies by the experts to question 6 of the Panel.

or less dangerous product. The EC point out that, at the meeting held on 17 January 2000, the four scientific experts clearly stated that all the substitute products used to replace chrysotile asbestos are safer than chrysotile-containing products. Therefore, the fact that chrysotile is carcinogenic has a special impact on the consumer's perception of the products containing it, compared to safer substitute products. The EC indicate that, contrary to Canada's claim, they have not changed their position, but have responded to the developments in the written and oral debates before the Panel. Therefore, even if the criterion of consumers' tastes and habits might seem to have little relevance to the present case, inasmuch as the products concerned are not to be consumed directly, it is nevertheless very useful to analyse the users' perception of these products when determining likeness. In these circumstances, in the EC's opinion, it must be concluded that asbestos and asbestos-containing products are not "like" the substitute products within the meaning of Article III:4 for three reasons: firstly, because the nature, quality and properties of these products are different to those of asbestos and asbestos-containing products; secondly, the consumer's perception of them is also different because of the health risks associated with the characteristics of asbestos; thirdly, the tariff classification of these products is also different to that of asbestos.

(iii) Imported products … shall not be subject to less favourable treatment

3.454 **Canada** claims that, by prohibiting sale, offering for sale or purchase, the Decree alters the conditions of competition on the domestic market for substitute fibres and products containing substitute fibres of French origin, on the one hand, and chrysotile fibres and products containing chrysotile fibre from Canada, on the other.

3.455 Canada asserts that France has an important fibro-cement industry. The two major producers of fibro-cement products are Eternit and Saint Gobain. Eternit manufactures PVA fibro-cement products and Saint Gobain glass-cement products. Eternit's products are manufactured at the former sites of four converted factories: Saint-Grégoire (Ille-et-Vilaine), Terssac (Tarn), Vitry-en-Charolais (Saône-et-Loire) and Thiant (Nord). Two production sites in France are used for the manufacture of glass-cement products: Descartes (Indre-et-Loire), where the factory has been converted, and Dunkerque (Pas-de-Calais), where two production lines have been introduced. PVA fibres, which are industrially synthesized, are of French origin. Glass fibres are also of French origin. Cellulose fibres are produced in France. The products marketed by Eternit are presented as a new generation of cement fibres without asbestos and are intended mainly for exterior siding and coverings. The glass-cement composites of the Saint Gobain group are used for cladding.

3.456 Canada claims that chrysotile fibre and chrysotile-cement products are subject to less favourable treatment than PVA, cellulose and glass fibres and fibro-cement products. The Decree banning asbestos is incompatible with the disciplines of Article III:4 of the GATT because its provisions subject chrysotile fibre and chrysotile-cement products to "treatment less favourable" than that accorded to like substitute fibres and fibro-cement products. According to the Panel's report in the case *United States – Section 337 of the Tariff Act of 1930*:

> "The words 'treatment no less favourable' in paragraph 4 call for effective equality of opportunities for imported products in respect of the application of laws, regulations and requirements affecting the internal sale, offering for sale, purchase, transportation, distribution or use of products."[558]

The French public authorities, in prohibiting the manufacture, processing, sale, export, release on the domestic market, possession for sale, offer and transfer on any basis of all varieties of asbestos fibres or of any product containing them, have eliminated the opportunities for competition by chrysotile

[558] *United States – Section 337 of the Tariff Act of 1930*, adopted on 7 November 1998, BISD 36S/345, para.5.11. See also *United States – Gasoline* cited above, para.6.10, and *Canada – Import, Distribution and Sale of Certain Alcoholic Drinks by Provincial Marketing Agencies*, adopted on 18 February, BISD 35S/37, para.5.6.

fibre and chrysotile-cement products on the French market. Canada maintains that the incompatibility of the Decree banning asbestos with Article III:4 of the GATT is due to the French Government's refusal to allow chrysotile fibre and products containing it imported from Canada the opportunity to compete, a benefit accorded fibres and like products of national origin.

3.457 The **European Communities** maintain that the contested measure accords with the fundamental purpose of Article III, which is to prevent protectionism. Before looking in detail at the specific provisions of Article III, and especially Article III:4, the interpretation of that article given by the Appellate Body in its Report on *Japan - Taxes on Alcoholic Beverages* must be borne in mind:

> "The broad and fundamental purpose of Article III is to avoid protectionism in the application of internal tax and regulatory measures. More specifically, the purpose of Article III 'is to ensure that internal measures "not be applied to imported or domestic products so as to afford protection to domestic production".'. Toward this end, Article III obliges Members of the WTO to provide equality of competitive conditions for imported products in relation to domestic products. (…) The broad purpose of Article III of avoiding protectionism must be remembered when considering the relationship between Article III and other provisions of the *WTO Agreement*."[559] [italics in the original]

3.458 The EC note that another Panel report *(United States - Measures Affecting Alcoholic and Malt Beverages*) indicated that:

> "The purpose of Article III is thus not to prevent contracting parties from using their fiscal and regulatory powers for purposes other than to afford protection to domestic production. Specifically, the purpose of Article III is not to prevent contracting parties from differentiating between different product categories for policy purposes unrelated to the protection of domestic production."[560]

In the EC's view, the measure complained of is not discriminatory, neither *de jure* nor *de facto*, inasmuch as it guarantees effective equality of opportunity for domestic and imported products, in accordance with the letter of the requirement spelled out in the Reports cited above and in the Report on *United States - Section 337 of the Tariff Act of 1930*.[561]

3.459 The EC maintain that the Decree does not introduce any *de jure* discrimination. Firstly, the context and circumstances in which the Decree was adopted show that it is in no way intended to discriminate against imported products or to protect domestic products. Its sole purpose is to curb the spread of any risk of death or serious illness linked to exposure to asbestos, in particular among those subject to repeated or occasional – and often unwitting – exposure. Secondly, none of the Decree's provisions makes a distinction in terms of treatment between French products and "like" imported products. For example: (i) both domestic asbestos fibres and imported asbestos fibres are prohibited; (ii) both domestic products containing asbestos fibres and imported products containing asbestos fibres are prohibited; (iii) both domestic asbestos fibres and imported asbestos fibres may be granted a temporary exemption on the same terms; (iv) both domestic products containing asbestos fibres and imported products containing asbestos fibres may be granted a temporary exemption on the same terms; and (v) both substitute domestic products and substitute imported products are permitted. It is thus clear to the EC that the Decree makes no distinction between imported products and domestic products, and neither its object nor its effect is to protect domestic production, so it is fully compatible with Article III.

3.460 The EC maintain that the Decree does not create any *de facto* discrimination. In its report on *Japan - Taxes on Alcoholic Beverages*, the Appellate Body recalled that "… Article III obliges

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[559] *Japan – Taxes on Alcoholic Beverages*, Report of the Appellate Body, adopted on 1 November 1996, WT/DS8/AB/R; WT/DS10/AB/R; WT/DS11/AB/R, pp.15 *et seq*.

[560] *United States – Measures Affecting Alcoholic and Malt Beverages*, adopted on 19 June 1992, BISD 39S/206, para.5.25.

[561] *United States – Section 337 of the Tariff Act of 1930*, adopted on 7 November 1998, BISD 36S/345.

Members of the WTO to provide equality of competitive conditions for imported products in relation to domestic products".[562] In this case, the effective equality of opportunity for domestic and imported products alike is not only reflected in law, but is also clearly evident from the facts. As the EC claimed in their factual arguments, most of the substitute products used in France are imported from various third countries. France has a negative trade balance in these substitute products. The EC note that, in Canada's view, the Decree favours the French fibre and substitute products industry. The fact is, however, that France chose to prohibit the use of asbestos on public health grounds. The changeover was a painful process, especially in human and financial terms, because the French measure prohibits exports of asbestos and asbestos-containing products, thus closing off external outlets for its domestic industries. Moreover, far from recommending the use of particular substitute products, the Decree leaves it to businesses to decide whether to replace asbestos by substitute fibre products or traditional products (plaster, ductile iron, etc.) of their choice. The Decree thus satisfies the "neutrality" requirement in terms of the choices made by enterprises, as set down in the Panel Report on *United States - Measures Affecting Alcoholic and Malt Beverages*:

> "The Article III:4 requirement is one addressed to relative competitive opportunities created by the government in the market, not to the actual choices made by enterprises in that market. Producers located in the states in question have the opportunity to choose their preferred method of marketing."[563]

The EC conclude that the Decree does not produce *de facto* discrimination between domestic products and imported products.

3.461 **Canada** maintains that the origin of the fibres claimed by Canada has not been disputed for all the like products, with the exception of PVA fibre. Canada notes that the EC claim that PVA fibres are produced only in China and Japan. Canada therefore wonders how it is possible for France to export PVA fibres if it has no industry manufacturing or processing them. In 1998 alone, France exported F 41 million worth of PVA fibres. These fibres exported by France are undoubtedly of domestic French origin.

3.462 Canada contends that the Decree discriminates by subjecting chrysotile fibre and products containing it to less favourable treatment than that accorded to similar substitute fibres and fibro-cement products containing them. Canada rejects the EC's arguments that the Decree does not constitute any form of *de jure* or *de facto* discrimination.

3.463 Canada maintains that the Decree, by prohibiting the manufacture, processing, sale, export, domestic marketing, possession for sale, offer or transfer on any basis of all varieties of asbestos fibres or of any product containing them, constitutes *de jure* discrimination in that it does not treat like products of national origin (substitute fibres or products containing them) in the same way. Not only does the ban apply only to asbestos fibre and products containing it, but, what is more, it is applicable only if there are like products to chrysotile fibre or to the products containing it. No exception to the ban will be permitted if there is a like product offering all the technical guarantees. The Decree therefore imposes a less favourable treatment in all cases where like products exist. What is more, the cases where an exception should be permitted, in the absence of a like product, are very rare. It is only on an "exceptional and temporary" basis that asbestos and asbestos-containing products may be granted effective equality of opportunity with like products of national origin. Canada notes that the EC claim that there is no *de jure* discrimination because asbestos fibres imported and of national origin are subject to the same treatment and because substitute products imported and of national origin are subject to the same treatment. In Canada's view, the EC are simply not comparing the right products. Article III:4 invoked by Canada provides that imported products "shall be accorded

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[562] *Japan – Taxes on Alcoholic Beverages*, Report of the Appellate Body, adopted on 1 November 1996, WT/DS8/AB/R; WT/DS10/AB/R; WT/DS11/AB/R, p.16.

[563] *United States – Measures Affecting Alcoholic and Malt Beverages*, adopted on 19 June 1992, BISD 39S/206, para.5.31.

treatment no less favourable than that accorded to like products of national origin". Canada indicates that the EC fail to compare the treatment given to imported products (chrysotile fibre and fibro-cement containing it) with that reserved for like products (PVA, cellulose or glass fibre and fibro-cement containing them). Canada calls on the Panel to conclude that the text of the Decree treats chrysotile and chrysotile-cement products less favourably than like products, and that the Decree therefore constitutes *de jure* discrimination.

3.464 Canada also claims that the effective inequality of opportunity available to imported products and to like products of national origin is apparent not only in law in the text of the Decree, but is also reflected in the facts. A total ban on chrysotile fibres and fibro-cement products can only benefit the French substitute fibres manufacturing and fibro-cement products industries. Canada points out that the EC, in their claim that the Decree does not favour the substitute products industry, cite a trade deficit in the case of PVA (the question of aramid fibres is not relevant to the analysis under Article III:4). In Canada's view, a trade deficit does not necessarily indicate that an industry is doing better or worse. In reality, the French PVA fibres industry is in better shape than ever; its exports more than doubled between 1994 and 1998. Canada notes that the EC also claim that the national cellulose fibre industry does not benefit from the ban, pointing out that imports from Canada have increased. This claim does not stand up to analysis: it is not because France has imported a marginal additional quantity of Canadian cellulose fibres since the Decree that the French domestic industry has not benefited from the ban to the detriment of imported products. According to Canada, the EC misleadingly use a passage from *United States – Measures Affecting Alcoholic and Malt Beverages* to claim that the Decree is neutral in its application and does not impose a choice on consumers. On the contrary, the Decree does indeed impose a choice on the French consumer, who is now prevented from using chrysotile fibre or products containing it. Finally, the fact that the asbestos industry in France has or has not suffered is of no consequence in this case. It is a matter of comparing the effects of the Decree on Canadian asbestos interests with its effects on French interests in the substitute products industries.

3.465 The **European Communities** refer the Panel to the arguments they have already put forward concerning the absence of *de jure* and *de facto* discrimination in the Decree's application (see paragraph 3.457-3.460 above).

3.466 The EC also point out that the Decree does not make any distinction between "like" national and imported products. It prohibits the use of all kinds of asbestos and asbestos-containing products in general, irrespective of origin. The substitute products used to replace asbestos are also treated in exactly the same way, irrespective of their origin. Therefore, the Decree in question does not discriminate in any way whatsoever, neither *de jure* nor *de facto*, between all types of asbestos of whatever origin and between all types of asbestos and substitute products for asbestos of whatever origin. Indeed, France imports very large quantities of a wide range of substitute products and treats them in exactly the same way it treats like substitute products of domestic origin, for the purpose of replacing asbestos. The EC also contend that the object and purpose of the Decree in question and the way it was elaborated confirm the view that the intention of the French authorities was not to protect domestic substitute products, but to protect human health from the risks of asbestos-related diseases. It follows that none of the conditions for the application of Article III:4 of the GATT is fulfilled in the present case. The EC maintain that, as Canada has failed to establish a violation of Article III:4 of the GATT, there is clearly no need to examine the applicability of Article XX(b) of the GATT in this case (see, for example, the Panel report on *Section 337* in 1989).

(c) Article XI of the GATT

3.467 **Canada** points out that, in the *Japan - Trade in Semi-Conductors* case, the Panel noted that " … this wording was comprehensive: it applied to all measures instituted or maintained by a contracting party prohibiting or restricting the importation, exportation or sale for export of products

other than measures that take the form of duties, taxes or other charges".[564] Canada maintains that the Decree is incompatible with Article XI:1 of the GATT, which applies to all measures instituted or maintained by a Member that prohibit or restrict the importation, exportation or sale for export of products, unless the measures are in the form of duties, taxes or other charges. Through the Decree, France is maintaining a ban or restriction on the importation of chrysotile and products containing it, other than by duties, taxes or other charges, contrary to its obligation under Article XI:1 of the GATT. Pursuant to Article 1, paragraphs 1 and 2, of the Decree, in order to protect workers and consumers " the importation … of all varieties of asbestos fibres, whether or not incorporated into materials, products or devices" is prohibited. Article XI:1 of the GATT applies because one aspect of the Decree deals specifically with prohibiting importation.[565] As a result of the total ban, producers of chrysotile or chrysotile-containing products, from Canada and elsewhere, cannot export their products to the French market. Similarly, French companies cannot import chrysotile fibre or products containing it because, with some limited and temporary exceptions, imports are prohibited and liable to a fine.

3.468 Canada points out that the penal provisions in the Decree prevent French industry from seeking to import chrysotile and, as a result, this product will never reach France's borders; similarly, a producer of raw chrysotile fibres will refrain from sending his product to France if he knows that its importation is prohibited. Since the Decree took effect on 1 January 1997, the chrysotile-cement industry has ceased operations. As of that date, the former chrysotile-cement industry was forced to convert to the use of chrysotile substitute products. Therefore, rather than speaking of the chrysotile-cement industry, the expression "fibro-cement industry" is now more appropriate. Canada claims that, in adopting the Decree, France instituted, and has since maintained, a prohibition or a restriction on the importation of chrysotile and chrysotile-containing products, originating in Canada and elsewhere, other than duties, taxes or charges, in violation of the provisions of Article XI of the GATT.

3.469 The **European Communities** claim that, as they indicated above[566], Article III:4 of the GATT is applicable and rules out application of Article XI.

3.470 **Canada** states that, in the event that the Panel recognizes the dual aspect of the measure, Canada refers it to the arguments put forward by Canada above.[567] If, however, the Panel decides that the Decree is indivisible and cannot involve two specific aspects that can be examined separately with respect to Article III:4 and Article XI:1 of the GATT, Canada is of the opinion that it must be deemed a measure affecting imports and, consequently, be examined in the light of Article XI:1. Taken as a whole, because of its substance and its true character, the Decree affects imports. It establishes a quantitative restriction on imports of chrysotile asbestos fibres. Among all the types of measure that come within the scope of Article XI:1 of the GATT, the quantitative restriction instituted by the Decree – the ban - is the most severe and the most extreme of all.

3.471 Canada claims that the Decree is a measure restricting or prohibiting imports within the meaning of Article XI of the GATT for a number of reasons. Firstly, the text of the Decree expressly stipulates that the "importation" of asbestos fibres and of asbestos-containing products is banned. According to the terms of Article 1, paragraphs 1 and 2, of the Decree, on the grounds of protecting workers and consumers "the importation ... of all varieties of asbestos fibres, whether or not these

[564] *Japan – Trade in Semi-Conductors*, L/6309, adopted on 4 May 1988, BISD 35S/116, para.104.

[565] Canada notes that the principle of the application of Article XI:1 in such circumstances has been established by several Panels under the GATT 1947, notably in *United States – Manufacturing Clause*, BISD 31S/74, adopted on 15/16 May 1984, para.34; and in *Japan – Trade in Semi-Conductors*, BISD 35S/116, adopted on 4 May 1988, paras.102 *et seq.*; and under the GATT 1994, in *United States – Shrimps*, Report of the Panel, WT/DS58/R, adopted on 6 November 1998, paras.7.11-7.17.

[566] See the EC's arguments in paras.3.395-3.400 and 3.403-3.407.

[567] See paras.3.467 and 3.468 above

substances are incorporated into materials, products or devices" is subject to a ban.[568] Secondly, as France does not produce or extract asbestos fibres on its territory, the ban on manufacturing, processing, selling and domestic marketing is equivalent, in practice, to an import ban on chrysotile asbestos fibres. With respect to chrysotile asbestos fibre, the ban on manufacturing, processing, sale and offering for sale are complementary to the import ban. These bans are a means by which France is pursuing a more basic objective, namely a ban on introducing chrysotile asbestos fibres into its territory. According to Canada, the EC acknowledge that the bans on manufacturing, processing, selling and marketing are complementary to the import ban. Indeed, they point out that deleting the word "importation" from the Decree would not change anything in the asbestos situation in France, which is equivalent to saying that the basic goals would in any case be attained: chrysotile asbestos fibres would not be introduced into France.[569] Thirdly, the Decree is a measure prohibiting or restricting imports within the meaning of Article XI by virtue of its goal. Canada notes that the EC claim that the goal indeed is to halt the spread of asbestos as far "upstream" in the production and distribution process as possible.[570] However, on French territory, the importation of chrysotile fibre represents the most "upstream" link in the commercial or industrial chain. The French Government has never concealed the fact that the goal of the ban was to prohibit asbestos on its territory in the future. With respect to asbestos fibres, this stated goal relates more to importation than to use because France does not produce asbestos fibres.

3.472 Canada points out that, even if the Decree were considered an internal regulatory measure, this would not necessarily mean that Article XI:1 would not apply. Article XI:1 can apply to an internal regulation that has the effect of restricting or prohibiting imports. Excluding any internal regulation from the scope of Article XI:1, simply because it is an internal regulation, would deprive the words "other measures" in the conclusion of Article XI:1 of any useful effect. Such an interpretation would also be contrary to the position adopted by the Panel in *Canada - Import, Distribution and Sale of Certain Alcoholic Drinks by Provincial Marketing Agencies*.[571] In that case, the Panel accepted the argument of the EC that the requirements of provincial liquor boards with respect to listing and delisting and points of sale, which discriminated against imported alcoholic beverages, were inconsistent with Article XI:1 of the GATT. However, the requirements in question were part of an internal regulatory framework as they concerned the distribution and marketing of alcoholic beverages. This did not prevent the Panel from concluding that these requirements were contrary to the provisions of Article XI:1 of the GATT. The Panel considered "that systematic discriminatory practices of the kind referred to should be considered as restrictions made effective through 'other measures' contrary to the provisions of Article XI:1".[572] The Panel also considered "that it was not necessary to decide in this particular case whether the practices complained of were contrary to Article III:4 because it had already found that they were inconsistent with Article XI".[573] Canada claims that, with respect to chrysotile asbestos fibres, the heart of the Decree is an import ban. For the purposes of this debate, which deals with Canadian imports of chrysotile asbestos fibres and their applications, the Decree, even when considered as a whole, must be deemed an import restriction or import ban within the meaning of Article XI:1 of the GATT, and examined in light of this provision.

[568] See footnote 565 above.
[569] See para.3.398 above.
[570] *Id.*
[571] *Canada - Import, Distribution and Sale of Certain Alcoholic Drinks by Provincial Marketing Agencies*, adopted on 18 February 1992, BISD 35S/37.
[572] *Id.*, para.4.24.
[573] *Id.*, para.4.26.

3.473 The **European Communities** maintain that the Decree must be examined as an internal measure to which Article III:4 of the GATT alone is applicable, thus ruling out the cumulative application of Article XI in this case.[574]

(d) Article XX(b) of the GATT

(i) Nature of Article XX and the burden of proof

3.474 The **European Communities** contend that, even if the Panel were to hold that the Decree is incompatible with Article III:4 of the GATT, it would nevertheless have to find that the measure falls under the exception provided in Article XX(b) of the GATT. Article XX allows Members an exemption from their obligations under the General Agreement subject to certain conditions. According to the precedent set by the Appellate Body in its Report on *United States - Shrimps*[575], the analysis of the measure in the light of Article XX must begin with the paragraph of Article XX invoked by the defending party, in this case (b), and continue with consideration of the introductory phrase ("chapeau") of that Article.[576] Following this line of approach, the EC will claim that: (i) the Decree is necessary to attain the underlying policy goal, in other words to protect human health and life (test of "necessary" in paragraph XX(b); (ii) the Decree is not applied in such a manner as to constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade ("chapeau" of Article XX).

3.475 **Canada** claims that it is clear from the practice of Panels that, in relation to Article XX(b), it is necessary to show that: (i) the policy which prompted the measure for which the provision is invoked falls within the category of policies intended notably to protect human life or health; (ii) the inconsistent measure for which the exemption is invoked is necessary to fulfil the objective of the aforesaid policy; and (iii) the measure is applied in compliance with the requirements of the introductory paragraph or "chapeau" of Article XX. The Appellate Body also noted that "... the ultimate availability of the exception is subject to the compliance by the invoking Member with the requirements of the chapeau".[577] Article XX permits a "*limited and conditional* exception from the obligations of the substantive provisions of the GATT"[578] [italics in the original] which must, according to the precedents, be interpreted narrowly.[579] Again according to the Appellate Body, " … the measures falling within the particular exceptions must be applied reasonably, with due regard both to the legal duties of the party claiming the exception and the legal rights of the other parties concerned".[580] Canada notes that the EC assert that they have the right to establish the level of protection they desire. In any event, this must be done in compliance with their obligations. The Appellate Body has condemned the abuse of rights under Article XX of the GATT.[581] Sir Leon Brittan, for his part, states that the WTO Agreements do not allow a country to invoke zero risk:

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[574] See the EC's arguments in paras.3.395-3.400 and 3.403-3.407 above.

[575] *United States – Shrimps*, Report of the Appellate Body, adopted on 6 November 1998, WT/DS58/AB/R, paras.83 *et seq.*

[576] *United States – Gasoline*, Appellate Body Report and Panel Report, adopted on 20 May 1996, WT/DS2/9, para.6.20.

[577] *United States – Shrimps*, Report of the Appellate Body, adopted on 6 November 1998, WT/DS58/AB/R, para.157.

[578] *Id.*

[579] See also *Canada – Administration of the Foreign Investment Review Act*, adopted on 7 February 1984, BISD 30S/140, para.5.20 and *United States – Section 337 of the Tariff Act of 1930*, adopted on 7 November 1989, BISD 36S/345, para.5.27.

[580] *United States – Gasoline*, Report of the Appellate Body, adopted on 20 May 1996, WT/DS2/AB/R, p.22.

[581] *United States – Shrimps*, Report of the Appellate Body, adopted on 6 November 1998, WT/DS58/AB/R, para.122.

> "Using the precautionary principle to justify action aimed at reducing risks to zero would clearly be excessive. We should therefore distinguish the precautionary principle from a zero risk approach. To try and adopt the latter across the board could bring us to a scientific standstill since there are risks involved in any new venture."[582]

3.476 Canada claims that it is up to the EC to demonstrate that the Decree is an exception to Article XX(b).[583] According to Canada, the EC did not discharge the burden of proof that lies with them in the arguments they put before the Panel.

(ii) Policy to protect human health

3.477 The **European Communities** maintain that, as explained in their factual arguments, because of their unique characteristics asbestos fibres and products containing them are a proven hazard for human health. The risks linked to the use of these fibres and products are recognized, both by the competent international organizations and by scientific studies, in particular the INSERM study, which was the basis of the Decree. The Decree seeks to halt the spread of this risk and thereby reduce the number of deaths among the French population. The measure taken is the only possible one that enables the spread of the risks due to asbestos exposure to be halted effectively. It therefore falls under the heading of measures for the purposes described in Article XX(b).

(iii) "… necessary to protect human health and life …"

3.478 The **European Communities** contend that the review in the light of Article XX cannot be allowed to undermine the health protection goal set by the Member concerned. Its sole purpose must be to assess whether the trade measure adopted is actually "necessary" to attain that goal. The Panel report on *United States - Gasoline* introduced the GATT 1947 rule on the test of necessity into the GATT 1994. The Panel noted specifically:

> "… the term 'necessary' had been interpreted in the context of Article XX(d) by the panel in the *Section 337* case which had stated that: a contracting party cannot justify a measure inconsistent with another GATT provision as 'necessary' in terms of Article XX(d) if an alternative measure which it could reasonably be expected to employ and which is not inconsistent with other GATT provisions is available to it. By the same token, in cases where a measure consistent with other GATT provisions is not reasonably available, a contracting party is bound to use, among the measures reasonably available to it, that which entails the least degree of inconsistency with other GATT provisions."[584] [italics in the original]

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[582] See notably *Who's Afraid of the WTO?:* Address by Sir Leon Brittan to the EPS Consumer Forum *Intergroup*, Strasbourg, 10 February 1999, available on-line: DG I, European Commission >http://europa.eu.int/comm/dg01/1002slb.htm> (access date: 15 May 1999). See *also Message of the European Community to the World Trade Organization*, High Level Symposium on Trade and the Environment, Geneva, 15-16 March 1999 available on-line: DG I, European Commission < http://europa.eu.int/comm/dg01/wtohlsf.htm> (access date: 15 May 1999) where Sir Leon Brittan states that "The principle does not mean [...] that a zero risk option should be pursued." See finally, on-line: *Green issues must be at the heart of the WTO, says Brittan*, European Commission, <http://www.eubusiness.com/approximately/990315co.htm> (access date: 15 May 1999): "I accept the legitimacy of the concept of precaution in the field of environment and health. However, there are dangers in allowing a general, open-ended precautionary principle without defining what it means and in what circumstances it might be used."

[583] According to Canada, it is well established that the burden of proof lies with the EC. See *United States – Gasoline*, Reports of the Appellate Body and the Panel, adopted on 20 May 1996, WT/DS2/AB/R and WT/DS2/9 p.22 and paras.6.20, 6.31 and 6.35; *Canada – Administration of the Foreign Investment Review Act*, adopted on 7 February 1984, BISD 30S/140, and *United States – Section 337 of the Tariff Act of 1930*, adopted on 7 November 1989, BISD 36S/345.

[584] *United States – Gasoline*, Appellate Body Report and Panel Report, adopted on 20 May 1996, WT/DS2/9, para.6.24.

3.479 The EC note that Panel report on *Thailand - Cigarettes* followed the same line of reasoning when reviewing a measure in the context of Article XX(b). This Panel saw no reason not to follow the same interpretation of "necessary" for Article XX(b) as for Article XX(d), stating that:

> "… the import restrictions imposed by Thailand could be considered to be 'necessary' in terms of Article XX(b) only if there were no alternative measure consistent with the General Agreement, or less inconsistent with it, which Thailand could reasonably be expected to employ to achieve its health policy objectives".[585]

It is this line of reasoning that should be followed in the present case in considering whether the French Decree is "necessary" in order to attain the goal of limiting the number of deaths caused by asbestos. The EC will claim that: (i) the ban is justified by the existence of risks to the health of the population; and (ii) the ban is the only measure that enables the objective set by the French authorities (halting the spread of the risk) to be attained.

3.480 The EC maintain that the test of necessity concerns the trade measure and not the level of protection set by the Member. They recall that the purpose of Article XX(b) is not to call into question the level of protection that a Member considers appropriate for its population. The fact that a Member is free to decide what level of protection it considers appropriate in order to safeguard the health of its population was firmly spelled out in the Panel Report on *United States - Restrictions on Imports of Tuna*[586], which stated that:

> "The Panel further noted that Article XX(b) allows each contracting party to set its human […] health standards. The conditions set out in Article XX(b) which limit resort to this exception [...] refer to the trade measure requiring justification under Article XX(b), not however to the life or health standard chosen by the contracting party. The Panel recalled the finding of a previous panel that this paragraph of Article XX was intended to allow contracting parties to impose trade restrictive measures inconsistent with the General Agreement to pursue overriding public policy goals to the extent that such inconsistencies were unavoidable." [587]

3.481 The EC point out that this principle was first established under the GATT 1994 in *United States - Gasoline*, when the Panel stated that:

> "… it was not the necessity of the policy goal that was to be examined, but whether or not it was necessary that imported gasoline be effectively prevented from benefitting from as favourable sales conditions as were afforded by an individual baseline tied to the producer of a product. It was the task of the Panel to address whether these inconsistent measures were necessary to achieve the policy goal under Article XX(b). It was therefore not the task of the Panel to examine the necessity of the environmental objectives of the Gasoline Rule…"[588]

3.482 The EC emphasize that there can be no questioning the right of the French authorities to decide the level of protection they wish to offer their population. According to the EC, this means that in this case the French authorities are free to choose to halt the spread of the risks due to exposure to asbestos, in particular for people who are occasionally and often unknowingly exposed to asbestos. The sole purpose of Article XX(b) is to consider whether the Decree is "necessary" as a regulatory option. The EC state that the so-called "safe" use advocated by

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[585] *Thailand - Cigarettes*, adopted on 7 November 1990, BISD 37S/200, para.75.

[586] *United States - Restrictions on Imports of Tuna*, circulated on 3 September 1991, not adopted, BISD 39S/155, para.5.27.

[587] The EC note that the Panel report on *United States - Restrictions on Imports of Tuna* refers to the Panel report on *Thailand – Cigarettes*, adopted on 7 November 1990, BISD 37S/200, paras.73 and 74.

[588] *United States – Gasoline*, Appellate Body Report and Panel Report, adopted on 20 May 1996, WT/DS2/9, para.6.22.

> Canada does not allow the objective of protecting human health, set by France, to be attained. Canada is thus setting trading interests above the legitimate goal of human health protection. The Panel Report on *Thailand - Cigarettes* states that: "this provision [Article XX(b)] clearly allowed contracting parties to give priority to human health over trade liberalization".[589]

3.483 The EC claim that the Decree constitutes the only adequate measure for the intended purpose. As was indicated in their factual arguments, the EC consider that the Decree pursues the realistic and "reasonable" goal of halting the spread of the risk due to any kind of exposure to asbestos, especially the risk due to occasional and often unwitting exposure. The EC maintain that the Decree is justified by the existence of risks to human health. Canada wrongly argues that asbestos and asbestos-containing products pose "no detectable risk" to health. In the EC's view, this claim relies on the contention that the risk due to levels of exposure in the atmosphere - on which Canada bases its entire submission - is comparable to the risks from the occasional but often very high levels of exposure that may be faced by a substantial proportion of a country's population. Canada seems to suggest that the dangers of inhaling asbestos only concern workers engaged in the extraction and processing of asbestos, in other words "primary users", whose number in Quebec is around 1,700. However, far from affecting only those involved in asbestos extraction and processing, the danger of inhaling asbestos at levels above the minimum threshold (0.1 fibre/ml) primarily concerns users of asbestos or asbestos-containing products, in other words "secondary users", whether occupational (workers in the textile, building, automobile industries, for example), para-occupational (servicing, maintenance), or domestic (such as do-it-yourself) users. In France, there are millions of such secondary users. Several hundred thousand daily users and several million occasional users thus come into contact with a product which, in 1977, was classed by the WHO as a proven carcinogen for humans (category I) and for which there is, according to the 1998 WHO report, no threshold of harmlessness. The EC note that Canada does not fully discuss the occupational risks and completely ignores the para-occupational and domestic risks, although these account for the vast majority of those who suffer exposure.

3.484 The EC maintain that, even in production and processing, which in principle are easier to monitor, there are limits to the so-called "safe" use of asbestos. The "controlled" use of asbestos does not halt the spread of the risks. The 1996 study by the British HSE found a substantially higher than normal incidence of deaths due to mesothelioma among workers entering the asbestos production and processing industries after 1969, in other words even after the United Kingdom had introduced "safe" use.

3.485 The EC also contend that not only is so-called "safe" use unable to halt the spread of risks from exposure to asbestos in production and processing – where the number of people involved is fairly limited and, in principle, easy to manage and control – but it is completely ineffective in cases of occasional exposure to asbestos. Indeed, the principle of "safe" use cannot be applied to the risks affecting a wide range of jobs involving an enormous variety of situations, especially in servicing and maintenance. These workers may only be exposed to asbestos occasionally, but they are subject to exposure peaks that sometimes far exceed the currently accepted dust thresholds. A worker using a grinder outside on corrugated asbestos-cement roofing is subject to a peak exposure of 41 fibres/ml – 410 times higher than the threshold. The EC note that a 1992 study by the Quebec CSST also shows that the risk of mesothelioma has been steadily rising in Canada since 1967, mainly among servicing and maintenance workers. Not once does Canada quote this study.

3.486 The EC point out that the same finding is all the more true for the general population at risk, in other words those who are exposed to inhalation of asbestos on a non-occupational basis. "do-it-yourself enthusiasts" are a typical example of a large sector of the public subject to exposure who are often unaware that this occasional or regular activity may expose them to a potentially fatal risk. According to the EC, Canada conveys the impression that the INSERM report did not appreciate the

[589] *Thailand – Cigarettes*, adopted on 7 November 1990, BISD 37S/200, para.73.

risks described above. Yet the INSERM report shows that it came to be realized during the 1980s and 1990s that the highest risk is no longer to workers in the asbestos industry, namely production and processing. The report clearly states that the risk occurs mainly among those who work with materials containing asbestos. With regard to para-occupational and domestic exposure, the INSERM report states:

> "These are studies which concern cases of mesothelioma in subjects with no known occupational exposure. Several case-control and cohort studies have shown the existence of cases of mesothelioma (pleural and/or peritoneal) attributed to exposure where the source was usually either soiled work clothing brought home by a person subject to occupational exposure or DIY activities. The levels of exposure to asbestos evaluated in these circumstances can be high, comparable to certain occupational exposures. The existence of an increased risk of mesothelioma among those exposed in para-occupational and domestic circumstances seems clearly established."[590]

3.487 The EC indicate that the INSERM report also states:

> "As far as para-occupational exposure is concerned - especially in connection with DIY activities - it is legitimate to consider the exposure peaks as identical to those found in industrial operations of the same nature. The main differences in the level of exposure, in terms of the dose inhaled, are in the length of exposure, as the DIY enthusiast does not generally perform these operations as frequently as the professional."[591]

3.488 The EC maintain that so-called "safe" use will not halt the spread of risk. The EC note that, in Canada's view, "safe" or "controlled" use of asbestos is possible and that, consequently, the prohibition is not "necessary" within the meaning of Article XX(b) of the GATT. Canada also cites the "negligible emissivity of chrysotile-cement products". In support of this statement, Canada argues that the "modern'' uses of chrysotile fibre mean that the fibre is bound in a matrix and cannot be released into the environment. The EC point out that what Canada describes as an innovation is nothing of the kind. For 40 years, the manufacture of asbestos-cement has involved "encapsulating" asbestos in cement (10 per cent asbestos fibres in 90 per cent cement). The EC indicate that, by referring to what it calls "modern" usage or even "modern" products, Canada is misleading the Panel by seeking to promote a "clean" image of chrysotile asbestos, although the name, while less ominous-sounding than amphibole asbestos, cannot hide the fact that is still classed by WHO in "category I" along with other products that are proven carcinogens for humans. The Panel should know that such "encapsulation" cannot be guaranteed to make asbestos-cement, for example, harmless. In fact, once the use of asbestos-cement is permitted, its use can no longer be controlled. Inevitably asbestos-cement, whether in an occupational, para-occupational or domestic context, will be worked in various ways – for instance by cutting, sanding, crushing or sawing. These operations will release large numbers of carcinogenic fibres in the form of dust. Consequently, the EC assert that the "modern" use of chrysotile asbestos to which Canada likes to refer is illusory and merely serves to mask the serious risks involved in the use of asbestos-cement.

3.489 The EC maintain that "safe" use is incapable of halting the spread of the risk due to occasional and often unwitting exposure to asbestos, because instituting the kind of tight constraints that are feasible for a small and "targeted" population - primary users - is wholly unrealistic for the general population. How could such use be effectively ensured for the hundreds of thousands of people exposed every day in sectors where there is little control in terms of health, such as the building industry, where at least 25 per cent of mesothelioma cases in France occur? Not to mention the millions of do-it-yourself enthusiasts subject to occasional and often unwitting inhalation of asbestos when performing quite ordinary operations such as cutting, for instance. The EC note that, as regards practical means of ensuring the effectiveness of "safe" use, Canada stated during consultations that there was no risk of asbestos fibres being released through cutting or sawing

[590] INSERM report, p.401.
[591] *Id.*, p.388.

asbestos-containing products as they were supplied "pre-cut". Canada also refers to an ISO standard issued more than 15 years ago, in 1984. The EC emphasize that, although the standard may have represented a major step forward at the time as compared with the earlier arrangements, it is not sufficient to guarantee an adequate level of protection, given the health objective of an exposure threshold of 0.1 fibre/ml that is recognized by many countries. The EC note that Canada states that "the cutting of roofing sheets or tiles is not a source of emission where the simple techniques laid down in ISO-7337 are followed". These "simple" techniques are: "the use of chains to break pipes by means of pressure, the use of low-speed saws or saws equipped with dust extractors, and the wetting of materials before any operation".

3.490 The EC point out that, in the real world, not all the pieces are pre-cut. And in the real world the thousands of people subject to occasional and unwitting inhalation of asbestos do not put on hermetically sealed protective suits when performing quite everyday tasks. Moreover, the use of a hand saw in accordance with the ISO standard leaves the worker exposed to a level 30 times higher than the permitted limit of 0.1 f/ml. According to the EC, Canada offers no answer to the problem of how to control operations performed further downstream in widely differing circumstances by many different people who are often unaware that they are being exposed to asbestos. The EC note that, once asbestos is on the market, there is no reasonable way of controlling its use and, in particular, of controlling the everyday operations (cutting, sawing, etc.) that many people are likely to perform on asbestos-containing products. In fact, there is clearly no way of ensuring that "safe" use as advocated by Canada can be effectively implemented. According to the EC, recent texts confirm that "safe" use is not feasible and this emerges very clearly from the 1998 WHO report, not cited by Canada, which states:

> "Some asbestos containing products pose particular concern and chrysotile use in those circumstances is not recommended. These uses include friable products with high exposure potential. Construction materials are of particular concern for several reasons. The construction industry work force is large and measures to control asbestos are difficult to institute. In-place building materials may also pose risk control to those doing alterations, maintenance and demolition. Minerals in place have the potential to deteriorate and create exposures."[592]

The EC add that, as the "safe" use of asbestos and asbestos-containing products is unable to halt the spread of risk and anyone affected by current exposure is quite likely to seek redress in the courts at some later stage. However, such claims for damages are notoriously hard to prove and run up against many obstacles, especially on the legal side. There is, then, this additional social justification for recognizing that the ban on asbestos is the only measure truly capable of halting the spread of the risk due to exposure to asbestos. That is the path France has chosen to follow. For the foregoing reasons, it is obvious that "safe" use cannot be implemented effectively and, in any event, significant risks remain for all categories of user.

3.491 The EC note that Canada gives the impression that France has prohibited asbestos and recommended the "indiscriminate use" of substitute products, reinforcing Canada's view that the measure is not necessary. This claim ignores the purpose of the French rules. Far from recommending the use of specific substitute products, the Decree leaves it to businesses to replace asbestos by whichever products or fibres they choose. The public authorities play no part in the actual choices made by enterprises on the market. In practice, firms will carry out technical tests with a view to replacing asbestos products by substitute products. However, if the tests are inconclusive and if firms can show that there are no safer substitute products, they can apply for an exemption in order to continue using asbestos. Such exemptions are provided for in the Decree and are granted only after careful scientific evaluation. Under the terms of Article 2 of the Decree, the use of asbestos is still permitted in exceptional cases and on a temporary basis, if there is no substitute which is capable of performing an equivalent function and which: (i) on the one hand, in the present state of scientific knowledge, poses a lesser occupational health risk to workers handling those materials, products or

[592] *IPCS Environmental Health Criteria (203) on Chrysotile*, WHO, Geneva, 1998, p.144.

devices; and (ii) on the other, provides all technical guarantees of safety corresponding to the use thereof. The EC point out that the replacement of asbestos fibres by substitute fibres is therefore reasonable and justified. In particular, it is grounded in the 1996 and 1998 WHO reports. To conclude on this issue, the EC reject Canada's claim that the only rationale for the excessive impact of the ban has to be the political will of the French Government to respond in spectacular fashion to the pressure it faced from public opinion. The EC maintain that their arguments set out above show, on the contrary, that the ban was the only appropriate solution capable of curbing the number of deaths due to exposure to asbestos. The foregoing shows that the Decree serves to attain the French policy goal regarding asbestos and is compatible with the test of necessity under Article XX(b).

3.492 **Canada** asserts that, in order to determine whether a measure falls under Article XX(b), it must first be examined whether the ban imposed by the Decree is "necessary" to protect human life or health. The only ban that the Decree adds, in practice, is the ban on chrysotile asbestos in non-friable products.[593] The only exposures that the Decree could affect are those, if any, to chrysotile encapsulated in high-density products. A measure will be deemed necessary "… only if there were no alternative measure consistent with the General Agreement, or less inconsistent with it, which [the party] could reasonably be expected to employ to achieve its health policy objectives".[594] The measure that one seeks to justify by invoking Article XX(b) must therefore involve the minimum restriction on international trade. Canada notes that the EC, taking the view that France's choice cannot be called into question, maintain that the French authorities have the right "to decide the level of protection they wish to offer their population … this means that in this case the French authorities are free to choose to halt the spread of the risks due to exposure to asbestos". However, in order to determine whether there is an equally effective alternative that is less restrictive for international trade and that is capable of protecting human life or health just as effectively, Canada considers that the health risk can and must be examined, regardless of what the EC say. The failure to consider whether in fact there is a risk would enable any country to cite a risk - real or not - in support of any prohibition measure.

3.493 Canada is of the opinion that the current uses of chrysotile in high-density non-friable products do not constitute a detectable risk to human health. The risks, which existed in the past and which still persist today in certain cases (amphiboles and friable materials in place), are associated with past uses of asbestos, very often amphiboles, in friable materials. Today, high-density non-friable chrysotile products do not pose a detectable risk. Canada notes that the EC identify the risk as existing both at the levels of extraction and processing and of secondary uses (textiles, construction, maintenance and custodial work, mechanics and do-it-yourself enthusiasts). According to Canada, the EC are clearly trying to mislead the Panel by invoking the risks of the asbestos extraction and processing industry, even though they have already recognized that controlled use is effective here in eliminating the risk. DG III affirmed in April 1997: "the principle of controlled use can be accepted in the asbestos industry".[595] INSERM is of the same opinion: "Given the occupational origin of exposures to asbestos, we are beginning to observe, in a few countries which instituted strict measures to protect workers at an early date, a stagnation in the trends of the incidence of mesothelioma."[596]

3.494 Canada asserts that the EC also show bad faith in citing the risks of building maintenance workers (electricians, plumbers, sheet metal workers and boiler-makers, etc.) and mechanics. The EC

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[593] Canada notes that the Decree is not aimed at the use of amphiboles and the manufacture of friable asbestos materials as these uses had already been banned in France.

[594] *Thailand – Cigarettes*, adopted on 7 November 1990, BISD 37S/200, para. 75. See also *United States - Section 337 of the Tariff Act of 1930*, adopted on 7 November 1989, BISD 36S/345, para. 5.26. See finally *United States – Gasoline*, Appellate Body Report and Panel Report, adopted on 20 May 1996, WT/DS2/9, para.6.24.

[595] European Commission (G. Lohan, DG III), European Justification of Decree No.96-1133 to the Canadian authorities (15 April 1997) following the French notification G/TBT/Notif.97.55, p.2.

[596] See INSERM report, p.182.

do not explain that these exposures are essentially to friable materials very often containing amphiboles of high pathogenic potential. Canada maintains that the risk associated with current uses of chrysotile, if any, is not detectable. According to the data of the United States Occupational Safety & Health Administration (OSHA), the institution of control measures lowers the average exposures of workers handling asbestos-cement pipes to 0.00253 f/ml and of workers handling asbestos-cement sheets to 0.00727 f/ml. The average exposure of mechanics handling friction products, is 0.00294 f/ml.[597] Canada indicates that, despite what the EC appear to believe, these hundreds of thousands of professionals have no need to don "space suits" every morning. Canada asserts that controlled use is sufficient. The use of pre-machined parts and fittings is not a far-fetched or utopian solution. According to OSHA: "pre-cut, pre-tapped pipe has received tremendous marketplace acceptance and represents a large majority of sales. [...] This is significant because the use of pre-cut, pre-tapped pipe may reduce or eliminate some types of field fabrication activities".[598] As a result of pre-fabrication, pre-machining, the use of fittings and compliance with work standards, workers are not exposed to rates of 3 f/ml.

3.495 Canada claims that the EC is wrong in stating that Canada is comparing the exposures associated with the use of chrysotile to those of ambient air. However, Canada, far from using ambient data, bases its position on data for occupational exposures under controlled use conditions to assert that there is no detectable health risk. As for do-it-yourself enthusiasts, Canada notes that the EC also show bad faith in failing to mention that these exposures are essentially attributable to friable materials containing amphiboles. Furthermore, they fail to mention the conclusions of the *Académie nationale de médecine* according to which "… no disease due to asbestos has been formally proven in France outside an occupational type of exposure".[599] Canada considers that few do-it-yourself enthusiasts, certainly not millions, work with high-density chrysotile products. Inasmuch as the only risk associated with asbestos is that of the past use of amphiboles and the use of friable materials, this risk cannot be eliminated by the Decree. The Decree, which prohibits the contemporary uses of chrysotile, is therefore not necessary - and even less useful - to protect human life or health from the risks associated with past uses of asbestos. Canada therefore asserts that the ban is not "necessary" to protect human life or health because high-density chrysotile products do not pose any detectable risk.

3.496 Canada contends that, in the event that, despite the scientific evidence submitted by Canada, Brazil and Zimbabwe, the Panel finds that contemporary uses of chrysotile are a hazard for human health, an examination of less trade-restrictive alternatives is necessary. In its arguments on controlled use, Canada has underlined the "possibility" and the effectiveness of controlled use. Controlled use indisputably constitutes an alternative to a total ban that is significantly less restrictive for international trade and eliminates the risk just as effectively, if any risk remains today. It follows from this analysis that the Decree banning current uses of chrysotile cannot fall under Article XX(b) because it is not necessary to protect human life or health.

3.497 Canada rejects the EC's claim that Canada is placing its trade interests ahead of the legitimate objective of protecting human health. Canada is rather of the opinion that the EC are misusing the objective of protecting human health to justify a measure that does not fall under the scope of Article XX(b). The Decree does not fall under paragraph (b) of Article XX and is not consistent with the introductory paragraph of Article XX. The EC therefore cannot take advantage of the exception provided in Article XX(b) to justify a violation of Article XI:1 and Article III:4 of the GATT. Lastly, Canada refers the Panel to the arguments on the concept of necessity in Article 2.2 of the TBT Agreement because, as it emphasized in its reply to question 33 of the Panel (see Annex II), Canada

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[597] See OSHA, on-line: OSHA: < http://www.osha-slc.gov/Preamble/AmendAsb_data/ASBESTOS_AB4.html> (access date: 20 June 1999), in Tables 5 and 6.

[598] *Id.*

[599] See Académie nationale de médecine (Etienne Fournier), *Amiante et protection de la population exposée à l'inhalation de fibres d'amiante dans les bâtiments publics et privés, Bulletin de l' Académie nationale de médecine*, vol.180, no.4, April 1996 .

contends that the criterion of necessity in Article 2.2 of the TBT Agreement is in many respects similar to that in Article XX(b) of the GATT.

3.498 The **European Communities** refer to the arguments put forward in connection with Article 2.2 of the TBT Agreement (see paragraphs 3.353-3.356 above), which also apply in the context of Article XX(b) of the GATT.

(iv) Preamble to Article XX

3.499 The **European Communities** recall that the Appellate Body stated that the "chapeau" of Article XX applies to: "… the manner in which that measure is applied" and that "If those exceptions [the exceptions under Article XX] are not to be abused or misused, … the particular exceptions must be applied reasonably…".[600] The Appellate Body also noted that:

> "The chapeau of Article XX is, in fact, but one expression of the principle of good faith. […] One application of this general principle, the application widely known as the doctrine of *abus de droit*, prohibits the abusive exercise of a state's rights and enjoins that whenever the assertion of a right 'impinges on the field covered by [a] treaty obligation, it must be exercised bona fide, that is to say, reasonably."[601]

Finally, the Appellate Body suggested that Panels should endeavour "to inquire into how the measure at stake was being *applied in such a manner* as to constitute abuse *or misuse of a given kind of exception*".[602] [italics in the original] The EC maintain that in the present case there is nothing to support the contention that France acted "in bad faith" or in an "unreasonable", "improper" or "abusive" manner in exercising its right under Article XX(b) of the GATT.

3.500 The EC maintain that the Decree is "reasonable". They note that, as has been recognized by the WHO since 1977, asbestos is a product that is a proven carcinogen for humans. It has caused thousands of deaths. So-called "safe" uses of the product cannot prevent deaths from mesothelioma among "primary users" (extraction and processing industries) and cannot feasibly be implemented for all para-occupational and domestic uses, which involve millions of people. Depending on their age, between 18 and 25 per cent of the male population in France have been exposed to asbestos at least once in the course of their working lives. Building industry trades account for a quarter of mesothelioma cases. In view of these figures, France considered that the only measure capable of halting the spread of the risk was the outright ban on the use of asbestos on French territory. The EC contend that, despite Canada's claims, France did not act on impulse. The French decision is based on a reliable scientific report that involved a critical and careful review of the most recent world scientific literature, proving the risks entailed by the use of asbestos, in particular for those subject to exposure in a para-occupational or domestic context. The report, like the Decree, was adopted after "mature reflection".

3.501 The EC claim that the Decree is not applied as a means of imposing arbitrary or unjustifiable discrimination between countries where the same conditions prevail. The prohibition covers products originating in any country (whether domestic or foreign), not only in Canada. The Panel report on *United States - Imports of Certain Automotive Spring Assemblies*, which dealt with a similar case, stated the following:

> "The Panel noted that the exclusion order was directed against imports of certain automotive spring assemblies produced in violation of a valid United States patent from all foreign sources, and not just

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[600] *United States – Gasoline*, Appellate Body Report and Panel Report, adopted on 20 May 1996, WT/DS2/9, pp.22 and 23.

[601] *United States – Shrimps*, Report of the Appellate Body, adopted on 6 November 1998, WT/DS58/AB/R, para.158.

[602] *Id.*, para.80.

> from Canada. It found, therefore, that the exclusion order was 'not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination against countries where the same conditions prevail'."[603]

3.502 The Appellate Body Report on *United States - Shrimps* elaborated on this idea, noting that:

> "In order for a measure to be applied in a manner which would constitute 'arbitrary or unjustifiable discrimination between countries where the same conditions prevail', three elements must exist. First, the application of the measure must result in *discrimination*. As we stated in *United States – Gasoline*, the nature and quality of this discrimination is different from the discrimination in the treatment of products which was already found to be inconsistent with one of the substantive obligations of GATT 1994, such as Articles I, III or XI. Second, the discrimination must be *arbitrary* or *unjustifiable* in character. We will examine this element of *arbitrariness* or *unjustifiability* in detail below. Third, this discrimination must occur *between countries where the same conditions prevail*. In *United States – Gasoline*, we accepted the assumption of the participants in that appeal that such discrimination could occur not only between different exporting Members, but also between exporting Members and the importing Member concerned."[604] [italics in the original]

3.503 The EC point out that, in this case, the application of the French measure does not involve any discrimination[605] between countries, including France, where the same conditions prevail. All countries that export asbestos or asbestos-containing products, including France (which used to have its own asbestos industry), are covered by the prohibition or by the exemptions, with no difference in treatment. As this does not meet the definition of discrimination laid down by the Appellate Body, the EC consider that the Decree is not being applied in such a manner as to constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail.

3.504 Lastly, the EC maintain that the Decree does not constitute a disguised restriction on international trade. On this question, the Appellate Body noted in its report on *United States - Gasoline* that:

> "… the kinds of considerations pertinent in deciding whether the application of a particular measure amounts to 'arbitrary or unjustifiable discrimination' may also be taken into account in determining the presence of a 'disguised restriction' on international trade. The fundamental theme is to be found in the purpose and object of avoiding abuse or illegitimate use of the exceptions to substantive rules available in Article XX. […] The resulting discrimination must have been foreseen, and was not merely inadvertent or unavoidable. In the light of the foregoing, our conclusion is that the baseline establishment rules in the Gasoline Rule, in their application, constitute 'unjustifiable discrimination' and a 'disguised restriction on international trade'."[606]

3.505 The EC have already shown that the Decree is not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail. This is proof enough that the Decree is not being applied in a manner which would constitute a "disguised restriction on international trade". The EC emphasize in this respect that: (i) the restriction applies to products of any origin (including domestic origin); (ii) the restriction is justified on public health grounds; (iii) the restriction was announced and published; (iv) many other Members of the WTO also apply restrictions to these products; and (v) the restriction takes international standards as a base. The EC therefore hold that the Decree cannot be considered as

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[603] *United States – Imports of Certain Automotive Spring Assemblies*, adopted on 26 May 1983, BISD 30S/107, para.55.

[604] *United States – Shrimps*, Report of the Appellate Body, adopted on 6 November 1998, WT/DS58/AB/R, para.150.

[605] Canada notes that the Appellate Body has held that this concept of discrimination is different from that already established under Articles I, III or XI of the GATT.

[606] *United States – Gasoline*, Appellate Body Report and Panel Report, adopted on 20 May 1996, WT/DS2/9, pp.25 and 29.

being applied in such a way as to constitute a "disguised restriction on international trade". Any other approach would imply that all international legislation on asbestos and asbestos-containing products (such legislation is, in practice, always restrictive) amounts to "a disguised restriction on international trade". The EC therefore maintain that they did not "abuse" or make "unreasonable" use of their right under Article XX(b) of the GATT.

3.506 **Canada** claims that, in the event that the Panel finds that the Decree is nonetheless covered by paragraph (b) of Article XX, the EC must justify it under the introductory clause of Article XX. However, "… it does not follow from the fact that a measure falls within the terms of [a paragraph of] Article XX that that measure also will necessarily comply with the requirements of the chapeau".[607] The introductory clause of Article XX prohibits any arbitrary or unjustifiable discrimination or disguised restriction on international trade. Whether a measure falls under one of these three types is commented on by the Appellate Body: "The fundamental theme is to be found in the purpose and object [of Article XX] of avoiding abuse or illegitimate use of the exceptions to substantive rules available in Article XX."[608]

3.507 Canada points out that it has already claimed, in respect of Article III:4, that the Decree was discriminatory. The Decree is arbitrary and unjustified first of all because the current uses of chrysotile do not pose any health risk. The ban is also arbitrary and unjustified because it does not have a solid scientific basis. It is arbitrary and unjustified because it takes the INSERM report as a basis for prohibiting current applications of chrysotile, even though this study did not assess the risks associated with modern uses of chrysotile. The ban is also arbitrary and unjustified because it is not motivated by the objective of protecting human life or health but rather by the desire to reassure a panicked population. According to Canada, even the French Senate and National Assembly state that the ban is "… a decision which concerns public opinion".[609] Furthermore, the purpose of the Decree is not to protect the population because it imposes, by its very nature, the blind use of substitute fibres whose lower toxicity is far from proven. What is more, the Decree fosters a false sense of security among the "reassured" population because the public is not afraid of the risks of substitute products, even though these risks are unknown and have not been quantified.

3.508 Canada claims that, in addition to constituting arbitrary and unjustified discrimination, the Decree also constitutes a disguised restriction on international trade. In order for a measure to be a "disguised" restriction on trade, it is not necessary that it be "concealed" or "unannounced". The Appellate Body excludes a narrow reading of the term "disguised restriction": "It is equally clear that *concealed* or *unannounced* restriction or discrimination in international trade does *not* exhaust the meaning of 'disguised restriction.'. " [italics in the original][610] Hence, the fact that the measure was published does not prevent it from being a disguised restriction on international trade. The ban is a disguised restriction on international trade and contrary to the introductory clause of Article XX in the sense that, under the cover of a public health decision, the Decree favours the French national industry of substitute products for chrysotile and products containing it.

(e) Article XXIII:1(b) of the GATT

3.509 **Canada** claims that the incompatibility between the Decree and the obligations of France pursuant to the TBT Agreement and the GATT establishes a presumption that a benefit pursuant to Article XXIII:1(a) of the GATT 1994 and of Article 3.8 of the Understanding has been nullified or

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[607] *United States – Shrimps*, Report of the Appellate Body, adopted on 6 November 1998, WT/DS58/AB/R, para.149.

[608] *United States – Gasoline*, Report of the Appellate Body, adopted on 20 May 1996, WT/DS2/AB/R, p.25.

[609] Le Déault, J.-Y. and Revol, H., *L'amiante dans l'environnement de l'homme: ses conséquences et son avenir*, (1990), 34 Ann. Occup. Hyg., 529.

[610] *United States – Gasoline*, Report of the Appellate Body, adopted on 20 May 1996, WT/DS2/AB/R, p.25.

impaired. However, in the event that the Panel were to conclude that the French measure complies with the TBT Agreement, the application of the latter nevertheless nullifies or impairs the benefits accruing to Canada under these Agreements, pursuant to Article XXIII:1(b) of the GATT. Within the framework of disputes arising from the GATT 1947, Article XXIII:1(b) was interpreted as meaning that, even if a measure is judged to be in compliance with the provisions of the GATT, such a measure may nevertheless be contested as nullifying or impairing benefits. Canada points out that, traditionally, panels under the GATT 1947 have deemed that three conditions must be met for a case of nullification or reduction of benefits in a non-violation situation. This reasoning was confirmed after adoption of the WTO Agreements in the matter *Japan – Measures affecting Consumer Photographic Film and Paper*.[611] These conditions are as follows: (i) the negotiation of a tariff concession; (ii) the subsequent adoption of a governmental measure unfavourably disrupts conditions of competition between the product for which the concessions were granted and the imported product that is a like or directly competitive product; and (iii) the adoption of the measure in question could not reasonably have been foreseen at the time of the tariff concession negotiations.[612]

3.510 Canada asserts that these three conditions are present in this case. First of all, asbestos and many asbestos-containing products are subject to tariff concessions granted by the EC during the Uruguay Round Negotiations.[613] At that time, the EC granted initial negotiating rights to Canada for asbestos. Asbestos and asbestos-containing products were the subject of tariff concessions by France starting in 1947;[614] they were taken up again by the European Economic Community after the 1960-1961 Tariff Conference and have been renewed until now.[615] Secondly, the effect of the Decree's adoption has been to disrupt the competitive relationship in the French market between, on the one hand, chrysotile asbestos fibre and products containing it and, on the other, like and competitive French products. In establishing a total ban, the Decree has destroyed this competitive relationship and has created a monopoly for substitute fibres and products containing them. Thirdly, at the time the tariff concessions were negotiated, Canada could not reasonably have foreseen that France would adopt the Decree. At the time of the negotiations on tariff concessions for asbestos, there was no indication that France was going to abandon its policy of controlled use of asbestos and compromise the value of its commitments by implementing a total ban on chrysotile and any possible use thereof.

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[611] *Japan – Measures affecting Consumer Photographic Film and Paper*, Report of the Panel, (not appealed), adopted on 22 April 1998, WT/DS44/R.

[612] *European Economic Community – Payments and Subsidies paid to Processors and Producers of Oilseeds and Related Animal-Feed Proteins*, adopted on 25 January 1990, BISD 37S/86, paras.142-154.

[613] Uruguay Round of Multilateral Trade Negotiations, Legal Instruments restating the results of the Uruguay Round of Multilateral Trade Negotiations effected in Marrakesh on 15 April 1994, volume 19, List LXXX – European Communities. After the 1996 binding, the numbers of the tariff items in this case, reproduced on the list CXL – European Communities are: 2524.00.30 (initial negotiating right), 2524.00.80 (initial negotiating right), 6811.10.00, 6811.20.11, 6811.20.80, 6811.30.00, 6811.90.00, 6812.10.00, 6812.20.00, 6812.30.00, 6812.40.00, 6812.50.00, 6812.60.00, 6812.70.00, 6812.90.10, 6812.90.90, 6813.10.10, 6813.10.90, 6813.90.10, 6813.90.90.

[614] General Agreement on Tariffs and Trade: Schedules of Tariff Concessions, vol. 3 (New York: GATT 1947), pp.32 *et seq*., Schedule XI – France, tariff item numbers 263, 1187A, 187B, 1188A, 1188B, 1188C, 1188D, 1188E, 1188F, 1188G, 1189.

[615] See *General Agreement on Tariffs and Trade: Protocol to the General Agreement on Tariffs and Trade Embodying Results of the 1960-61 Tariff Conference*, (Geneva: 16 July 1962), Schedule XL – European Economic Community – Part I: tariff headings 25.24, 68.13, 68.14.

3.511 Canada claims that, at the time of the negotiations on the WTO Agreements, it could in no way foresee that France was going to adopt a measure with regard to chrysotile that is obviously incompatible with the treatment it grants to other potentially hazardous products. Other raw materials, such as lead and copper, are potentially hazardous but are not banned. Certain uses of these products are indeed banned, restricted or subject to regulation. Canada was reasonably entitled to expect a similar approach to chrysotile on the part of France. The excessiveness of the French measure could not have been foreseen by Canada. The excess of the measure can be seen in the treatment given to chrysotile-cement products to be withdrawn from the market. As of 1 January 1997, stocks of chrysotile-cement products became "waste" to be handled and stored according to strict orders stipulated in two other measures adopted by France.[616] One of these measures is particularly revealing of the incompatibility and the excessive nature of the overall French regulatory approach to chrysotile. Indeed, a section of the *Note relative aux conséquences de l'interdiction de l'amiante et à l'élimination des déchets* [Note on the effects of the ban on asbestos and the elimination of waste] states that "for waste containing bonded asbestos […] if the waste is composed of asbestos combined only with inert matter, it may be eliminated in accordance with the circular of 9 January 1997 on the elimination of asbestos-cement waste".[617] If France recognizes that products containing bonded asbestos are inert, Canada cannot understand why it had to ban chrysotile and dense products containing it. Thus, a benefit accruing to Canada under the WTO Agreement was nullified or impaired. This benefit was seriously nullified or impaired, i.e. more than *de minimis*. For the foregoing reasons, the Decree has a negative effect on the objective of liberalizing international trade in the WTO Agreement, in violation of Article XXIII:1(b).[618]

3.512 The **European Communities** indicate that, in order to determine whether a measure nullifies or impairs a benefit enjoyed by a Member by virtue of the General Agreement, in the context of Article XXIII:1(b) of the GATT, it must be shown that: (i) the Member enjoys a benefit accruing to it under the GATT; and (ii) the measure in question nullifies or impairs that benefit. To conclude that a measure does indeed nullify or impair that benefit, the complainant must establish that: (i) the measure could not reasonably have been anticipated by that Member when the concession was negotiated; and (ii) the measure upsets the competitive relationship between domestic and imported products that prevailed before the measure was adopted. By way of a preliminary remark, the EC stress that the burden of proof for the application of Article XXIII:1(b) is particularly onerous as a result of Article 26:1(a) of the Understanding, which states that: "the complaining party shall present a detailed justification in support of any complaint relating to a measure which does not conflict with the relevant covered agreement". This provision essentially reflects the practice established under the GATT 1947. A forceful reminder of the weight of the burden of proof was also given under the GATT 1994 in the Panel Report on *Japan - Measures affecting Consumer Photographic Film and Paper*, which found that, in this context, it was the duty of the complainant to provide "a detailed justification for its claim in order to establish a presumption that what is claimed is true".[619] In the

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[616] *Circulaire no. 97-15 relative à l'élimination des déchets d'amiante-ciment générés lors des travaux de réhabilitation et de démolition du bâtiment et des travaux publics, des produits d'amiante-ciment retirés de la vente et provenant des industries de fabrication d'amiante-ciment et des points de vente ainsi que tous autres stocks*, dated 9 January 1997; and Note DPPR/SDPD/BGTD/LT/LT No 97-320 *relative aux conséquences de l'interdiction de l'amiante et à l'élimination des déchets*, dated 12 March 1997.

[617] Note DPPR/SDPD/BGTD/LT/LT No. 97-320 of 12 March 1997, Section III.

[618] Canada notes that Article 26.1 of the Understanding provides that: "Where the provisions of Article XXIII:1(b) of the GATT 1994 are applicable to a covered agreement, a panel… may only make rulings and recommendations where a party to the dispute considers that any benefit accruing to it directly or indirectly under the relevant covered agreement is being nullified or impaired or the attainment of any objective of that Agreement is being impeded as a result of the application by a Member of any measure, whether or not it conflicts with the provisions of that Agreement." The provisions of Article XXIII:1(b) apply to WTO Agreements (because the General Agreement is an integral part of the WTO Agreements under Article II:2 of the WTO Agreement) and to the General Agreement.

[619] *Japan – Measures affecting Consumer Photographic Film and Paper*, Report of the Panel, (not appealed), adopted on 22 April 1998, WT/DS44/R, para.10.32.

case at issue, the EC consider that the very brief explanations supplied by Canada are insufficient to discharge the burden of proof incumbent upon it. In any event, the EC claim that Canada's submission under Article XXIII:1(b) is unjustified for the following reasons: (i) Canada could reasonably have anticipated the French measure when the concession was negotiated under the Uruguay Round; and (ii) the French measure has not upset the competitive relationship between domestic and imported products that prevailed before the measure was adopted.

3.513 Before considering the conditions set out above, the EC point to the observations by the Panel on *Japan - Measures affecting Consumer Photographic Film and Paper*, namely, that the Article in question has been invoked only eight times during the fifty-year existence of the GATT 1947 and that "… most of the cases of non-violation nullification or impairment have dealt with situations where a GATT-consistent domestic subsidy for the producer of a product has been introduced or modified following the grant of a tariff concession on that product".[620] While acknowledging that Article XXIII:1(b) could be applied in contexts other than subsidies, the Panel stated that it "should be approached with caution and treated as an exceptional concept".[621]

3.514 The EC maintain that Canada fails to demonstrate how the French measure could not reasonably have been anticipated. The Panel on *Japan - Measures affecting Consumer Photographic Film and Paper* made the following comments regarding this condition:

> "The second required element which must be considered to establish a case of non-violation nullification or impairment under Article XXIII:1(b) is the existence of a benefit accruing to a WTO Member under the relevant agreement (in this case, GATT 1994). In all but one of the past GATT cases dealing with Article XXIII:1(b) claims, the claimed benefit has been that of legitimate expectations of improved market-access opportunities arising out of relevant tariff concessions. This same set of GATT precedents suggests that for expectations to be legitimate, they must take into account all measures of the party making the concession that could have been reasonably anticipated at the time of the concession ... Of course, as with the first element (application of a measure), the complaining party has the burden of demonstrating the 'benefit accruing'. […] If the measures were anticipated, a Member could not have had a legitimate expectation of improved market access to the extent of the impairment caused by these measures."[622]

3.515 The EC contend that it is important first of all to note that there can be no "legitimate expectations" in the case of a measure that is taken to protect human health and can therefore be justified, particularly with regard to Article XX(b) of the GATT or Article 2.2 of the TBT Agreement. While a Member may have "legitimate expectations" in connection with a purely commercial measure, no such expectations can be pleaded when it comes to health protection matters. The protection of human health is a fundamental duty of any government and it cannot be compromised or restricted by the concept of non-violation.[623] The EC contend that, by their very nature, science and scientific evidence are constantly evolving and a restriction on the right of Members to protect the health of their people, based on Canada's arguments, would run counter to the scope, aims and structure of the GATT as a whole. For example, a Member might have legitimate expectations of computer markets opening up, but it cannot have legitimate expectations of improved access to the market for a carcinogenic product. On the contrary, if there is any expectation, it is that access to that market may be barred or restricted rather than improved. In the EC's view, Canada has been unable to prove that the measure in question could not have been anticipated at the time when the concession

[620] *Id.*, para.10.38.
[621] *Id.*, para.10.36.
[622] *Id.*, paras.10.61 and 10.76.
[623] The EC note that Article XX states that, "Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:... (b) necessary to protect human, animal or plant life or health..."

was negotiated. Canada had good reason to suppose that France would adopt rules prohibiting asbestos.

3.516 The EC point out that, since 1977, asbestos fibres, in particular chrysotile, have been classified as category I carcinogenic products by the WHO. The EC claim that, when the tariff negotiations took place, Canada knew that there was a danger that the product under negotiation could at any time be prohibited by Members of the WTO, particularly if non-hazardous or less hazardous substitutes could be used. In 1986, ILO Convention 162 on asbestos stated that national legislation should provide wherever possible for the "replacement of asbestos or of certain types of asbestos or products containing asbestos by other materials or products or the use of alternative technology, scientifically evaluated by the competent authority as harmless or less harmful …".[624]

3.517 The EC maintain that the scientifically proven carcinogenicity of chrysotile and the impossibility of keeping the risk under control in all cases led the French Government to halt any spread of the risk by applying the principle recommended by the WHO and the ILO - and provided for by the European Union - with regard to carcinogenic products, namely that they be replaced by less hazardous products wherever technically possible. Since 1990, the European Community has provided for the replacement of asbestos under Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC), Official Journal L 196 of 26 July 1990. Under this Directive, the European Community recommends a framework for the health and safety of workers, including the principle of replacing a dangerous substance or process with a non-dangerous or less dangerous substance or process, where they exist. Regarding carcinogens, the principle is set out in the Directive on carcinogens, which provides explicitly for carcinogens to be replaced by less dangerous substances, preparations or processes where technically possible.[625] In 1983, WTO Members began to ban the use of asbestos, including chrysotile. The EC consider that the ban imposed by France could have been anticipated by Canada. Many WTO Members, including Canada itself, have banned amphibole asbestos for many years. In the EC's view, this means that Canada considered that it was impossible to envisage a "safe" use of amphibole asbestos. Based on this and the fact that chrysotile asbestos is classified in the same category of products proven to be carcinogenic for humans as amphibole forms of asbestos, Canada should have expected that several Members, including France, would take steps to ban chrysotile asbestos. Moreover, the EC indicate that France is not the first European Union country to have banned chrysotile fibre. Austria banned chrysotile in 1990, followed by Finland and Italy in 1992, and Germany in 1993. As several European Union countries have banned chrysotile asbestos, Canada could easily have anticipated that other European Union countries, including France, would follow suit.

3.518 The EC maintain that Canada's argument that it could not legitimately have anticipated the ban imposed by the Decree because France did not simultaneously ban other potentially dangerous substances (such as lead and copper) is misleading. There are no provisions in the GATT or the TBT Agreement requiring Members to be so consistent in applying health measures against substances that pose a carcinogenic risk for human health. The EC consider that accepting Canada's argument would be equivalent to preventing Members entirely from taking measures to protect human health on their territory. In the EC's view, Canada can no longer claim a legitimate expectation at the time of the

[624] ILO, Convention concerning Safety in the Use of Asbestos (Convention 162), adopted on 24 June 1996, International Labour Conference, Geneva, Article 10(a).

[625] Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) Official Journal L 196, 26.7.90, p.1. Council Directive 97/42/EC of 27 June 1997 amending for the first time Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) Official Journal L 179, 8.7.1997, p.4.

concession because such a legitimate expectation would have to concern "improved" market-access opportunities. It is clear that a product which entails risks for human health cannot legitimately offer "improved" market-access opportunities. Moreover, the facts clearly show that in industrialized countries the trend in asbestos fibre imports is going down rather than up. The EC maintain that Canada could not therefore have had a legitimate expectation that the opportunities for access to the market in chrysotile fibres would "improve". It also appears that the tariff concession invoked by Canada actually dates from at least as far back as the 1960-1961 negotiating round. The Panel on *Japan - Measures affecting Consumer Photographic Film and Paper* pointed out that "… the establishment of a case based on expectations from rounds concluded 18 or 30 years ago may be difficult".[626] In the case at issue, the EC maintain that Canada must give detailed reasons as to why it could legitimately have expected that France would not adopt measures restricting or eliminating the use of any asbestos product after the Uruguay Round negotiations, given the growing scientific evidence that all types of asbestos and asbestos-containing products were carcinogenic to humans.

3.519 The EC claim that Canada fails to demonstrate how the French measure upsets the competitive relationship between asbestos and fibrous or non-fibrous substitute products. As the EC maintained in the section relating to Article III of the GATT, there is no "similarity" between asbestos and fibrous or non-fibrous substitute products. Because of their different characteristics there can be no distortion of competition between these products. Asbestos and asbestos-containing products (and asbestos-cement in particular) are replaced by many fibrous or non-fibrous products (plaster, ductile iron, etc …). Finally, Canada's exports were essentially, if not exclusively, of raw chrysotile asbestos, which is like only to amphibole asbestos. The EC note that, on this subject, the Panel on *Japan - Measures affecting Consumer Photographic Film and Paper* found that:

> "… it must be demonstrated that the competitive position of the imported products subject to and benefitting from a relevant market access (tariff) concession is being *upset by* ('nullified or impaired ... as the result of') the application of a measure not reasonably anticipated... Thus, in this case, it is up to the United States to prove that the governmental measures that it cites have upset the competitive relationship between domestic and imported photographic film and paper in Japan to the detriment of imports. In other words, the United States must show a clear correlation between the measures and the adverse effect on the relevant competitive relationships."[627] [italics in the original]

3.520 The EC contend that Canada has in no way established such a clear correlation. Furthermore, the conditions of competition on the French market have not been upset. On this point, Canada claims that "the effect of the Decree's adoption has been to disrupt the competitive relationship in the French market between, on the one hand, chrysotile asbestos fibre and products containing it and, on the other, like and competitive French products". On this issue, the EC point to the findings of the Panel on *Japan - Measures affecting Consumer Photographic Film and Paper*: "in an Article XXIII:1(b) case the issue is not whether equality of competitive conditions exists but whether the relative conditions of competition which existed between domestic and foreign products as a consequence of the relevant tariff concessions have been upset".[628]

3.521 The EC claim that the products for which the competitive conditions must be examined are those covered by the tariff concession. If a tariff concession is granted for asbestos, the competitive conditions to be examined are those concerning Canadian asbestos and French asbestos. It is therefore irrelevant for Canada to try to compare chrysotile with French substitute products because such products cannot be considered in terms of the same relevant tariff concession. In conclusion, the EC consider that Canada has not provided detailed explanations to justify its claim that the Decree nullified a tariff concession which, in its view, it could legitimately have expected under the GATT.

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[626] *Japan – Measures affecting Consumer Photographic Film and Paper*, report of the Panel, (not appealed), adopted on 22 April 1998, WT/DS44/R, para.10.70.

[627] *Id.*, para.10.82.

[628] *Id.*, para.10.86.

3.522 **Canada** maintains all its arguments concerning the incompatibility of the French measure with Article XXIII:1(b) of the GATT. It contends that it could not have anticipated, at the time of the most recent tariff negotiations, that France would adopt such a drastic and unreasonable measure as a ban on all forms of asbestos and products containing it. Canada maintains that it could not have anticipated, at the time of the negotiations, that France was going to nullify and impair in this manner its tariff concession concerning chrysotile and products containing it. Canada maintains that, when a complainant proves that it enjoys a tariff concession and the respondent subsequently adopts a measure that affects the value of this concession, the complainant benefits from the presumption that it could not reasonably anticipate that this concession would be nullified or otherwise impaired by this measure. In such circumstances, it is up to the respondent to prove that the complainant should have anticipated the possibility that such a measure would be adopted.[629] In Canada's opinion, the EC have not proved this. Although Canada recognizes France's right to take action in order to protect human health and the health of workers, Canada could not reasonably have anticipated that France was going to adopt a measure totally prohibiting asbestos, without distinction as to the types of fibre or their use. This measure did not exist at the time of the negotiations and there was nothing to suggest that France was going to adopt such a radical measure as a ban on chrysotile and asbestos-cement. The lack of consistency in the nature of the regulatory intervention, as well as its severity compared to the type of regulatory intervention then in place in France and still in effect now concerning products equally harmful, if not more harmful, than chrysotile, mean that it would have been impossible for Canada reasonably to anticipate that France was going to act in the manner that it did.

3.523 Canada claims that, at the time of the most recent tariff negotiations, conducted by the EC during the Uruguay Round, France maintained a controlled use approach for chrysotile asbestos and there was nothing to suggest at the time that it was going to ban the product suddenly without any scientific reason to justify this maximum increase in the restrictive effects on trade in the products concerned. Similarly, at the time these concessions were negotiated, many hazardous products were, and still remain today subject to a controlled use approach whereby certain uses of these products continue to be permitted. Canada therefore had every reason to believe that the controlled use approach was going to continue to be preferred for these products, including chrysotile asbestos. Canada had every reason to believe that the adoption of such a radical measure as a total ban on asbestos was not going to be adopted. In light of the regulatory approach advocated by France up to that point, the extreme nature of such a measure made it unforeseeable. As Canada has already claimed, there is nothing exceptional in the case of chrysotile and products containing it in terms of risk management, if there is any risk. Other products, which moreover have been proven to be hazardous, are the subject of a controlled use policy. Furthermore, the effect of the French prohibition is to impose the replacement of chrysotile by a range of substitute products of domestic or foreign origin, even though they are suspected of being carcinogenic by the French authority which is presented as being the source of the ban on chrysotile, namely INSERM. In these circumstances, Canada's reasonable expectations were that the competitive position of imported chrysotile in France and of products containing it would not be affected by a measure such as a total ban, without distinction as to the types of fibre or their use, in favour of substitute fibres of domestic or other origin. Canada's reasonable expectations were also that this type of measure would not be adopted unless there were exceptional circumstances, which is certainly not the case with respect to the circumstances surrounding the use of chrysotile. There have been no new scientific developments that have changed anything in terms of managing the risks or the effects associated with chrysotile. Finally, Canada's reasonable expectations were that such a ban would not be adopted in favour of substitute products unless these products had been subjected to a rigorous process of examination to

[629] See *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Report of the Appellate Body adopted on 16 January 1998, WT/DS50/1/AB/R, para. 41; *Japan – Measures Affecting Consumer Photographic Film and Paper*, Report of the Panel (not appealed), adopted on 22 April 1998, WT/DS44/R, para.10.79.

prove that their use satisfies the public health objectives invoked by France. The evidence submitted by Canada in this respect shows very clearly that the substitutes do not meet this requirement.

3.524 Canada maintains that Article XXIII:1(b) of the GATT is applicable to the present case because the Decree radically alters the competitive conditions between chrysotile asbestos exported by Canada and substitute products. As a result of the Decree, the latter enjoy a decisive advantage over Canadian chrysotile asbestos, which can no longer be exported to France. Canada rejects the EC's claim that an examination of the impact of the Decree's effect on competitive conditions must be limited to Canadian asbestos and French asbestos, and exclude any examination of the competitive relationship between Canadian chrysotile asbestos and substitute products of French or other origin. Canada points out that this European claim is contradicted by the Panel decisions in *Treatment by Germany of Imports of Sardines*[630] as well as in *Australian Subsidy on Ammonium Sulphate*.[631] In the first case, the Panel sided with Norway on the basis of Article XXIII:1(b) of the GATT 1947, ruling that a German measure which resulted in a reduction of the customs tariff on sardines nullified or impaired a benefit accruing to Norway under a tariff concession relating to sprats and herrings. The Panel invoked Article XXIII:1(b) of the GATT 1947 because it considered that the German measure upset the competitive relationship between these species of fish. It should be noted that sprats and herrings, on the one hand, and sardines, on the other, were treated separately from a tariff standpoint and they were not considered by the Panel as like products for the purposes of Article I of the GATT 1947. Similarly, in *Australian Subsidy on Ammonium Sulphate*, the Panel concluded that benefits had been impaired or nullified within the meaning of Article XXIII:1(b) of the GATT 1947 because the Australian measure upset the competitive relationship between ammonium sulphate and sodium nitrate (mainly Chilean). These two fertilizers were treated separately from a tariff standpoint and were not considered by the Panel as like products. In Canada's view, these two cases therefore clearly establish that Article XXIII:1(b) can be invoked in the case of a measure which upsets the competitive relationship between two products that are not identical.

3.525 For these reasons, Canada asserts that, without regard to the question of whether the measure is consistent with the provisions of the GATT 1994, it nullifies or impairs the tariff concessions granted to Canada by the EC with respect to access to the French market for chrysotile asbestos and products containing it.

3.526 The **European Communities** point out that the Decree cannot be considered incompatible with the provisions of Article XXIII:1(b) of the GATT. The EC stress that the burden of proof, in the context of Article XXIII:1(b) of the GATT, is particularly heavy and lies with Canada. The EC consider that Canada has not provided sufficient evidence of incompatibility with this Article.

3.527 The EC claim that the rules on "non-violation" apply only if the measure in question does not fall under other provisions of the GATT. The EC recall that the Panel on *Japan - Measures affecting Consumer Photographic Film and Paper* noted that "We reach this conclusion in considering the purpose of Article XXIII:1(b), which is to protect the balance of concessions under GATT by providing a means to redress government actions not otherwise regulated by GATT rules ..."[632] The EC consider that Article XXIII:1(b) is applicable only if the Panel reaches the conclusion that the Decree is consistent with Article III of the GATT, or possibly with the TBT Agreement if the Panel were to apply that Agreement to the present case. Otherwise, the EC consider that there cannot be "non-violation". Moreover, in this connection, the EC recall that Article XX of the GATT provides, in particular, that "... nothing in this Agreement shall be construed to prevent the adoption or

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[630] *Treatment by Germany of Imports of Sardines*, Report of the Panel, adopted on 31 October 1952, BISD 1S/53.

[631] *Australian Subsidy on Ammonium Sulphate*, Report of the Panel, adopted on 3 April 1950, Vol.II/188.

[632] *Japan – Measures affecting Consumer Photographic Film and Paper*, report of the Panel, (not appealed), adopted on 22 April 1998, WT/DS44/R, para.10.50.

enforcement by any contracting party of measures: ...(b) necessary to protect human ... life or health". Similarly, the preamble to the TBT Agreement states that ".. no country should be prevented from taking measures necessary ... for the protection of human ... life or health ...". The EC therefore conclude that, if the French measure is considered "necessary" for the protection of human health by the Panel and hence if specific rules have been applied in this respect, the provisions of Article XXIII:1(b) of the GATT are inapplicable.

3.528 The EC maintain that Canada could not have "legitimate expectations" with respect to a measure taken to protect human health and which can therefore be justified, particularly with regard to Article XX(b) of the GATT or Article 2.2 of the TBT Agreement. While a Member may have "legitimate expectations" in connection with a purely commercial measure, no such expectations can be pleaded when it comes to health protection matters. The EC note, moreover, that the United States shares this point of view.[633] The EC indicate that Canada, which was aware of past and present scientific research and of the steps being taken by the relevant international organizations to encourage the rapid replacement of asbestos by substitute products, could not have had "legitimate expectations" arising out of relevant tariff concessions, whatever the date of those concessions.

3.529 **Canada** reiterates its arguments on non-violation set out above. The following comments are limited to rejecting certain claims by the EC in paragraphs 3.526-3.528. Canada notes that the EC claim that in a situation of non-violation no action can be taken against a measure deemed justified in accordance with Article XX of the GATT. According to Canada, the cases of *Uruguayan Recourse to Article XXIII*[634] and *United States – Trade Measures affecting Nicaragua*[635] do not support such an interpretation. In the Uruguay case, the Panel considered that measures to protect human health contrary to Article XI but justified under Article XX(b) could nevertheless lead to recourse in a non-violation situation. In the Nicaragua case, the whole procedure was based on the premise that the American embargo was justified under Article XXI. Although it would have been correct to claim that an appeal in a non-violation situation cannot be made if a measure is an exception, in the Nicaragua case, the Panel did not carry out an in-depth examination. This question was, however, never raised by the United States and the Panel therefore carried out an examination and published its findings.

3.530 Canada points out that the EC's reasoning is not substantiated for three additional reasons. Firstly, contrary to the EC's claim, inasmuch as Article 26:1(b) of the Understanding does not provide for the granting of compensation rather than withdrawal of a measure, recourse in non-violation affects neither "the adoption" nor "the application" of the contested measure. Secondly, the EC's attempt to develop a category of "measure(s) of a purely commercial nature" in comparison with a "measure which has health-protection related aspects" is, to say the least, dubious. Not only is it purely artificial, but this distinction has no basis, neither in the texts of the WTO Agreement nor in the case law. Nothing in Article XXIII:1(b) provides for such a distinction. Canada claims that a legitimate expectation does not in any way concern a particular measure or series of measures adopted by a Member, but rather legitimate expectations in relation to the opportunities for competition agreed during multilateral trade negotiations on a given product. Canada notes that the reasoning of the United States cited by the EC suffers from the same confusion. Lastly, the European reasoning is wrong because it does not concur with what was expressed during the preparatory work on the GATT 1947, as it appears in the theory "(…) one of the principal objectives of the Article [XXIII:1(b)] is to prevent circumvention of the provisions of [the Agreement]. Under this Article, if a Member State utilizes the exceptions provided in the Article [XX(b)] as a means of protection, any other Member may take the matter up with the ITO and obtain satisfaction. It is virtually impossible to foresee exceptions that will not lend themselves to abuse if good faith is lacking. The League of

[633] See Section IV above.

[634] *Uruguayan Recourse to Article XXIII*, L/1923, adopted on 16 November 1962, BISD 11S/95, paras.14-19.

[635] *United States – Trade Measures affecting Nicaragua*, L/6053 (1986), p.14.

Nations adopted an article along the lines of the Article [XXIII:1(b)] precisely because it was unable to find a formula for exceptions that excluded any possibility of abuse".[636] Canada claims that it has provided detailed proof of the elements set out in the case of *Japan – Measures affecting Consumer Photographic Film and Paper*[637] that make it possible to determine that the French measure, even if consistent with the GATT, nonetheless nullifies or impairs benefits accruing to Canada under the WTO Agreements or the attainment of one of the objectives of the Agreements.

3.531 The **European Communities** claim that the Decree is not incompatible with the provisions of Article XXIII:1(b) of the GATT and its case law. As they have already pointed out, it is not possible to claim "legitimate expectations" with respect to a measure that is taken to protect human health and can therefore be justified, particularly with regard to Article XX(b) of the GATT or Article 2.2 of the TBT Agreement. While a Member may have legitimate expectations in connection with a purely commercial measure, no such expectations can be pleaded when it comes to measures taken to protect human health. This is also the position taken by the United States in its third party intervention. The EC note that Canada referred to two Panel Reports, one concerning Uruguay (1962)[638] and the other Nicaragua (1986)[639], to claim support for its proposition that a non-violation claim can be made in this case. According to the EC, neither of the two Panel Reports referred to by Canada, nor any other panel report, lends support to such claims. The first Panel has no relevance whatsoever to the issues discussed here. The second, unadopted, Panel Report in the Nicaraguan case is also irrelevant, as the Panel in that case specifically stated that it refrained from taking any position on the non-violation claims made by Nicaragua. The EC note that Canada also argued that the background to Article XXIII.1(b) supports the view that non-violation complaints may and should remain possible to deal with situations of bad faith and abuse in the application of the provisions of the General Agreement and of Article XX. This is not correct. Canada takes a selective look at some parts of the preparatory documents. As the Appellate Body stated in the *United States - Shrimps* case, the conditions laid down in the chapeau of Article XX(b) are meant precisely to address situations in which a Member applies in bad faith and in an abusive manner the exceptions laid down in Article XX. In the EC's view, this means that the potential problem of abuse and bad faith, alluded to by Canada, is adequately covered by the "chapeau" of Article XX and there cannot be two sets of provisions (non-violation and the chapeau of Article XX) which address the same problem twice. The EC therefore propose that this argument of Canada also be rejected.

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[636] Analytical Index, p.764.
[637] WT/DS44/R.
[638] *Uruguayan Recourse to Article XXIII*, L/1923, adopted on 16 November 1962, BISD 11S/95, paras.14-19.
[639] *United States – Trade Measures affecting Nicaragua*, Report circulated on 13 October 1986, not adopted, L/6053.

IV. ARGUMENTS PRESENTED BY THIRD PARTIES

A. BRAZIL

1. Introduction

4.1 Brazil explains that the proceeding challenges the WTO-consistency of France's 1 January 1997 Decree, which bans the manufacture, processing, sale and possession for sale, importation, exportation, domestic marketing, offer and transfer of all varieties of asbestos fibres and products containing them (the Decree or the ban).[1] The ban has four narrow exceptions that apply where no substitutes exist for chrysotile products. The substitute products that do exist generally are more expensive than chrysotile products. Thus, the ban clearly operates to create a commercial advantage for substitute products. According to Brazil, a ban is the most trade restrictive of measures. Therefore, the justification for any ban must be subject to the strictest scrutiny, especially as applied to a developing country such as Brazil. The ban has ended Brazilian exports of uncontaminated chrysotile to France. In 1994 and 1995, France imported from Brazil 1,100 and 1,500 metric tonnes of uncontaminated chrysotile, respectively. Since the ban took effect in 1997, France has not imported any chrysotile from Brazil.

4.2 According to Brazil, the importance of this proceeding extends far beyond the French ban – the proceeding is a test case. Will other WTO Members be allowed to ban products of developing countries that can be safely used with appropriate, tested precautions simply to appease the public? Modern economies use hundreds of products that present health risks if they are misused, but that present no risks if they are used properly. Uncontaminated chrysotile is one of them; if properly used, uncontaminated chrysotile presents no health risk. Similar products include organic fibres, man-made fibres, benzene, mercury, ammonia, nearly all forms of pesticide, etc. Societies regulate these products to ensure they are used safely so as to protect the health of workers handling them directly and of the general population which is exposed to them indirectly. The same treatment is appropriate for uncontaminated chrysotile. Uncontaminated chrysotile—the only asbestos fibre Brazil mines and exports – is the safest by far of all asbestos fibres. In particular, it is much safer than amphibole, the asbestos responsible for current health problems from past exposure. All of the asbestos that Brazil mines, produces and exports is uncontaminated chrysotile. For this reason, Brazil's chrysotile products are among the safest in the world. The medical explanation for these facts is set forth in detail in a recent bio-persistence study by Dr. David S. Bernstein, an expert in fibre toxicology (indeed, the EC often seeks his expertise on this topic).[2]

4.3 Brazil asserts that the primary issue in this proceeding is not - as the EC would suggest - whether asbestos can be hazardous to human health. It can. Years of misuse and unsafe utilization of the most hazardous form of asbestos – amphibole - have caused significant damage to health. All countries, including Brazil, regret the harm to human health caused by decades of exposure earlier this century to amphibole produced and used worldwide. Brazil understands well the basis of the public outcry, experienced in many countries (including Brazil), that led the French Government to commission the INSERM Report[3] (a study focusing on the health effects of earlier, unsafe uses of amphibole asbestos) and then to ban asbestos. France imposed the ban only one day after INSERM released its Report. The Report was commissioned and released to provide a scientific "cover" for a political decision that had already been taken. However, as a review of the INSERM Report demonstrates, the causes of asbestos-related health problems in France are past uses, especially in the

[1]Decree No. 96-1133, dated 24 December 1996, (J.O. dated 26 December 1996).

[2]David S. Bernstein, *Summary of the Final Reports on the Chrysotile Bio-Persistence Study* (Geneva Switzerland; 2 October 1998).

[3]INSERM, *Effets sur la santé des principaux types d'exposition à l'amiante*, Les Éditions INSERM, Paris, 1997 (INSERM Report).

spraying of brittle amphibole on to fireproof buildings and, until quite recently, warships (flocking). Given the long latency period between exposure to amphibole and the onset of any related diseases, workers who were victims of heavy exposure with virtually no protection 30 years ago are experiencing serious health problems today. The INSERM Report is based on analyses of these workers' health. The INSERM Report does not focus on data from studies of modern uses of chrysotile. Moreover, in the Report, INSERM concedes that it was unable to produce "scientifically certain" conclusions, but could present only an "aid to understanding" based on "plausible, though uncertain, estimates.[4]" Quite simply, the INSERM Report is an inadequate basis for the ban.

4.4 Brazil argues that it has a deep appreciation of the desire - indeed, the need - for the French Government to address public concern and protect public health. Brazil also understands the frustration of being unable to remedy or even mitigate the health consequences of past exposure from unsafe use of amphibole, and the frustration of being unable to take measures to remedy or decrease exposure from flocked amphibole asbestos that is already in French buildings (because disturbing flocking increases exposure). However, when France approved the WTO Agreement, it agreed not to restrict trade merely to appease domestic sentiment, no matter how strong. Brazil cannot accept France's adoption of a politically motivated measure that will neither (i) make those already sick from asbestos exposure healthy; nor (ii) reduce risk to the healthy beyond existing levels of protection guaranteed by modern, controlled uses of chrysotile. As the European Commission recently stated:

> [V]arious national organisations, including the Health and Safety Executive in the United Kingdom, have made very disturbing projections about the numbers of deaths which are likely to be attributable to asbestos over the next few decades. However, it is important to note that these figures relate to past exposures to mixed asbestos types, including the fibres which have already been banned. It would be wrong to use these statistics alone to justify a ban on the marketing and use of chrysotile because such a ban would not lead to a lower risk of exposure for workers to asbestos which is already in place, nor would it reduce the number of deaths which are occurring today as a result of past exposure to asbestos.[5]

4.5 Modern uses of asbestos are or should be limited to chrysotile, which most parties, including INSERM, agree is safer than other forms of asbestos. Moreover, modern uses are or should be confined to products in which the fibres are bonded in a finished product and, thus, cannot escape, e.g., asbestos-cement products.[6] For these and other reasons, modern uses are quite safe; they involve

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[4]See para. 4.30 below.

[5]Official Journal of the European Communities, C 135/108 (14 May 1999) (30 September 1998 answer of Mr. Bangemann to Written Question E-2736/98 of Christine Oddy (PSE)). See also Official Journal of the European Communities, C 13/123 (18 January 1999) (24 July 1998 answer of Mr. Bangemann to Written Question E-1950/98 of Anita Pollack (PSE)) ("[I]t is important to mention that a new ban would not lead to a lower risk of exposure to existing asbestos for workers, nor would it reduce the number of deaths from past exposure to asbestos. Possible contamination from asbestos in existing buildings (e.g. in relation to maintenance activities and asbestos removal operations) will remain an important cause of exposure to workers for many years.").

[6]Brazil notes that in the chrysotile-cement industry, the largest present-day use of chrysotile, the manufacturing process uses a water slurry mixture of chrysotile and cement. No dust or pollution is created during this process. See also American Lung Association, *Asbestos,* pp. 2 and 3 (http://www.lungusa.org/air/envasbestos.html) ("Asbestos is rarely used alone, and it is generally safe when combined with other materials with strong bonding agents. As long as the material remains bonded so that fibers are not released, it poses no health risk."); National Cancer Institute, (1996), p. 3 (http://www.ncih.nih.gov./clinpdq/risk/Questions_and_Answers_About_Asbestos_Exposure.html) ("Asbestos that is bonded into finished products such as walls, tiles, and pipes poses no risk to health as long as it is not damaged or disturbed (for example, by sawing or drilling) in such a way as to release fibers into the air . . .. [N]o fiber type can be considered harmless, and proper safety precautions should always be taken by people working with asbestos.").

exceedingly low levels of exposure (that often do not exceed even the "natural" levels in ambient air). Chrysotile is used in a very wide variety of products. It is used as a flame retardant, to strengthen friction materials (e.g., truck brakes) and to create cement pipes for carrying water that are far less subject to corrosion, cracking and breaking than traditional cement pipes. In most applications, chrysotile is used because it *increases* public safety; thus, using other, less-efficient products in its place often decreases public safety. The use of chrysotile as a fire retardant needs no explanation. However, a discussion of its use in friction materials may be illuminating. Chrysotile is used primarily in truck brake pads, drum brakes and brake blocks to control heat build-up, thus maximizing friction and stopping power. It is the preferred product for this application. As one of the authors of an American Society of Mechanical Engineers (ASME) study commissioned by the EPA concluded:

(a) The "replacement/substitution of asbestos-based with non-asbestos brake linings will produce grave risks"; and

(b) "the expected increase of skid-related highway accidents and resultant traffic deaths would certainly be expected to overshadow any potential health-related benefits of fiber substitution."[7]

4.6 Brazil pleads that chrysotile's numerous public safety benefits - the many contributions it makes to societies around the world - not be ignored in this proceeding, as they were when France passed its ban. In Brazil's view, the primary question in this proceeding is quite narrow - is a complete ban necessary to protect public health or can public health be ensured by regulating modern, controlled uses of chrysotile and chrysotile products? The answer arrived at by those countries in the Americas that have examined the issue closely, ranging south from Canada, to the United States, to Brazil, is that public health can be ensured by regulating modern controlled uses. France may, of course, take measures that are designed to, and actually do, protect its citizens. However, the ban does not meet even this very generous characterization of the general rule set forth in the WTO Agreement on Technical Barriers to Trade (the TBT Agreement). France must not be allowed to impose a ban on imports and safe, modern uses of chrysotile as a response to public pressure. That the ban does not apply to man-made fibres produced in France, which the available scientific data show present greater risks when their use is not controlled and which have not been proven safer, confirms that the basis for the ban may be political and economic, but is *not* scientific or medical.

4.7 Brazil argues that in many respects, the French reaction is identical to that of the United States Environmental Protection Agency (the EPA) promulgated in 1989, when it banned asbestos under pressure from panicked U.S. public opinion. The EPA was unable to justify its ban scientifically to the United States Court of Appeals for the Fifth Circuit. After lengthy legal proceedings, the Fifth Circuit ordered the EPA to reverse its decision and to acknowledge publicly that modern products containing chrysotile enclosed in a matrix of cement or resin do not pose any detectable risk to public health.[8] (Today, although amphiboles are prohibited in the United States, a number of products containing non-brittle chrysotile are permitted, including the products manufactured by Brazil and previously manufactured in France from Brazilian chrysotile.) Unfortunately, France has adopted a measure that unnecessarily and to no good effect impedes international trade.

4.8 Brazil makes the following claims regarding the ban: (1) the ban is inconsistent with Article 2.2 of the TBT Agreement because it creates unnecessary obstacles to trade and is more trade restrictive than necessary; (2) the ban is inconsistent with Article XI of the General Agreement on

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In developing countries such as Brazil, the availability of low-cost, high-quality building and piping materials, such as chrysotile-cement products, is crucial. Substitute products are more expensive and thus less available to those who need them most.

[7]See *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1224, n.25 (5th Cir. 1991) (*Corrosion Proof)* (written testimony of Mr. Arnold Anderson, ASME).

[8]*Id.*

Tariffs and Trade 1994 (GATT 1994) because it is a quantitative restriction that is not excused by the exceptions in Article XI:2 or Article XX; (3) the ban is inconsistent with Article 2.8 of the TBT Agreement because it applies to asbestos but not to man-made fibres or other substitute products and thus operates as a technical regulation setting forth an unnecessary design or descriptive characteristic; (4) the ban is inconsistent with Article 2.4 of the TBT Agreement because international standards for producing and using chrysotile and chrysotile products exist and France should have used them; (5) the ban is inconsistent with Article III:4 of the GATT 1994 and Article 2.1 of the TBT Agreement (national treatment) because it does not apply to domestic man-made fibres and other substitute products, which are like products to chrysotile; and (6) the ban is inconsistent with Article I:1 of the GATT 1994 and Article 2.1 of the TBT Agreement (MFN) because, insofar as it bans imports of chrysotile and chrysotile products, but not imported like product substitutes, it improperly discriminates among imports.

2. Factual Aspects

4.9 **Brazil** concurs with practically all aspects of Canada's presentation, agreeing (i) that the French ban was passed in response to public outcry in France over the deaths associated with the intensive exposure to amphibole that had taken place early on in the century; (ii) with the circumstances and risks of exposure presented by Canada. In particular, it agrees with the statement that exposure, even in asbestos product plants, has decreased significantly and that, apart from existing flocked amphibole, current exposure is limited, or could be limited, entirely to chrysotile; in contrast, past exposure and current exposure from past uses (e.g. flocking) included exposure to amphibole; (iii) that current levels of exposure to modern uses of chrysotile are not significant and are not associated with substantial health risks; (iv) with the fact that current controlled-use policies and standards which are accepted internationally are sufficient to ensure the health of chrysotile workers and others exposed to chrysotile and to guarantee their safety; and, (v) with Canada's argument that the INSERM Report has many defects and that it was not the reason for France's ban on modern, controlled uses of chrysotile and chrysotile products.

4.10 Brazil considers that a "battle of experts", with one side presenting experts who support banning chrysotile and the other presenting experts who oppose banning chrysotile would be, in this case, both uninformative and unnecessary because the INSERM Report and the Synthesis[9], as a matter of law, not fact, cannot support the ban.[10] This Report and the Synthesis have several defects that render them utterly incapable of supporting the ban.[11] INSERM has not conducted original research, but merely based itself on existing studies and, furthermore, it has not examined all existing studies as it has deliberately excluded those that have established a distinction between chrysotile and amphiboles. More specifically, the shortcomings of the INSERM Report include the following. First, the Report completely fails to examine the modern uses of chrysotile and chrysotile products and, thus, ignores the current state of the industry. Instead, it focuses on the health effects of exposure to amphibole that took place in previous decades. INSERM concedes that it does not have "direct, certain scientific" data on the health risks associated with current levels of exposure to the modern uses of any form of asbestos, much less chrysotile.[12] In short, INSERM does not examine current uses and exposure levels and does not distinguish among the different levels of risk associated with the

[9]INSERM, *Rapport sur les effets sur la santé des principaux types d'exposition à l'amiante, Expertise collective INSERM,* Paris, 1997, (hereinafter "INSERM Report"); INSERM, *Effets Sur la Sante des Fibres de Substitution à l'Amiante-Synthèse, Expetise collective INSERM,* Paris, 1998, (hereinafter "Synthesis").

[10]Brazil concurs with Canada that the weight of all available scientific evidence, including the INSERM Report, leads to the conclusion that the ban serves no purpose other than restricting trade.

[11]Brazil notes that, because it is only the INSERM Report which preceded the ban, the ban must be supported by the Report alone. Brazil has discussed both the Synthesis and the Report because the former underscores some of the defects of the latter.

[12]INSERM, (1998), *Effets sur la sante des fibres de substitution à l'amiante-synthèse*, Paris, p. 226.

different types of asbestos fibres (chrysotile, the only type produced and exported by Brazil, as well as used in it, is accepted as being the safest of asbestos fibres, even by INSERM itself).[13]

4.11 Second, the INSERM Report fails to examine the efficiency of the ways in which worker exposure has been reduced through the use of air filters in mines and plants[14], and employing masks, laundry services, etc. Third, it does not even compare the risks of the past to the risks associated with man-made fibres[15] and substitute products (such as ductile iron or polyvinyl chloride (PVC) pipes).[16] By the time INSERM began to examine substitutes, the ban had already been in effect for 1.5 years and, in any case, INSERM issued only a synthesis and not a complete report on these substitutes. INSERM concedes in its Report that it lacked the data required to recommend the banning of chrysotile and only to allow its substitutes.[17] INSERM emphasizes that because it is the structure (size and shape) of fibres that makes them toxic when inhaled, any substitute fibre must be viewed as dangerous to human health.[18] Finally, INSERM concedes that, although the health data it applied to chrysotile are from past, massive and prolonged exposure to amphibole, the data being collected for substitutes is based on much lower levels of exposure, replicating modern conditions. Most telling is that INSERM states that toxicity levels for "asbestos" as a whole (and not merely for chrysotile) would yield similar results to those obtained for substitutes if similar testing conditions had been used.[19]

4.12 Brazil further argues that INSERM uses a linear risk model to assume illogically and without any evidence that a threshold does not exist for safe exposure.[20] France and INSERM are forced to commit this methodological error (the assumption) due to the fact that they had data from past prolonged exposure to amphibole but not to current, much lower exposure to chrysotile.[21] To justify

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[13]Ibid., p. 409 ("France used asbestos much later and to a much lesser degree than other countries, and doubtlessly the asbestos used contained a lower proportion of amphibole-type fibres. Because of these differences, it is not possible to simply transpose to France the results of projections concerning mesothelioma [and cancer] cases prepared recently for Great Britain.").

[14]Brazil notes that the Cana Brava Mine, in Brazil, for example, has an exceedingly complex and effective air filtration system. The mine is the first and only asbestos mine in the world to have been certified as complying with ISO 14001. It was certified by Det Norske Veritas of Rotterdam, the Netherlands.

[15]See, e.g., Cossette, M., *Substitutes for Asbestos*, 4 December 1998; Anderson, A., *Fibres in Friction Materials*, December 1998; Davis, J.M.G., *The Biological Effects of Fibres Proposed as Substitutes for Chrysotile Asbestos: Current State of Knowledge in 1998*, 1998; *INSERM Synthesis*. Brazil notes that these studies demonstrate that substitute fibres, both when manufactured and used, are likely to present health risks similar to those from chrysotile.

[16]See *Corrosion Proof*, 947 F.2d pp. 1226-27 (even while banning asbestos, the EPA conceded that ductile iron pipes and PVC pipes present health (cancer) risks "similar" to those presented by asbestos-cement pipes).

[17]INSERM, *Effets sur la sante des fibres de substitution à l'amiante-synthèse*, Paris, 1998, pp. 376 and 428. Brazil notes that the European Commission has also recognized this as an important issue: "There is a key scientific issue which Member States and the Commission agree still needs to be clarified. This is an assessment of the relative risk posed by the substitutes in comparison to the risk posed by chrysotile." Official Journal of the European Communities, C 13/35 (18 January 1999) (11 June 1998, Answer of Mr. Bangemann to Written Question P-1451/98 of Peter Skinner (PSE)).

[18]INSERM Synthesis, p. 2.

[19]Ibid., p. 33.

[20]According to Brazil, the assumption is contrary to logic because a threshold must exist given that asbestos is ubiquitous in water and air. Only those who have suffered intensive, prolonged, exposure have contracted asbestos-related diseases.

[21]See also *Asbestos in Public and Commercial Buildings: A Literature Review and Synthesis of Current Knowledge*, Health Effects Institute - Asbestos Research (1991) at pp. 6-9, para. 6.2.2 (Health hazards caused by asbestos at levels encountered in buildings today are "on the order of 50,000 times lower than industrial exposure levels of the past."); *Report of the Royal Commission on Matters of Health and Safety Arising from the Use of Asbestos in Ontario* (1984), Background Briefing Notes No.1 - "Health Effects of Asbestos" (Current exposure of the general public is "thousands of times less" than occupational levels in the

the ban on the modern uses of chrysotile, France/INSERM had to assume that significant risk is present at all levels of exposure, even at those that are insignificant, out of political self-interest. INSERM adopted the linear risk model despite the fact that studies cited by the European Communities (hereinafter "EC") themselves indicate that "*bricoleurs*" are not at risk. The study conducted by Iwatsubo *et al.*[22] indicates that low, sporadic, intermittent and cumulative exposure of up to 0.5 fibres/ml-years does not present increased risk of mesothelioma. In commenting upon the results of an earlier study, the authors note that "no significant risk was observed for those whose exposure was intermittent".

4.13 Brazil argues that a close examination of the INSERM Report reveals that: (i) prolonged exposure to amphibole (its past uses) is associated with severe health problems (a proposition with which everyone agrees); (ii) substitute fibres have similar structures and, thus, when subject to scientific scrutiny, are expected to have similar health effects at similar levels of exposure; (iii) insufficient data exists on the health effects of current levels of exposure to chrysotile and substitute fibres, but the available data suggests that their health effects would be the same; and (iv) the Report does not purport to be as conclusive as France would have all believe; rather, to overcome (iii) above, INSERM extrapolated from the data used in (i), which as it itself concedes "does not produce scientifically certain knowledge, but only an aid to understanding the implications for risk management.[23]" Brazil contends that the ban has been based on the irrelevant data described above. France employs the linear risk model as a tool to make data on past uses relevant to the imposition of the ban. However, INSERM researchers themselves recognize the limitations of this model and clearly state that it cannot produce "scientifically certain knowledge," but can only serve as an "aid to understanding," based on "plausible, though uncertain, estimates.[24]" These "conclusions" do not support significant trade restrictions, much less the ban. Rather, they are merely a call for further research.

4.14 Brazil argues that recent research focusing on uncontaminated chrysotile demonstrates why it presents no health risks whatsoever. According to Dr. David Bernstein's medical explanation[25], the serpentine (braided) structure of chrysotile leads it to unravel in the lungs (whereas the tubular structure of amphibole and substitute fibres does not allow them to unravel and is unchanging); and once unravelled, the smaller and thinner particles are more easily and rapidly enveloped by macrophages and/or expelled from the lungs. Dr. Bernstein's research demonstrates that uncontaminated Brazilian chrysotile of less than 20 microns (the length that has been associated with pathogenicity for all fibres) is very quickly cleared. The clearance half-time is 1.3 days (and is 2.4 days for fibres of a length of 5-20 microns). He concludes that, once in the lung, chrysotile fibres defibrillate (or unravel), breaking down into shorter fibres. According to Dr. Bernstein, this result "is in stark contrast to amphibole asbestos where a portion of the fibres longer than 20 [microns] remains indefinitely or with synthetic mineral fibres where even very soluble fibres are removed by dissolution in the lung with half-times greater than this."[26] He concludes that uncontaminated chrysotile's lack of bio-persistence suggests that it has "little if any toxicological effect."[27] However, it is of course a fact

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three decades during and after World War II (p. 3); the best estimates are that exposure of current occupants of asbestos-containing buildings "is 1,000 to 10,000 times lower than the average exposure of insulation workers in the past" (Volume 2 p. 585).

[22]Iwatsubo Y. et al., *Pleural Mesothelioma: Dose-Response Relation at Low Levels of Asbestos Exposure in a French Population-based Case-Control Study*, American Journal of Epidemiology, 1998, Vol. 148, N° 2.

[23]INSERM Report, pp. 239 and 414..

[24] *Ibid.*, pp. 239 and 232.

[25]Bernstein D., *Summary of the Final Report on the Chrysotile Bio-Persistence Study*, Geneva, 2 October 1998 (document presented by Brazil to the Panel).

[26]Ibid., p. 4.

[27]Ibid., p. 10.

that if used improperly, uncontaminated chrysotile could be dangerous, but that would be the case for virtually all products in existence and not just chrysotile.

4.15 Brazil indicates that it mines, produces and exports only uncontaminated chrysotile and chrysotile products, and subjects mining, production and use to strict regulations. In 1990, it signed the ILO Convention and Recommendation Concerning Safety in the Use of Asbestos (Convention 162 and Recommendation 172). To ensure safety in the mining, manufacture and use of chrysotile and chrysotile products and to meet its ILO obligations, Brazil passed a primary law[28] and decree[29] on asbestos. In addition, the production and use of chrysotile and chrysotile products is governed by "national tripartite (government-industry-workers) agreements". These set exposure limits, and processes of production and safety procedures to be used to guarantee worker safety. Finally, the Brazilian Asbestos Association (ABRA), a watchdog organization comprised of asbestos producers and sellers, further regulates the safety of, and trade in, chrysotile and chrysotile products.

4.16 Brazil explains that the ILO Convention and Recommendation are international standards that establish safety procedures for the handling of chrysotile and chrysotile products. They follow the ILO Code of Practice on Safety in the Use of Asbestos.[30] The goal of the Code is to prevent the risks of exposure to asbestos and its harmful effects and to provide practical control procedures for its use. Convention 162 and Recommendation 172 recommend the controlled and safe use of asbestos. Their wording clearly indicates that the replacement of asbestos fibres should only take place when it is established that this is necessary to protect worker health and when replacement is technically feasible. The replacement of chrysotile asbestos fibres contained in modern materials or products (i.e. where it is sealed in a matrix and cannot be released into the environment) is not necessary since these products do not pose any detectable health risks. International standards, such as Convention 162 and Recommendation 172, recommend the regulation of asbestos on the basis of the type of asbestos fibre employed, the products in which certain fibres are included, and their planned use. Thus, Convention 162 and Recommendation 172 stipulate the prohibition of crocidolite and materials containing friable asbestos for flocking[31], but permit many uses of chrysotile, including those central to this dispute (asbestos-cement and friction products). They allow countries to prohibit other specific uses if national authorities deem this necessary for worker protection, but only on condition that substitute products be subjected to a thorough scientific examination of their health effects.[32]

4.17 In 1995, Brazil passed Law No. 9055 to discipline the extraction, industrialization, use, commercialization and transportation of asbestos and of asbestos-containing products, as well as of natural and synthetic fibres of any source used for the same purpose. The Law (i) bans the processing and use of all types of asbestos, except chrysotile and chrysotile-containing products; (ii) bans the crushing and spraying (flocking) of all types of asbestos, including chrysotile, and of all substitute fibres; (iii) provides the framework for the tripartite agreements in that it sets deadlines for the government's confiscation of the operating licences of companies that do not execute the tripartite agreements, establishes medical inspection requirements for workers, and sets exposure limits for those who work with chrysotile and substitute fibres subject to annual reduction. (In compliance with Article 2.4 of the TBT Agreement, the exposure limits are determined based, in part, on the recommendations of "international entities which are scientifically accredited"); (iv) prohibits miners

[28]Brazilian Law No. 9055 of 1 July 1995.

[29]Brazilian Decree No. 2350 of 15 October 1997.

[30]*Safety in the Use of Asbestos*, Code of Practice, International Labour Organization, Geneva, 1990.

[31]Convention 162, Article 12.

[32]Article 12 of Recommendation 172 states:

(1) The competent authority, wherever necessary for the protection of the workers, should require the replacement of asbestos by substitute materials, wherever possible.

(2) *Before being* accepted for use in any process, all potential substitute materials should be *thoroughly evaluated* for their *possible harmful effects* on health. The health of workers exposed to such materials should be continuously supervised, if judged necessary. (Emphasis added.)

and wholesalers from supplying chrysotile or substitute fibres to companies that do not comply with all provisions of the Law; (v) applies special restrictions to the use of chrysotile and substitutes in products currently considered to be the riskiest, such as textiles; (vi) calls for research into the health effects of chrysotile and substitute fibres and provides financing for the effort; and (vii) provides for prompt Department of Justice action against infractions.

4.18 Brazilian Decree No. 2350 implements the Law, and (i) requires that prior to marketing, all products containing chrysotile of imported or national origin bear a "seal of compliance to the Brazilian System of Certification", and provides for the development of the certification system; (ii) requires research into and confirmation of the health effects of chrysotile and its substitutes; (iii) establishes additional requirements for the tripartite agreements which apply to all mines and companies producing chrysotile and chrysotile products; (iv) establishes requirements for monitoring and controlling the use of chrysotile and its substitutes, and ensures that a record is kept of the exposure measurements made by companies while guaranteeing access to them; and (v) establishes a permanent National Commission on Amianthus (NCA) to ensure the safety of workers involved in the chrysotile or substitute fibre industry. The Decree also establishes certain bodies, such as the NCA, composed of government and industry officials as well as workers, to ensure worker safety.

4.19 The tripartite agreements (otherwise known as *The National Agreements for the Furtherance of the Safe Use of Asbestos*) are required by both the Law and Decree. They are executed by the Federal Government of Brazil, the industries involved (e.g. the mining or asbestos-cement industry) and the workers in the industry (through their unions). They establish mandatory medical procedures inspection and safety measures, as well as exposure limits. They also give workers certain rights, both individual and collective, within their industries. Their objective is to continuously work towards improved worker safety and to decrease exposure limits as well as actual exposure. First, tripartite agreements set the maximum permissible exposure limits to 0.30f/cm3, with 50 per cent of all measurements being below 0.10 f/cm3 (and without there being any constant exposure above 0.3 f/cm3, even when the workers exposed have special breathing equipment). Second, they require the use of specific "collective protection" procedures to protect workers. The procedures are to include the installation of air filter and exhaust systems, the use of wet processes in the handling of chrysotile (which reduces dust release and, thus, exposure), the sealing of workspaces and processes to limit exposure, the demarcation of areas of exposure for warning, the prohibition of dry sandpapering processes, the implementation of a daily programme for the washing, wetting or vacuum cleaning of production sites, and provisions for a change of work clothes (which may not be taken off site), of laundry services and showers for employees. Third, the agreements require employers to provide workers with individual protection equipment that complies with relevant standards. Fourth, they also require them to conduct regular and detailed environmental evaluations of working conditions as well as to medically inspect their employees. All results are to be filed with the Control Commission on the Safe Use of Asbestos and with the Brazilian Asbestos Association, known as ABRA. The Control Commission is comprised of plant workers elected by their peers. Fifth, they require the provision of worker education programmes to communicate the health risks of exposure to chrysotile, the measures which can be taken to reduce exposure, and the "multiplier effect" which tobacco smoking has on exposure. Sixth, they make ABRA responsible for providing the companies with technical assistance regarding controls and preventive measures.

4.20 Founded in 1984, ABRA is an industry watchdog group composed of companies from Brazil's asbestos industry. Its main goal is to oversee industrial activity in order to ensure that ABRA members comply with the Law, the Decree and the tripartite agreements, as well as to educate workers, wholesalers and end-users of chrysotile asbestos and asbestos products on safe use. To accomplish this goal, ABRA has an extensive, independent, monitoring programme. Biannually, it conducts spot measurements at the facilities of its members. It maintains an ISO 9000-certified laboratory and sends control samples once a year to independent laboratories in Edinburgh (AFRICA) and Paris (LHCF) to ensure the accuracy of its measurements. If the company that has been tested

fails to meet the applicable exposure limits, ABRA sends it a letter and informs its suppliers. It then provides the company with a maximum number of days in which to comply, and instructs its suppliers to withhold chrysotile and/or chrysotile products from the company until it is able to notify its compliance. The agreement restates the requirements of both the Law and Decree, and develops certain safety procedures. In exchange for compliance (and dues), ABRA serves as a low-cost repository for state-of-the-art safe-use technologies, covering areas such as plant, air filter and process design. It attempts to encourage as well as facilitate safe use, with its overarching objective being to regulate the industry in such a manner as to render additional government regulation unnecessary. The regulatory regime (consisting of the Law, the tripartite agreements and ABRA itself), aligns the self-interests of the industry with those of its workers. The industry and the workers individually, as well as through Safety Commissions and Unions, cooperate to reduce health risks. The result of this cooperation has been the creation of an extremely safe workplace with very low exposure levels. In general, this system encourages individual plants to exceed applicable requirements in order to guarantee worker and user safety. At the Capivari Asbestos Cement Plant, which is the largest chrysotile-cement plant in South America, the on-site doctor did not report a single case of asbestos-related disease among the employees whose contact with asbestos had been limited to the plant.

4.21 With respect to regulation of asbestos in the United States, Brazil asserts that, in response to public outcry based on sensationalist media reports on the dangers of asbestos, the Environmental Protection Agency (EPA) banned asbestos in 1989.[33] It prohibited "at staged intervals, the future manufacture, importation, processing, and distribution in commerce of asbestos in almost all products […]". In reaction, a United States company that manufactured asbestos pipes, Corrosion Proof Fittings, filed suit against EPA arguing that the ban was not based on scientific and medical information. In a 1991 decision, the United States Court of Appeals for the Fifth Circuit called for the lifting of the ban and ordered EPA to issue new rules grounded in science.[34] The Fifth Circuit concluded that EPA had presented "insufficient evidence to justify its asbestos ban." [35] Specifically, it found that the EPA had failed to (i) consider all of the necessary and relevant evidence, and (ii) "give adequate weight to statutory language requiring it to promulgate the least burdensome, reasonable regulation" that would protect human health.[36] Similarly, France has failed to (i) examine existing evidence on the modern, controlled uses of chrysotile, (ii) assess the danger associated with substitute products, and (iii) impose a regulation that is not more restrictive than necessary. In 1993, EPA lifted the ban and issued new provisions regulating the production and use of asbestos and asbestos products.[37] Based on a thorough scientific and medical review, EPA then authorized more asbestos products (18) than it banned (6). None of the uses that are banned are at issue in this proceeding. Of the authorized uses, two are central to Brazil's exports to France and had previously been allowed (they include chrysotile-cement products and chrysotile friction materials).[38] Under existing regulations, the United States produced 6,890 metric tonnes of chrysotile and imported 20,900 metric tonnes in 1997.[39] In the same year, it consumed nearly 21,000 metric tonnes of chrysotile, exported unmanufactured fibre for a total value of US$5,690,000 and manufactured products for a total of US$197,000,000.[40] Public health has not suffered in the United States and public outcry did not resume. United States regulations ban the dangerous uses of asbestos, and regulate those that are safe.

[33]EPA Final Rule, 54 Fed. Reg. 29460 (1989).
[34]*Corrosion Proof v. EPA*, 947 F.2d 1201 (5th Circuit 1991).
[35]Ibid., p. 1215.
[36]Ibid.
[37]EPA Final Rule, 58 Fed. Reg. 58964 (1993).
[38]The current US regulations on this topic are set forth at 40 C.F.R. part 763, Sub-Part I (1998).
[39]United States Government Geological Survey, Minerals Yearbook 1997, Volume I at 4-5.
[40]Ibid.

3. Legal Aspects

4.22 Brazil argued that, as it turns to Brazil's legal arguments, the Panel should recall Brazil's complex system of regulation that ensures public safety. The Panel should serve the same role regarding France's political decision which the Fifth Circuit served regarding EPA's political decision - that of a neutral arbitrator. Brazil understands that the *Corrosion Proof* decision does not in the least bind the Panel - the procedures, legal standards and status of the parties are quite distinct. However, the court there faced similar circumstances and issues, and in the face of contrary public sentiment, issued a very focused, well-reasoned opinion, which is precisely what Brazil seeks here.

(a) The Agreement on Technical Barriers to Trade

(i) Article 12 of the TBT Agreement

4.23 Brazil argues that a prohibition of the trade and use of a product, such as France's ban, is the most restrictive of all possible trade measures and must be closely scrutinized by the Panel. It requests the Panel to devote particular attention to the ban on imports from Brazil, which is a developing country (and from Zimbabwe, a least-developed country). In general, WTO agreements provide for the special and differential treatment of developing and least-developed country exports. In the context of the TBT Agreement, special provisions are set forth in Article 12, which obliges Members that are developing technical regulations and standards to consider the special needs of developing and least-developed countries and to provide them with differential treatment. Article 12.2 obliges France to "take into account the special development, financial and trade needs" of developing countries and of least-developed countries, when developing its technical regulations. France did not meet this obligation. Rather, it adopted an outright ban that advantages French producers of substitute fibres and products to the detriment of Brazil's chrysotile and chrysotile product producers (and to Zimbabwe's detriment as well). Moreover, the ban has not contributed to improving public health in France.

4.24 France violated Article 12.3 which covers the "preparation and application" of technical regulations and standards. Article 12.3 requires France to ensure that its technical regulations "do not create unnecessary obstacles to exports" from developing countries such as Brazil (and from least-developed countries such as Zimbabwe). However, France's ban applies to Brazilian (and Zimbabwean) exports and creates, to say the least, an "obstacle" to their trade. The obstacle is "unnecessary" because it does not contribute to the supposed objective of increasing safety. The only trade permissible under the ban is that of chrysotile and chrysotile product substitutes. The risks associated with substitute fibres are unknown, but they are suspect. Meanwhile the risks associated with the modern, controlled uses of chrysotile, are zero.

(ii) Article 2.2 of the TBT Agreement

4.25 Brazil argues that the ban is inconsistent with Article 2.2 of the TBT Agreement because it is more trade restrictive than necessary to fulfil a legitimate objective. Once it is established that the Decree is a "technical regulation", the EC must demonstrate (and have the burden of proving) that four different conditions have been met if they are to argue that the ban is in fact consistent with Article 2.2.[41] To defend the ban, the EC must demonstrate to the satisfaction of the Panel that (i) the objective of the ban is "legitimate", (ii) that it "fulfils" this legitimate objective, (iii) that it is not

[41]According to Brazil, general rules of pleading, but also Article 2.5 of the TBT Agreement confirm that France has the burden of justifying its trade restrictive measure. According to Article 2.5, a standard shall be "rebuttably presumed not to create an unnecessary obstacle to trade" when it pursues a legitimate objective and is "in accordance with relevant international standards." France cannot take advantage of this exception to normal rules of pleading because, as demonstrated below**,** the ban is contrary to relevant international standards.

"more trade restrictive than necessary" to fulfil the legitimate objective, and (iv) that France evaluated the health effects (i.e. "the risks non-fulfilment would create") on the basis of "available scientific and technical information". According to Brazil, the ban meets only the first of these four conditions.

4.26 Brazil argues that the Decree is a "technical regulation" within the meaning of the TBT Agreement. The ban sets out certain (i) product characteristics, (ii) process and production methods, (iii) administrative provisions, as well as (iv) packaging, marking and labelling requirements with which compliance is mandatory. Article 1 of the Decree prohibits the production, importation, exportation, manufacture, transformation, sale and offer for sale of all types of asbestos fibres and asbestos-containing products (except those temporarily excepted from the ban by virtue of Article 2.I). Thus, the ban is explicitly directed at product characteristics (asbestos and asbestos-containing products) and at process and production methods (all forms of production, manufacture and transformation of asbestos and asbestos-containing products). Both the prohibition imposed by Article 1 and the procedures for implementing and reviewing the entitlement to the exceptions set out in Articles 2.II and 3 of the Decree are "applicable administrative provisions" relating to product characteristics and process and production methods. Article 4 of the Decree prescribes certain marking and labelling requirements for those few asbestos-containing products excepted under Article 2. Compliance with the ban is mandatory and violations are penalized under Article 5. Brazil argues that both France and the EC have conceded that the Decree is a technical regulation. In WTO document G/TBT/Notif.97.55, dated 21 February 1997, the French Government notified the ban to the TBT Committee as a technical regulation. Paragraph 3 of the Notification indicates that the ban was being notified under Articles 2.9.2 and 2.10.1 of the TBT Agreement, both of which establish notification obligations for technical regulations. The European Commission has also recognized that the ban is a technical regulation both in a 15 April 1997 document justifying the French ban and during the 8 July 1998 consultations on this dispute. Therefore, both France and the EC concede that the ban falls within the scope of paragraph 1 of Annex 1 of the TBT Agreement and is a technical regulation.

4.27 Brazil does not contest that the objective of protecting the health of French workers and consumers is a "legitimate objective" within the meaning of Article 2.2 of the TBT Agreement. However, it argues that the ban imposed by the Decree creates an unnecessary obstacle to trade. It does not in reality fulfil its stated objective, and is more trade-restrictive than necessary to protect the health of French workers and consumers. In using the word "fulfil" (as in the requirement that "technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective"), the text of Article 2.2 requires the existence of a rational link between the regulation and its stated objective.[42] However, this rational link is absent as the ban does nothing to accomplish its objective. It does not make those who are now sick healthy and removing it would not make any of those now healthy, sick. The lack of a rational link between the ban and its purported objective is demonstrated by the following: (i) that asbestos-related health risks are due to old and already prohibited uses of asbestos; (ii) that there are no detectable health risks associated with modern uses

[42]Brazil notes that, while no WTO panel or Appellate Body reports have addressed this issue under the TBT Agreement, relevant precedents under the SPS Agreement exist: In *Japan - Apples*, the Appellate Body found that an SPS measure was justified only if the Member imposing the measure demonstrated a "rational relationship" between the SPS measure and available scientific information. *Japan - Measures Affecting Agricultural Products* (22 February 1999), WT/DS76/AB/R, para. 84; similarly, in *EC - Hormones*, the Appellate Body required the EC to establish "an objective relationship between two elements, that is to say, an objective situation that persists and is observable between an SPS measure and a risk assessment." *EC - Measures Concerning Meat and Meat Products (Hormones)* (16 January 1998), WT/DS26/AB/R, para. 189; the Appellate Body has also held that a finding that an SPS measure is not based on an actual assessment of health risks is "a strong indication" that the measure does not really protect health but is instead "a trade-restrictive measure in the guise of an SPS measure." *Australia - Measures Affecting Importation of Salmon* (20 October 1998), WT/DS18/AB/R, para. 166. This is precisely the case with the ban.

of chrysotile; and (iii) that health risks associated with substitute fibres remain unknown and are suspect.

4.28 Brazil asserts that the health risks addressed in the INSERM Report are based on past exposure to high levels of asbestos fibres (largely amphiboles) and to exposure to old uses of asbestos, such as flocking. In prohibiting future importation and sale of chrysotile and modern chrysotile-containing products, the ban does nothing to address the effects (today) of exposure between 1940 and the early 1960s to extremely high levels of asbestos, mainly amphibole fibres. It does not cure workers who now suffer because of long-term exposure in the past to amphibole, the use of which was banned in France in 1994, or to unregulated concentrations of fibres that are "50,000 times" higher than the modern-day internationally recognized controlled-use level of 1 f/ml.[43] Likewise, prohibiting the future importation and sale of chrysotile and modern chrysotile-containing products does nothing to address the effects of exposure to (or the disturbance of) friable asbestos, mainly amphibole, in French buildings prior to the 1978 French ban on flocking. This was recognized by European Commissioner, Mr. Bangemann, who, in response to a question posed by the European Parliament, responded that "[I]t is important to mention that a new ban would not lead to a lower risk of exposure to existing asbestos for workers, nor would it reduce the number of deaths from past exposure to asbestos."[44]

4.29 Brazil maintains that there are no detectable health risks associated with modern uses of chrysotile. There is no rational link between the ban and its purported objective because modern uses of uncontaminated chrysotile are safe. Prior to the ban, more than 90 per cent of the chrysotile imported into France was used in the manufacture of chrysotile-cement products.[45] Currently, the chrysotile is bound to the cement and encapsulated in it, without there being any loose or friable fibres. Furthermore, most chrysotile-cement products are produced in such a way that sawing or drilling are unnecessary, and in the few instances when either or both are required, widely recognized and well-established procedures have been developed for these tasks which prevent fibre release.[46] Similarly, in all other modern uses of chrysotile, the fibres are sealed, bonded or encapsulated in the product. In no instance are loose, friable fibres allowed to be. Brazil contends that France does not have credible evidence to suggest that (i) sealed, bonded or encapsulated chrysotile poses a health risk, (ii) concentrations of chrysotile fibres at or below the internationally-recognized controlled use level of 1 f/ml present a health risk, and (iii) controls do not eradicate all risk throughout a product's life-cycle (from mining to manufacture, distribution, sale and use, and eventual disposal). On the other hand, much science-based research concludes that the level of chrysotile encountered in the workplace today, or in buildings, presents no detectable health risk. After an exhaustive study of the existing scientific literature, the Health Effects Institute concluded in 1991 that the health hazards created by asbestos at the levels commonly encountered today are "unlikely to be large enough to be actually

[43]Health Effects Institute – Asbestos Research, *Asbestos in Public and Commercial Buildings: A Literature Review and Synthesis of Current Knowledge*, Cambridge, 1991, pp. 6-9.

[44]Official Journal of the European Communities, C 13/123 (18 January 1999) (24 July 1998 answer of Mr. Bangemann to Written Question E-1950/98 of Anita Pollack (PSE)).

[45]Le Déaut J.-Y. and Revol H., *L'amiante dans l'environnement de l'homme: ses conséquences et son avenir*, Office parlementaire d'évaluation des choix scientifiques et technologiques, Assemblée nationale no. 329 / Sénat no. 41, 16 October 1997.

[46]ISO 7337, §§ 4 and 5 (pp. 2-9): Brazil notes that the cutting of plates or tiles for roofing is not a source of emission if ISO-7337 is followed. ISO-7337 addresses the use of chains to break pipes through pressure, low-speed saws, saws equipped with a vacuum dust extractor, and, also, proper wetting of the materials prior to any action. The cutting or grinding of all cement pipe (even that which does not contain chrysotile) emits silica in the air, in the absence of proper controls. The International Association for Research on Cancer (IARC) rates silica as a Type 1 carcinogen (for man), like asbestos. The worker who cuts any cement pipe therefore has an interest in following ISO-7337.

observed and measured.[47]" This conclusion (which was reached by an independent United States health watchdog), confirmed the 1984 findings of the Ontario Royal Commission.[48] Similarly, in the case brought by Corrosion Proof Fittings against the EPA, the Fifth Circuit made the following comment on the risk of asbestos products relative to toothpicks:

> "As the petitioners point out, the EPA regularly rejects, as unjustified, regulations that would save more lives at less cost. For example, over the next 13 years, we can expect more than a dozen deaths from ingested *toothpicks* - a death toll more than twice what the EPA predicts will flow from the quarter-billion-dollar bans of asbestos pipe, shingles, and roof coatings."[49]

Brazil concludes that, because there are no detectable risks attributable to modern uses of chrysotile, there is no rational link between the French ban and its purported objective.

4.30 Brazil asserts that the French ban induces consumers to use chrysotile substitutes, whose health risks are unknown, in place of chrysotile, whose risks are known. In his 1998 paper on the biological effects of substitute fibres, Dr. J. M. G. Davis concluded that "replacement [of chrysotile by substitute fibres] is premature in the present state of our knowledge .... The need for full toxicology testing of new fibre products is recommended before these products are marketed."[50] This conclusion was shared by the European Communities Directorate General for Consumer Protection Policies, which stated that "there is no significant epidemiology base to judge the human health risks [of substitute fibres] … hence the conclusion that [the uses of] specific substitute materials pose a substantially lower risk to human health, particularly public health, than the current use of chrysotile, is not well founded … ".[51] The INSERM Report itself acknowledges that the risks associated with substitute fibres are unknown. INSERM "urgently" cautions against their use until further scientific tests are conducted. It states that "[T]he absence of epidemiological data concerning the long-term safety of these substitute products should not obscure the results of experimental systems indicating the possibility that pathological modifications could result. It is urgently important that suitable research into this area be conducted prior to the widespread use of substitute fibres."[52] Despite this urgent warning from its own experts, the French Government banned chrysotile and not its substitutes the day after it received the INSERM Report. Thus, the French Government knowingly shifted consumption from chrysotile used in modern ways, and for which there is no detectable health risk, to substitute fibres for which "experimental systems indicate the possibility that pathological modifications could result". Brazil concludes, therefore, that the ban does not "fulfil" a legitimate objective as required by Article 2.2 of the TBT Agreement. The rational link between the ban and its stated health objective does not exist because, as demonstrated above, (i) asbestos-related health risks are due to old, already prohibited, uses of asbestos, and not to the modern uses of chrysotile, (ii) no detectable health risks are associated with the modern uses of chrysotile, and (iii) substitute fibres, whose health risks are unknown, will replace chrysotile.

4.31 Brazil further argues that even if there were a rational link between the ban and the purported objective, the French ban would nonetheless be inconsistent with Article 2.2 of the TBT Agreement

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[47]Health Effects Institute – Asbestos Research, *Asbestos in Public and Commercial Buildings: A Literature Review and Synthesis of Current Knowledge*, Cambridge, 1991, pp. 6-9.

[48]Report of the Royal Commission on Matters of Health and Safety Arising from the Use of Asbestos in Ontario (1984), vol. 2, p. 585.

[49]*Corrosion Proof v. EPA*, 947 F.2d 1201 (5th Circuit 1991. See also L. Budnick, *Toothpick-Related Injuries in the United States, 1979 Through 1982*, 252 J. Am. Med. Ass'n., 10 Aug. 1984, p. 796 (which shows that toothpick-related deaths average approximately one per year).

[50]Davis J.M.G., *The Biological Effects of Fibres Proposed as Substitutes for Chrysotile Asbestos: Current State of Knowledge in 1998*, p. 1 and 5.

[51]European Commission, DG XXIV, Opinion on a Study Commissioned by Directorate General III on Recent Assessments of Hazards and Risks Posed by Asbestos and Substitute Fibres (9 February 1998), p. 1.

[52]INSERM Report, p. 434.

because it is "more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create.[53]" A ban is the most trade-restrictive measure possible. It could be justified only if France were able to prove that there was no reasonably available, less trade-restrictive, alternative. France cannot do so. Controlled use policies demonstrably fulfil the objective of protecting the health and safety of French workers and consumers. In assessing whether the ban is more trade-restrictive than necessary, within the meaning of Article 2.2, the Panel should examine both the risks of non-fulfilment and whether a less trade-restrictive measure is available to fulfil the objective.

4.32 Brazil argues that available scientific and technical information does not support the imposition of the ban. Article 2.2 provides that, in assessing the risk that a technical regulation is meant to address, Panels should consider, *inter alia*, relevant scientific and technical information, related processing technology and intended end uses of products. The risk to be avoided in the dispute at hand is the risk of illness resulting from exposure to (a) modern uses of chrysotile and chrysotile-containing products and (b) the disturbance of previously installed friable asbestos (largely amphibole) in buildings. Illnesses associated with old, previously banned, uses of asbestos are not relevant to this analysis. Moreover, they cannot be addressed through the present ban on trade, domestic sale and use. The INSERM Report, which provides the supposed scientific justification for the ban, does not assess the health effects of current levels of exposure to modern uses of chrysotile. To determine the health risk associated with exposure to low levels of bonded, sealed and encapsulated chrysotile in chrysotile-cement and other modern applications, it applies the same risk of exposure associated in previous decades with higher levels of exposure to friable asbestos (largely amphibole). There is no scientific logic for such an extrapolation. The INSERM Report itself concedes that its conclusions are not "scientifically certain" but are merely "plausible, though uncertain, estimates". Several other scientific reports concur that there is no detectable health risk from modern uses of chrysotile.[54]

4.33 Brazil explains that all modern-day uses of chrysotile involve bonding, sealing or encapsulation. Such uses, or modern products, do not contain loose, friable chrysotile fibres – which were the cause of past asbestos-related illnesses. The risk associated with modern use is undetectable. Most modern products are manufactured to specifications well known in the building and public works trades, so that sawing or drilling operations are seldom necessary. When sawing or drilling are necessary, there are well-established procedures to ensure that workers are not exposed to fibre release. Thus, Brazil argues that neither available scientific information, intended end-uses nor processing technology, necessitate a ban on chrysotile. Brazil argues that while the term "necessary" has not yet been interpreted in the context of Article 2.2 of the TBT Agreement, the interpretation provided by the Panel in the case on *Section 337 of the Tariff Act of 1930* is instructive:

> "[I]t was clear to the Panel that a contracting party cannot justify a measure inconsistent with another GATT provision as 'necessary' in terms of Article XX:(d) if an alternative measure which it could reasonably be expected to employ and which is not inconsistent with other GATT provisions is available to it. By the same token, in cases where a measure consistent with other GATT provisions is not reasonably available, a contracting party is bound to use, among the measures reasonably available to it, that which entails the least degree of inconsistency with other GATT provisions."[55]

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[53]Brazil notes that, similarly, under the SPS Agreement, in determining whether an SPS measure is more trade-restrictive than required, the authorities must evaluate whether an alternative, less trade-restrictive, SPS measure would achieve the importing country's appropriate level of protection. *See Australia - Measures Affecting Importation of Salmon* (20 October 1998), WT/DS18/AB/R, paras. 208-210.

[54]See paragraph 4.29 above, regarding the conclusions of the American Health Effects Institute, the Royal Commission and the U. S. Court of Appeals for the Fifth Circuit.

[55]*United States – Section 337 of the Tariff Act of 1930,* adopted on 7 November 1989, BISD 36S/345, pp. 392-93, para. 5.26.

4.34 Brazil argues that the focus is on the range of measures "reasonably available" to France. Just as under Article XX(d), under Article 2.2 of the TBT Agreement, the French ban cannot be justified as "necessary" since a less trade-restrictive measure that fulfils the legitimate objective is available. There are numerous examples of controlled use that are both readily available and effective in addressing the health risks associated with the modern uses of chrysotile. First, the ILO Convention and Recommendation Concerning Safety in the Use of Asbestos (Convention 162 and Recommendation 172) establish procedures to ensure safety in the handling of chrysotile and chrysotile products. Second, the ILO's 1990 Code of Practice on Safety in the Use of Asbestos details appropriate controlled use procedures to ensure worker safety with respect to all chrysotile-containing products currently in use. Third, Brazil, the United States and Canada have demonstrated that controlled-use policy is effective in eliminating the health risks attributable to the modern uses of chrysotile. Controlled use policy is less restrictive than a ban. Trade and sales are permitted as long as appropriate safety measures are employed in the manufacture, installation and use of chrysotile-containing products. While complying with safety regulations could be expensive for firms, the decision of whether or not to use chrysotile or substitutes under the safety regulations should be determined by the marketplace and not by government. Given the availability of controlled use policy and its effectiveness in addressing the legitimate public health objective which France wishes to achieve, the ban is inconsistent with Article 2.2 in that it is more trade-restrictive than necessary to fulfil its objective.

(iii) Article 2.4 of the TBT Agreement

4.35 Brazil contends that the French ban is inconsistent with Article 2.4 of the TBT Agreement because it ignores appropriate and effective international standards. Article 2.4 obliges France to base its technical regulations on existing international standards, or on any "parts of them", that would be effective and appropriate in any given circumstance. France violated this obligation when it banned chrysotile and chrysotile products, ignoring existing international standards that would have been both appropriate and effective. To establish that France has not violated Article 2.4, the EC must show that: (i) there are no international standards that apply to asbestos; (ii) if international standards exist, that the ban is consistent with them; or (iii) if international standards exist and the ban is inconsistent with them, that the international standards would not have been an effective or appropriate means of accomplishing France's stated objective. The EC cannot make such arguments.

4.36 Brazil argues that a number of international standards apply to chrysotile and chrysotile products, including ILO Convention 162 and Recommendation 172, on the types of asbestos that can be used (only chrysotile) and how, and the International Organization for Standardization's (ISO) 7337 standard, entitled Chrysotile Cement Products Guidelines for On-Site Work, regarding the proper installation and use of chrysotile-cement products. The fact that the ISO 7337 standard is an applicable international standard is beyond doubt. Annexes 1 and 3 to the TBT Agreement expressly recognize the authority and status of ISO as an international standard-setting body, and the ISO 7337 standard directly governs the primary chrysotile product group. Each of these documents state that chrysotile products may be manufactured and used, but only under controlled conditions and in modern applications. Each of the standards sets out specific controls to guarantee the safety of workers and end-users. They have been incorporated into Brazilian legislation as well as that of many other countries, including the United States and Canada. The ban is inconsistent with these international standards because it bans all imports, manufacture, use, etc., of chrysotile and chrysotile products, whereas these permit their use in modern applications. They only subject them to safety controls. Current international standards provide an effective and appropriate means of fulfilling France's stated objective and the EC cannot argue otherwise. ILO and ISO standards are "appropriate" for France's stated objective since they were specifically drafted to protect the health of industrial workers, the general public and others who may come into contact with asbestos. ILO and ISO standards would also be "effective" in achieving France's stated objective since they have successfully

protected human health in economies as diverse as those of Brazil, the United States and Canada. The EC would be hard pressed to provide evidence of a deterioration in the health of citizens from Brazil, the United States or Canada due to adherence to ILO or ISO standards.

4.37 Brazil states that a closer examination of the term "ineffective and inappropriate means" is justified. The text of Article 2.4 clarifies that this exception is to be quite narrowly construed and applied. Were it not to be so, Article 2.4 would be rendered useless.[56] Members would all too easily claim that the applicable international standard was "inappropriate". Second, the Article provides examples of the situations in which exceptions to the use of international standards are allowed. These include when an international standard would be ineffective or inappropriate due to fundamental climatic or geographical factors or fundamental technological problems. Thus, a Member may ignore an international standard only if the standard will not achieve the results it seeks because of its unique conditions in terms of climate, geography, or its economy (i.e. level of technological development). No such conditions exist in France. The EC would be unable to present any evidence to suggest that different conditions apply to France so as to make the standards followed by Brazil, the United States and Canada inappropriate or ineffective for it. France ignored ILO and ISO standards because it wished to ban chrysotile to appease public opinion and advantage domestically-produced and substitute products.

(iv) Article 2.8 of the TBT Agreement

4.38 Brazil argues that the French ban is inconsistent with Article 2.8 of the TBT Agreement because it establishes design requirements for products. France's ban is inconsistent with this obligation because, by prohibiting chrysotile and its use in any product, the ban sets out an impermissible "design or descriptive characteristic". To establish that France has not violated Article 2.8, the EC must demonstrate that (i) the ban is a performance requirement; or, in this case, (ii) that adopting a performance requirement would not have been "appropriate". The Communities can demonstrate neither of these points. The ban sets out an impermissible "design or descriptive characteristic" because it regulates on the basis of the content and description of a product. France has banned chrysotile and products containing it but has not banned competing fibres and products that contain them. Therefore, the ban advantages French-produced substitute fibres, products which are "like"[57] chrysotile, and chrysotile containing products. The ban does not contain regulations based on the performance of a product. Rather, it states that certain products may be imported and sold only if they do not contain a certain input, namely chrysotile. Article 2.8 obliges France to adopt a performance requirement "whenever possible". In the case of chrysotile, France could have adopted any of a number of performance requirements that would have enabled it to achieve its stated objective.

4.39 According to Brazil, France could have adopted, for example, detailed regulations regarding the importation, production, modern use and disposal of chrysotile and substitute fibres and their products (as France had previously done and as do Brazil, the United States, Canada and many other countries). Alternatively, France could have established a single, never-to-be-exceeded exposure level to apply to the manufacture, use and disposal of chrysotile and substitute fibres, and to their products. France could, and should, have adopted a performance requirement for chrysotile and the products which contain it. Instead, it adopted a design or descriptive requirement and violated Article 2.8 of the TBT Agreement. Were any other findings to be reached by the Panel, it would allow Member countries to take the much easier route of banning, rather than regulating, products which they claim

[56]Brazil notes that interpretations that render a treaty provision null or void, or consign it to "inutility" are to be avoided whenever possible. See *United States – Standards for Reformulated and Conventional Gasoline* (20 May 1996), WT/DS2/AB/R, p. 23.

[57]Brazil notes that paragraphs 4.42-4.43 below demonstrate that the man-made substitute fibres and products are like products to chrysotile and chrysotile products.

create health risk. The TBT Agreement is based on the assumption that certain products present risks and that those risks are to be managed through standards. To allow a Member to ban, instead of to regulate, products due to perceived risks would render the Agreement meaningless.

(b) The General Agreement on Tariffs and Trade

(i) Article XI of the GATT

4.40 Brazil submits that the ban is also inconsistent with GATT Article XI because it is a quantitative restriction that is not permitted by the WTO. The ban includes (i) a prohibition of the sale in France of chrysotile and chrysotile products, which is a violation of GATT Article III:4, and (ii) a prohibition of the importation of chrysotile and chrysotile products. In fact, paragraphs I and II of Article 1 of the ban prohibit "the import […] of all kinds of asbestos fibres […] whether or not these substances are incorporated into materials, products or devices". The latter aspect violates Article XI. In reference to paragraph 1 of Article XI, Brazil argues that the ban on importation is not a "duty, tax or other charge," but is a "prohibition or restriction" that France has instituted and maintained on the importation of chrysotile from Brazil. Indeed, the ban is the most restrictive of all quantitative restrictions in that it sets a quota at the level of zero imports.[58] Therefore, the portion of the Decree that bans imports is inconsistent with Article XI:1.[59] Brazil further argues that none of the three exceptions contained in paragraph 2 of Article XI apply to the ban. Simply put, the ban is an outright prohibition of all imports, supposedly imposed to protect public health. It is not a "standard or regulation for the classification, grading or marketing" of chrysotile or chrysotile products.[60] Moreover, whether chrysotile is a "commodity" within the meaning of this exception is questionable. All three exceptions only relate to agricultural products.

(ii) Article III of the GATT and Article 2.1 of the TBT Agreement

4.41 Brazil argues that the ban is inconsistent with France's national treatment obligations under GATT Article III:4 and Article 2.1 of the TBT Agreement. The national treatment obligations of Article III:4 and TBT Article 2.1 are violated when a law, regulation or requirement (or a technical regulation) that affects the internal sale, offering for sale, purchase, transportation, distribution or use of any imported product, accords less favourable treatment to the imported product than that accorded to "like" domestic products. Each of these criteria are satisfied with respect to the ban. The ban is indisputably a law and its three implementing "Arrêtés" are regulations. For the purpose of Article 2.1 of the TBT Agreement, the ban is a technical regulation. Article 1 of the Decree bans, among other things, the manufacture, processing, sale, offer for sale, distribution and use of all varieties of asbestos fibres and all asbestos-containing products (except for the few temporary exceptions permitted by its Article 2). Thus, it indisputably meets the second criterion for the application of GATT Article III:4

[58]The fact that Article XI applies to the ban is further confirmed by Article XI:2(b) which applies to "import […] prohibitions," among other restrictions. *See also Japan – Trade in Semi-Conductors*, L/6309, adopted 4 May 1988, BISD 35S/126, para. 104 (finding Article XI:1 "comprehensive" and applicable to all types of non-tariff prohibitions).

[59]The applicability of Article XI:1 to such circumstances has been confirmed by various panels under the GATT 1947 and GATT 1994. *See*, *e.g.*, *United States Manufacturing Clause*, L/5609, adopted 15/16 May 1984, BISD 31S/74, 88, para. 34; *Japan – Trade in Semi-Conductors*, L/6309, adopted 4 May 1988, BISD 35S/116, 152-53, para. 102; *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/R (15 May , 1998), paras. 7.11 to 7.17.

[60]Brazil notes that a GATT Panel has held that a ban (which, of course, precludes marketing) is not "related" to marketing under Article XI:2(b). *See Canada - Measures Affecting Exports of Unprocessed Herring and Salmon*, L/6268, adopted 22 March 1988, BISD 35S/98, 112, paras. 4.2-4.3 (rejecting Canadian argument that a ban on exports of certain unprocessed fish was related to marketing, and finding that, to fall under Exception Two, the regulation in question must apply to "marketing as such," and that Exception Two does not apply to just any regulation facilitating foreign sales).

and TBT Article 2.1. It provides less-favourable treatment to chrysotile and chrysotile-containing products (which, prior to the ban, were imported from Brazil), than that which it does to French products used as asbestos substitutes (and which are not banned).[61]

4.42 Finally, the ban itself recognizes that the so-called "substitute fibres", and products incorporating them, are "like" chrysotile and chrysotile-containing products. The few exemptions permitted by Article 2 of the ban apply when no substitute fibre is equivalent in terms of its end-use to chrysotile.[62] In other words, whenever a French substitute fibre can replace chrysotile, chrysotile is banned. There can be no more convincing proof that chrysotile and substitute fibres are "like" products. Even if the ban did not by its own terms prove the "likeness" of French substitute fibres to imported chrysotile, analysis of the precedents set under GATT demonstrate that chrysotile and substitute fibres are indeed alike, as are chrysotile and substitute fibre-containing products. Using the criteria identified by the Appellate Body in the case on *Taxes on Alcoholic Beverages* for establishing "likeness"[63], it is self-evident that the end uses of chrysotile and substitute fibres are the same. The fibres are used solely because they emulate the desired characteristics of chrysotile in particular products. With regard to "consumers' tastes and habits", chrysotile and substitute fibres are not consumer goods. They are used solely as inputs in certain products (primarily in various cement products today). Industrial consumers purchase substitute fibres rather than chrysotile based on considerations of cost and availability. They can do so because substitute fibres are intended to emulate chrysotile's characteristics.

4.43 Brazil asserts that the same reasoning applies to the assessment of the products' properties, nature and quality. Substitute fibres are "like" chrysotile precisely because they emulate chrysotile's characteristics. An additional criterion to determine likeness was added after *Border Tax decision – tariff classification*.[64] As previously noted, almost all chrysotile is used as an input into various cement products. Chrysotile and other fibre-cement products are classified under the same Harmonized Tariff System heading (which is number 68.11). In all instances, the six and eight digit classification of chrysotile and other fibre-containing cement products are the same. Therefore, France's conduct violates GATT Article III:4 and the TBT Agreement's Article 2.1, and is inconsistent with France's national treatment obligation.

(iii) Article I of the GATT and Article 2.1 of the TBT Agreement

4.44 The most-favoured-nation obligations of Articles I:1[65] and 2.1 are violated "with respect to all matters referred to in paragraphs 2 and 4 of Article III" (or, for purposes of the TBT Agreement, Article 2.1), whenever any "advantage, favour, privilege or immunity" is granted to a product from one country and is not "accorded immediately and unconditionally" to a "like product" from other WTO Members. This happens to be the case with the French ban. As previously demonstrated, Brazil argues that the ban violates GATT Article III:4 and, for the purposes of Article 2.1 of the TBT Agreement, is a technical regulation. The fact that substitute fibres may be imported into France

[61]According to Brazil, the absence of imports because of the imposition of a ban does not provide a valid basis for asserting that GATT Article III:4 (and TBT Article 2.1) cannot be applied. Interpretations that render a treaty provision null or void, or consign it to "inutility" are to be avoided whenever possible. See *United States – Standards for Reformulated and Conventional Gasoline* (20 May 1996), WT/DS2/AB/R, p. 23.

[62]Brazil notes that the EC acknowledges this when explaining that the French ban does not include chrysotile diaphragms for use in chlorine environments because substitutes cannot safely be used.

[63]*Japan - Taxes on Alcoholic Beverages* (4 October 1996), WT/DS8/AB/R, p. 20, quoting *Report of the Working Party on Border Tax Adjustments* (2 December 1970) BISD 18S/87, 102, para. 18.

[64]Brazil notes that this criterion was first cited in *EEC – Measures on Animal Feed Proteins*, L/4599, adopted 14 March 1978, BISD 25S/49, 63, para. 4.2.

[65]Brazil recognizes that Canada has not alleged a violation of GATT Article I:1. However, as demonstrated, the French ban violates the most-favoured-nation obligations of both that Article and of Article 2.1 of the TBT Agreement.

while chrysotile imports are banned constitutes an "advantage, favour, privilege or immunity." This advantage is accorded to imported substitute fibres but is denied to imported chrysotile, which is banned.

(iv) Article XX of the GATT

4.45 Brazil argues that the General Exceptions of Article XX do not excuse the Decree. To obtain an exception under Article XX, the EC must establish that (i) the ban does not "constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail", (ii) that it is not a "disguised restriction on international trade", and (iii) that it is "necessary to protect human life or health." The EC cannot argue that the ban meets these conditions. As demonstrated above, the ban discriminates between like products, without advancing its stated objective. Therefore, it is a "means of arbitrary or unjustifiable discrimination". Also, it disadvantages imports of chrysotile, but not imports of man-made fibres. Countries like Brazil (and Canada) produce both chrysotile and substitute fibres. Therefore, the criterion of "discrimination between countries where the same conditions prevail" is obviously satisfied. Similarly, as previously demonstrated, the ban is a "disguised restriction on international trade". Although it masquerades as a measure designed to protect public health, it is an outright product ban that is designed to quell public outrage and advantage domestic and European manufacturers of substitute fibres and products. Moreover, it cannot be argued that the ban is "necessary" to protect human life or health. For these reasons, the EC should not be granted recourse to Article XX.

B. UNITED STATES

1. Introduction

4.46 The United States' submission first discusses the facts concerning the health risks of exposure to chrysotile asbestos, and reduction of these risks through regulation. In this connection, the United States supplies information correcting certain errors and mischaracterizations in Canada's description of the United States regulation of asbestos and the former United States ban and phaseout on asbestos-containing products. United States regulations are not at issue in this proceeding. The United States' submission nevertheless seeks to set the record straight because of Canada's assertions concerning United States policy. Following a factual discussion, it addresses the legal provisions that the Panel has been asked to interpret.

4.47 In the view of the United States, chrysotile asbestos is a toxic material that presents a serious risk to human health. Chrysotile asbestos is no less toxic than other forms of asbestos. A regulatory approach that treats all forms of asbestos on a par with each other is scientifically justified. France, like all other Members of the WTO, has the right to set its own desired level of protection against risks arising from exposure to asbestos, and its regulation on asbestos appears neither discriminatory nor unnecessarily trade restrictive in ensuring that level of protection. The United States currently relies on specified work practices and other controls (including a limited ban) to reduce the risk to human health from asbestos exposure. However, the United States does not consider its approach to be the only appropriate one for regulation of asbestos. Specification of work practices and other controls does not avoid all the risks associated with a hazardous material such as chrysotile asbestos. First, "controlled use" does not eliminate all the risks associated with asbestos. Although it is generally true that asbestos contained in a cement matrix does not present substantial risks while that product is intact, the same is not true during the production, installation, maintenance, removal, or disposal of that product. Second, in many cases a matrix containing asbestos does not remain intact during its useful life. Moreover, while the bulk of Canada's submission focuses on cement-matrix applications, it also acknowledges that chrysotile asbestos is currently used in brake linings and spun fibres for the production of insulating tissues or cords. Significant health risks attend the manufacture and repair of such substances. Finally, even the best work practice is effective only to the extent that it is followed;

accidents, use of improper techniques, and intentional non-compliance are virtually inevitable in the use of these products. For these reasons, France's ban on the manufacture, processing, distribution in commerce, export, import and sale of asbestos and its products appears to be a WTO-consistent response to the risks posed by the use of asbestos.

4.48 As for the legal issues: In the view of the United States, Canada has not met its burden of proof with respect to *any* violation by the French Decree of provisions of the GATT or the Agreement on Technical Barriers to Trade ("TBT Agreement"). In particular, Canada has not shown that imported asbestos and asbestos-containing products are "like products" with respect to substitute fibres and products containing them which are of French origin. As a finding that these products are not "like products" eliminates any violation of Article III:4, and Article XI:1 is simply irrelevant to the analysis of this measure, there does not appear to be any violation of the GATT 1994. With respect to the TBT Agreement, the United States disagrees with the EC position that the TBT Agreement is inapplicable to the French Decree. The Panel should reject the EC's position and find that the Decree is a "technical regulation" within the meaning of Annex 1 of the Agreement; any other result will open up a loophole which could entirely nullify the TBT Agreement. Nevertheless, in the United States view Canada has not proven any violation of Articles 2.2, 2.4, 2.8 or 2.1 of the Agreement. Finally, Canada has not met the particularly high burden of proof for cases of non-violation nullification and impairment.

2. Factual Aspects

4.49 The **United States** argues that asbestos - whether chrysotile or in other forms[66] - is a toxic substance. In United States lexicography, it is a "Class A carcinogen", meaning a substance whose carcinogenic properties have been proven conclusively.[67] The IPCS has reached the same conclusion: "[E]xposure to chrysotile asbestos poses increased risks for asbestosis, lung cancer and mesothelioma in a dose-dependent manner."[68] The IPCS Report also concludes: "[C]ommercial grades of chrysotile have been associated with an increased risk of pneumoconiosis, lung cancer and mesothelioma in numerous epidemiological studies of exposed workers."[69] In regulating asbestos, the United States treats chrysotile asbestos the same as any other recognized form of the substance.[70] The findings presented by Stayner *et al.*[71] support the decision not to distinguish between chrysotile and other forms of asbestos. This study concluded that it is prudent to treat chrysotile with virtually the same level of concern as the amphibole forms of asbestos, based on the evidence of a significant lung cancer risk, the fact that workers are generally exposed to a mixture of fibres, and the lack of conclusive evidence for the "amphibole hypothesis".[72] More recent confirmation of the hazardous nature of chrysotile was

[66]The United States notes that its arguments focus on chrysotile asbestos, as that is the subject of the Canadian challenge.

[67]United States Environmental Protection Agency ("EPA"), Integrated Risk Information System (IRIS), Asbestos Substance File (1993) (www.epa.gov/ngispgm3/iris/subst/0371.htm#II) (includes summary of weight-of evidence classification and human carcinogenicity data, including data showing the carcinogenicity of chrysotile asbestos).

[68]*IPCS Environmental Health Criteria 203 – Chrysotile Asbestos*, WHO, 1998, p. 144. (The IPCS document cites numerous studies supporting this conclusion).

[69]*IPCS Environmental Health Criteria 203 – Chrysotile Asbestos,* WHO, 1998, p. 7.

[70]*Airborne Asbestos Health Assessment Update,* p. 118 (EPA, June 1986) (concluding that "while differences in pleural mesothelioma risk attributable to fibre type may exist, they are much less than differences attributable to other factors").

[71]Stayner, L. T., Dankovic, D. A., and Lemen, R. A., *Occupational Exposure to Chrysotile Asbestos and Cancer Risk: A Review of the Amphibole Hypothesis*, 86 American Journal of Public Health, 179-186, 1996.

[72]The United States notes that the "amphibole hypothesis" postulates that the mesotheliomas among the workers exposed to chrysotile may be explained by confounding exposures to amphiboles, and that chrysotile may have a lower carcinogenic potency than amphiboles.

provided by Landrigan, concluding on the basis of an epidemiological study undertaken in Quebec that "chrysotile asbestos is still indisputably a human carcinogen.[73]" Concerning exposure to asbestos, IARC stated in 1976 that "at present it is not possible to assess whether there is a level of exposure in humans [to asbestos] below which an increased risk of cancer would not occur."[74] The IPCS reaffirmed this conclusion specifically with regard to chrysotile asbestos in 1998, stating: "[N]o threshold has been identified for carcinogenic risks" with regard to chrysotile asbestos.[75] That means that it cannot be assumed that any exposure, no matter how small, to asbestos is safe. Canada questions France's scientific approach, attacking the use of a "linear risk model". The United States takes issue with Canada's criticism of the INSERM Report's use of a linear dose-response model to estimate cancer risk. The use of such a model is entirely appropriate when it comes to estimating the risk of cancer from exposure to asbestos.

4.50 The United States notes that it is not in a position to draw definitive conclusions concerning the regulatory process in France and the actual factual basis for the French Decree. However, generally speaking, regulatory decision-making relating to carcinogens involves two components: risk assessment and risk management. Risk assessment defines the adverse health consequences of exposure to toxic agents. Risk management combines the risk assessment with the directives of regulatory legislation, together with socioeconomic, technical, political, and other considerations, to reach a decision as to whether or how much to control future exposure to the suspected toxic agents.[76] Risk assessments are carried out independently from considerations of the consequences of regulatory action.[77] A risk assessment involves, among other things, quantitative and/or qualitative estimation of risks associated with low levels of exposure to carcinogens. While it is always preferable to rely on human data, epidemiological studies are often either not available or sufficiently definitive, particularly regarding the specific exposure levels involved, and thus often cannot be relied upon as the sole basis for a risk assessment.[78] In addition, because testing of thousands of animals would be necessary in order to have the sensitivity to detect any but large effects, it generally is not practical to measure risks at low exposure levels directly in animal experiments.[79] Accordingly, a number of mathematical models have been developed to extrapolate from high dose animal studies to low human doses.[80]

4.51 In the United States, models or procedures that incorporate low-dose linearity have been adopted when data and information are limited and when there is uncertainty regarding the mechanism of carcinogenic action.[81] While low-dose linearity may not be appropriate for all carcinogenic risk

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[73]Landrigan, P. L., *Asbestos - Still a Carcinogen,* 338 New England Journal of Medicine 1619 (28 May 1998).

[74]*Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man*, Vol. 14, IARC, 1976, p. 81.

[75]*IPCS Environmental Health Criteria 203 – Chrysotile Asbestos,* WHO, 1998, p. 144.

[76]*Final Guidelines for Carcinogen Risk Assessment*, 51 Federal Register 33992, 33993, col. 3 (EPA, 24 Sept. 1986).

[77]51 Federal Register 33992, 33993, col.3 (24 September 1986).

[78]The United States notes that, as the 1986 EPA carcinogen risk assessment guidelines point out: "It should be recognized that epidemiological studies are inherently capable of detecting only comparatively large increases in the relative risk of cancer. Negative results from such studies cannot prove the absence of carcinogenic action … ". (51 Federal Register 33992 (24 September 1986), pp. 33995-96). Canada's statement that "no epidemiological study to date has detected a higher health risk [than the linear risk model] resulting from low-level exposures" must be viewed in this light.

[79]51 Federal Register 33992 (24 September 1986), p. 33993, col. 3.

[80]51 Federal Register 33992 (24 September 1986), p. 33997. See also EPA Proposed guidelines for carcinogen risk assessment, 61 Federal Register 17960, 17962 (23 April 1996). Although these most recent guidelines are not yet final, they demonstrate that EPA's reassessment of the issues is similar to the approach taken previously.

[81]51 Federal Register 33992 (24 September 1986), p. 33997, col.3.

assessment, it is commonly used in the United States as a default methodology. This methodology is supported by scientific studies and is a reasonably protective approach in the face of uncertainty.[82] The use of a linear model is appropriate for a quantitative estimation of the risks associated with low levels of exposure to asbestos because of the observed linearity of the response in occupational studies. The United States has adopted this approach, in addition, because of the incomplete understanding of how asbestos causes diseases in humans.[83] In assessing the risk from asbestos, EPA notes that "[d]irect evidence for linearity of response with asbestos exposure is available from seven studies (two of the same plant) that compared lung cancer mortality to the cumulative total dust exposure in asbestos workplaces"[citations omitted].[84] Similarly, the limited data that exist for mesothelioma also indicate a linear relationship.[85] The IPCS states: "there was a clear dose-response relationship, with crude rates of mesotheliomas (cases/1000 person-years) ranging from 0.15 for those with cumulative exposures less than 3530 million particles per cubic meter years … to 0.97 for those with exposures of more than 10,590 mpcm-years […].[86]" After identifying and defining the adverse effects of asbestos through the risk assessment process, the next step is to make risk management decisions. A risk management decision, while taking into account the scientific findings of the risk assessment process, also includes a country's choice on whether and how much to regulate a toxic agent. It is at this stage that a country selects measures and regulations that will achieve its chosen level of protection relating to the health of its people.

4.52 In its arguments, Canada has referred to United States regulations concerning asbestos. Because its description of the U.S. regulatory approach is substantially inaccurate, the United States proceeds to set the record straight. The U.S. regulatory approach at present includes a mix of control measures, including bans and required work practices. This approach involves a number of complex statutes, some of which require the consideration of cost, feasibility and other factors besides human health. Almost all control measures are designed to protect workers and building occupants from exposures resulting from contact with asbestos in installed products. Although France's approach to the same problem is different, this different approach is also reasonable under the circumstances.

4.53 Canada references the 1989 rule promulgated by the EPA prohibiting the future manufacture, importation, processing and distribution in commerce of asbestos in almost all products ("the Asbestos Ban and Phase-Out Rule").[87] Several of Canada's statements on this point are factually inaccurate. According to the United States, the Asbestos Ban and Phase-Out Rule was in large part vacated and remanded to EPA by the United States Court of Appeals for the Fifth Circuit in a case entitled *Corrosion Proof Fittings vs. Environmental Protection Agency*[88], based on the court's view that EPA had not appropriately addressed cost-benefit issues. Contrary to the claims made by Canada that EPA was incapable of scientifically justifying its ban, and that the risks posed by asbestos were not supported by scientific facts, the court specifically agreed with EPA's scientific judgment by recognizing that "[a]sbestos is a toxic material, and occupational exposure to asbestos dust can result in mesothelioma, asbestosis, and lung cancer."[89] Indeed, in the record of rulemaking, EPA provided, among other things, a number of scientific studies and reports on the health risks of asbestos, including: Airborne Asbestos Health Assessment Update[90], Report to the United States Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Asbestos[91], Asbestiform

[82]61 Federal Register 17960 (23 April 1996), p. 17965.
[83]*IPCS Environmental Health Criteria 203 – Chrysotile Asbestos*, WHO, 1998, p. 7.
[84]*Airborne Asbestos Health Assessment Update,* EPA, June 1986, p. 23.
[85]*Airborne Asbestos Health Assessment Update,* EPA, June 1986, pp. 23-30.
[86]*IPCS Environmental Health Criteria 203 – Chrysotile Asbestos*, WHO, 1998, p. 8.
[87]54 Federal Register 29460-29513, 12 July 1989.
[88]*Corrosion Proof Fittings v. Environmental Protection Agency,* 947 F.2d 1201 (5th Cir. 1991).
[89]Ibid., p. 1207.
[90]*Airborne Asbestos Health Assessment Update* (EPA, June 1986).
[91]*Chronic Hazard Advisory Panel on Asbestos,* U.S. Consumer Product Safety Commission, July 1983.

Fibres: Non-occupational Health Risks[92] and "Short-term asbestos work exposure and long-term observation.[93]" These studies and reports were discussed in the preamble to the Rule.[94] The court based its decision on procedural flaws in the EPA rulemaking process and on the court's own interpretation of the applicable United States statutory risk/benefit balancing standard for promulgating such rules, not on any disagreement with EPA's findings concerning the health hazards posed by asbestos. After the judicial remand, EPA imposed a more limited ban on asbestos-containing products, including a ban on any new uses of asbestos.[95] That ban remains in place.

4.54 The United States notes that Canada makes much of the argument that asbestos entrained in a cement matrix does not present "detectable risk.[96]" However, Canada's focus ignores the risks presented by asbestos products throughout their life-cycle. The most significant sources of exposure to asbestos, and therefore risk from asbestos-containing products derive from their manufacture, installation, repair, removal, and disposal, including disposal of products containing asbestos in a cement or resin matrix. Moreover, while Canada appears to acknowledge France's concern about protecting health in general terms, it appears to disagree about how protective France should be. By arguing that certain small risks are equivalent to zero risks, the Canadian submission implicitly questions the sovereign authority of a WTO Member to determine the appropriate level of protection for its citizens. What Canada or the United States might consider to be adequate protection in a particular context is not necessarily what other countries must choose. To put it another way, Canada concedes that a ban is acceptable for "certain uses where exposure cannot be controlled to an acceptable degree". The United States agrees, but submits that it is up to each Member to determine what that "acceptable degree" is. Canada indicates that among the most important commercial applications of asbestos are as part of brake linings or clutches and in the form of spun fibres for the production of insulating tissues or cords. In connection with its analysis of "friction products", which include brake linings and clutches, the United States court in the Corrosion Proof Fittings case recognized that "[w]orkers are exposed to asbestos during the manufacture, use, repair and disposal of these products" and that, in the asbestos ban and phase-out rule, "EPA demonstrates that the population exposure to asbestos in this area is great."[97] The court agreed with EPA's determination that friction products containing asbestos pose a risk to human health.[98]

4.55 With respect to Canada's argument that a major commercial application for asbestos is as a reinforcement material for cement, plastic, or rubber, the United States asserts that, in the Asbestos Ban and Phase-Out Rule, EPA made certain determinations respecting worker exposure to these products that were not questioned by the Corrosion Proof Fittings court. EPA determined that the manufacture, installation, repair, and disposal of flat and corrugated asbestos-cement sheet expose

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[92]*Asbestiform Fibres: Non-Occupational Health Risks*, NAS, NRC, 1984.

[93]Seidman, H., Selikoff, I .J., Hammond E. C., *Short-Term Asbestos Work Exposure and Long-Term Observation*, 330 Annals of the New York Academy of Sciences 61-89, 1979.

[94]54 Federal Register 29460 (12 July 1989), p. 29468-70.

[95]40 Code of Federal Regulations (CFR) 763.165-763.169 (59 FR 33208, 28 June 1994).

[96]The United States notes that it is not entirely clear what Canada means by the term "undetectable risk". The presence of asbestos fibres in the air or other media can be detectable or undetectable. A risk can be significant, insignificant, or non-existent. It appears that Canada uses the term "undetectable risk" to refer to a risk that Canada deems insignificant. Significance, however, is a judgment call that can only be made by the regulatory authority responsible for public health and safety. It is up to France to determine what level of risk to the French people from asbestos (or any other hazard) is significant.

[97]*Corrosion Proof Fittings v. Environmental Protection Agency*, 947 F.2d 1201 (5th Cir. 1991), p. 1224.

[98]Significant damages have been awarded in U.S. courts with respect to brake applications of asbestos. In 1985, a retired brake mechanic who was dying of mesothelioma won a verdict of $2 million in a court action against Raybestos Manhattan. See McDonald AD, et al., *Dust Exposure and Mortality in an American Chrysotile Asbestos Friction Products Plant*, 41 Br J Ind Med 151-157, 1984; Newhouse M. L. and Sullivan K. R., *A Mortality Study of Workers Manufacturing Friction Materials: 1941-86*, 46 Br J Ind. Med, 176-179, 1989.

workers to asbestos.[99] Similarly, EPA determined that the manufacture and installation of asbestos-cement pipe provide "primary routes of exposure" of workers to asbestos from these products, and workers may also be exposed during the removal of asbestos-cement pipe.[100] The United States generally agrees with Canada's assertion that as long as asbestos is held within a cement or resin matrix in an undisturbed state, there is minimal exposure to the fibres - but only while the matrix retains its integrity. Much asbestos has been installed in United States buildings. Because of the high health risk from disturbed building materials and the reduced risk from intact asbestos-containing materials, EPA has issued guidance recommending management of asbestos-containing materials in place.[101] Unfortunately, cement and resin matrices do not remain undisturbed. Putting aside significant releases that occur during the manufacturing process[102], releases of asbestos can occur when, for example, asbestos-cement pipes are installed (which requires cutting the material), and when asbestos-containing material (such as cement) deteriorates, as through peeling, cracking, or crumbling. Fibre release could also result when the material is dry, has the capacity to be crumbled, pulverized or reduced to powder by hand pressure, or is subject to sanding, grinding, cutting or abrading.[103]

4.56 The United States asserts that a cement matrix in which asbestos is bound can undergo a natural process of erosion or degradation resulting in asbestos fibre release: "[T]he release of fibres from external asbestos-cement products [such as siding] due to weathering can be an important external source of asbestos contamination that can be carried into or can infiltrate into the building environment". This has been acknowledged by the 1991 Health Effects Institute-Asbestos Research (HEI-AR) report, *Asbestos in Public and Commercial Buildings: A Literature Review and Synthesis of Current Knowledge*.[104] As reported in the HEI-AR document, researchers found that weathered asbestos-cement sheet products washed from gutters and onto walkways were an important source of chrysotile carried by foot or wind into a classroom.[105] The report also cited a research finding of increased ambient air concentrations in the vicinity of buildings with asbestos-cement products on their exterior.[106] Mere maintenance of some asbestos bound in a matrix may disturb the matrix and thereby create additional exposures to the asbestos fibres. For example, in an EPA study[107] conducted at 17 schools in New Jersey involving spray buffing of resilient floor tile containing asbestos, airborne asbestos concentrations were approximately five times higher during than before spray-buffing with high-speed machines, whereas spray-buffing with low speed machines showed a two-fold increase. For school maintenance workers, the maximum estimated eight-hour time-weighted average exposure concentration was 0.093 f/cc. Similarly, routine spray-buffing and wet-stripping as well as ultra-high speed burnishing and wet-stripping of asbestos-containing resilient floor tile can result in elevated

[99]54 Federal Register 29460-29513 (12 July 1989), p. 29491.

[100]54 Federal Register 29460-29513 (12 July 1989), pp. 29496-97.

[101]*Managing Asbestos in Place: A Building Owner's Guide to Operations and Maintenance Programs for Asbestos-Containing Materials*, EPA, July 1990.

[102]The United States notes that, for example, a study of mortality among long-term employees of an Ontario asbestos-cement factory found a substantially increased risk of death from lung cancer and mesothelioma. Finkelstein, M. M., *Mortality Among Long-Term Employees of an Ontario [Canada] Asbestos-Cement Factory*, 40 Br. J. Ind. Med. 138-44, 1983.

[103]The United States notes that this has been recognized by EPA's asbestos National Emission Standard for Hazardous Air Pollutants (NESHAP), promulgated under §112 of the Clean Air Act, 42 U.S.C. 7412. 55 Federal Register 48406, 48408-09 (Nov. 20, 1990), codified at 40 CFR part 61, subpart M.

[104]*Asbestos in Public and Commercial Buildings: A Literature Review and Synthesis of Current Knowledge*, Health Effects Institute-Asbestos Research Report, 1991, p. 4-32.

[105]Ibid., pp. 4-32 and 4-33.

[106]Ibid., pp. 4-33.

[107]*Project Summary: Airborne Asbestos Concentrations During Buffing of Resilient Floor Tile*, EPA, October 1993, p. 4.

levels of airborne asbestos.[108] Part 2 of the Kominsky study demonstrates that the ultra high-speed burnishing and wet-stripping procedures were associated with a maximum estimated eight-hour time-weighted average exposure concentration of 0.275 f/cc to operations and maintenance staff.[109] Likewise, the HEI-AR Report states that: "buffing, wax stripping, and other abrasive treatments may cause the release of particulate material from the surface of the floor tile".[110]

4.57 The United States' regulatory programme on asbestos is largely aimed at controlling exposure to asbestos when it is no longer bound in a matrix. United States regulations address renovation and demolition of buildings[111] and identification and management of asbestos-containing material in schools.[112] Regulations of the Occupational Safety and Health Administration (OSHA) of the Department of Labor address worker exposures to asbestos including manufacture, installation, renovation, removal and custodial work where workers come into contact with asbestos-containing material. OSHA has established a permissible exposure limit and mandated extensive work practice controls, enclosures, hazard communication, training, medical and other industrial hygiene practices to protect both workers contacting asbestos and other workers who are nearby. Enforcing and complying with these regulations entail a significant commitment of resources by both the public and private sectors. Even within a cement or resin matrix, the risk from asbestos is not negligible. According to an analysis conducted in 1991 by the Health Effects Institute-Asbestos Research[113], janitors, custodians and maintenance workers exposed to ambient asbestos fibre levels of 0.1 f/ml (the permissible exposure limit currently allowed by OSHA regulations) were subject to an estimated increased risk of death from cancer of 2 in 1,000. The same analysis estimated that building occupants (school children and office workers) exposed to airborne asbestos fibres from asbestos-containing materials (presumably many of which, as building materials, would have been encased in cement or resin) have a lifetime cancer risk from such asbestos exposure of 4 to 60 per 1,000,000. Contrary to Canada's suggestion, such risks are not equivalent to zero. Each country must determine for itself what level of protection from risks of exposure to asbestos it wishes to achieve, i.e. what risks to its population it is willing to accept. It is not for another country to tell France that certain risks to its population are not significant. By way of illustration, the United States regulates risks on the order of 1 in 100,000 (1×10^{-5}) or 1 in a million (1×10^{-6}) in a number of instances. Canada concedes that "[t]he principle of controlled use also means that certain uses for which exposure cannot be controlled to an acceptable degree would be banned". The discussion above demonstrates that exposure to asbestos even in a cement or resin matrix cannot be controlled sufficiently to eliminate all risk.

4.58 The United States argues that both of the parties have mischaracterized the substitutes for asbestos and asbestos-containing products. Some products that currently contain asbestos may be manufactured simply by removing the asbestos, thus eliminating any substitution of risk. Alternatively, a wide variety of fibrous substances are being used commercially as replacement materials for asbestos-containing products. These include the man-made mineral fibres (consisting of glass fibres, rock wool, slag wool, refractory ceramic fibres), selected organic fibres (e.g., aramid, carbon/graphite, polyolefin), and several naturally occurring mineral fibres other than asbestos (e.g., wollastonite, sepiolite, palygorskite). The potential health effects for these non-asbestos fibres

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[108]Kominsky J. R., Freyberg R. W., Clark P. J., Edwards A; Wilmoth, R. C., Brackett, K. A., *Asbestos Exposures During Routine Floor Tile Maintenance. Part 1: Spray-Buffing and Wet-Stripping; Part 2: Ultra High Speed Burnishing and Wet-Stripping*, 13 Appl. Occup. Environ Hyg. 101-112 (February 1998).

[109]Ibid., pp. 107-112

[110]*Asbestos in Public and Commercial Buildings: A Literature Review and Synthesis of Current Knowledge,* Health Effects Institute-Asbestos Research Report, 1991, pp. 4-70.

[111]Asbestos NESHAP, 40 CFR 61.145.

[112]Regulations issued under the Asbestos Hazard Emergency Response Act (AHERA), 15 USC 2641 et seq.: 40 CFR part 763, subpart E.

[113]*Asbestos in Public and Commercial Buildings: A Literature Review and Synthesis of Current Knowledge,* Health Effects Institute-Asbestos Research Report, 1991, pp. 8-9 - 8-10.

have been evaluated by EPA,[114] the IARC[115] and the IPCS.[116] Although limited health effects information exists for many of these fibres, available data do not indicate that these fibres are as toxic as chrysotile asbestos. For example, none of these fibres have been found to cause either malignant or non-malignant respiratory diseases similar to those associated with asbestos exposure in humans. Unlike asbestos fibres, these substitute fibres have not been classified as carcinogenic to humans or known human carcinogens. The only fibre that has been shown to be more hazardous than asbestos fibres is erionite. Erionite, however, is not known to be available in commerce at this time.[117]

4.59 The United States notes that Canada continually urges that "controlled use" will bring the risk associated with chrysotile asbestos to "undetectable" levels. It also compares the risk from asbestos to that of other products and activities, concluding that many are more risky than asbestos. Canada overstates the efficacy of "controlled use". For example, Canada states that where it is necessary to cut chrysotile-cement materials on site, "the use of tools that almost entirely eliminate emissions (low-speed saws, with water injection or equipped with suction units), and the wearing of a mask by the operator guarantee their safety". United States regulations recognize, however, that masks may not be sufficient in some situations and require the use of a supplied-air respirator which is obviously more cumbersome and costly.[118] When a government makes its choice whether to ban a product or to opt for controlled use, it must necessarily take into account the anticipated effect of the regulations on its population. Beyond the obvious point that "almost" eliminating emissions of asbestos fibres is not the same as eliminating them, it must be acknowledged that 100 per cent compliance with "controlled use" of asbestos is not a realistic expectation due to the burdensome nature of certain work practices concerned. Even the best work practice is effective only to the extent that it is followed; accidents, use of improper techniques, and international non-compliance are virtually inevitable in the use of these products.[119]

4.60 The United States argues that Brazil has made a number of unjustified and inaccurate assertions concerning the U.S. Environmental Protection Agency's former ban on all forms of asbestos and asbestos-containing products in the United States, and a domestic court decision concerning the EPA ban. Of course, this U.S. domestic court did not rule on the consistency of the EPA ban with the TBT Agreement or the GATT. It only dealt with whether EPA had complied with the risk/benefit balancing requirements of the U.S. Toxic Substances Control Act (TSCA). The risk/benefit standard in this U.S. statute is irrelevant to the Panel's present task of determining whether France's ban on asbestos is consistent with the WTO Agreement. France has not adopted such a risk/benefit balancing standard as the basis for a ban. First, Brazil misrepresents the domestic court decision and the situation following, repeating errors made by Canada. The court in 1991 upheld EPA's determination that "[a]sbestos is a toxic material, and occupational exposure to asbestos dust can result in mesothelioma, asbestosis, and lung cancer". The court based its decision not on any disagreement with EPA's findings concerning the health hazards posed by asbestos, but instead on procedural flaws in the EPA rulemaking process and on the Court's own interpretation of the statutory risk/benefit

[114]*Health Hazard Assessment of Non-Asbestos Fibres*, EPA, 1988.

[115]*Man-Made Mineral Fibres and Radon: Monographs on the Evaluation of Carcinogenic Risks to Humans*, Volume 43, pp. 39, 148-52, IARC 1988.

[116]*Asbestos and other Natural Mineral Fibres,* IPCS, 1986, Environmental Health Criteria 53, International Programme on Chemical Safety, World Health Organization, Geneva; *Man-Made Mineral Fibres* (IPCS 1988), Environmental Health Criteria 77, International Programme on Chemical Safety, World Health Organization, Geneva; *Selected Synthetic Organic Fibres,* (IPCS 1993), Environmental Health Criteria 151, International Programme on Chemical Safety, World Health Organization, Geneva.

[117]In addition, see the US answer to question 4 of the EC (contained in Annex II, Section II.A.4).

[118]40 CFR 763.121(h) (EPA regulations covering employees of certain state and local governments conducting asbestos abatement projects); 29 CFR 1926.1101(g)(2)(v) (OSHA asbestos regulations for construction).

[119]In addition, see the US answer to question 2 of the EC (contained in Annex II, Section II.A.4).

balancing required by TSCA. Because the court agreed with EPA on the health effects of asbestos, EPA did not, after the court decision, need to carry out a "thorough review of scientific and medical data" as a basis to authorize or ban the products Brazil has listed. All EPA did, pursuant to the court's instructions, was to determine which product categories were no longer manufactured, imported, or processed when the rule was issued. For all such products the ban was maintained. EPA also banned new uses of asbestos.[120]

4.61 Second, contrary to what is alleged by Brazil, the United States has not determined that controlled-use policy effectively eliminates the health risk attributable to modern-day uses of chrysotile. Third, Brazil has downplayed the health risk from asbestos by lifting a quotation out of context from the Health Effects Institute report, in a manner that does not accurately reflect the discussion of mathematical models found in this section of the HEI report.[121] The United States addressed these issues as described above at paragraph 4.40. Finally, concerning Brazil's discussion of the French Decree, the United States notes that Brazil concedes that the objective of the Decree - protection of the health of workers and the public - is a legitimate objective within the meaning of Article 2.2 of the TBT Agreement. The United States agrees with Brazil on this point but would also note that France has a right to set its "legitimate objective" to establish the protection of the health of French workers and consumers at the level it deems appropriate. However, when alleging that there is no "rational link" between the French Decree and health protection, stating that the Decree will not make those now sick healthy, and removing it would not make any of those now healthy sick, Brazil conveniently omits the function of the Decree in preventing future exposure and future disease that would result from that exposure.

3. Legal Aspects

4.62 For the reasons below, the United States suggests that the Panel should find that Canada has failed to meet its burden of proof that the French Decree violates any provision of the WTO Agreement. The Panel should also find that Canada has failed to make a showing that the French Decree gives rise to non-violation nullification or impairment of benefits accruing to Canada.

(a) The General Agreement on Tariffs and Trade

(i) Article XI of the GATT

4.63 With respect to Canada's argument that the Decree violates Art. XI:1 because it imposes an absolute prohibition or restriction on imports, the United States agrees with the EC that Article XI is simply not relevant to these proceedings, and the Decree should be analyzed under Article III instead. The Decree regulates characteristics of asbestos and asbestos-containing products. It applies to all asbestos, and is applied to imported products "at the time or point of importation," in the words of the Note *Ad* Article III.

(ii) Article III of the GATT

4.64 With respect to Canada's allegation that the Decree violates the national treatment obligations embodied in GATT Article III:4, the United States argues that, to show a violation of Article III, there must be discrimination - that is, unlike treatment of like products. Yet the relevant domestic and imported products here are not "like products" for the purposes of Article III:4. As the EC has noted, the classic statement of the factors relevant in determining what constitutes a "like product" is found

[120]For the details, see 40 Code of Federal Regulations 763.160, 763.165-763.169 (59 Federal Register 33208 (28 June 1994).

[121]Health Effects Institute – Asbestos Research, *Asbestos in Public and Commercial Buildings: A Literature Review and Synthesis of Current Knowledge*, Cambridge, 1991, pp. 6-9.

in the Working Party report on Border Tax Adjustments of 1968, which defined like products in terms of "the product's end-uses in a given market; consumers' tastes and habits, which change from country to country; the product's properties, nature and quality".[122] The United States generally agrees with the EC's analysis that the properties, nature and quality of asbestos and asbestos-containing products on the one hand, and substitutes on the other, are not "like". The substitutes are by definition substitutable for asbestos and asbestos-containing products for certain uses, but that does not mean that they are "like products".

4.65 According to the United States, Canada has not made the correct product comparison for the purpose of determining whether the relevant products are "like products" under Article III:4. In considering a regulation that bans asbestos and requires the use of substitutes, the relevant products to compare are the following: (i) asbestos must be compared to substitute fibres; and (ii) products containing asbestos must be compared to products that do not contain asbestos but which perform the same function. Where the asbestos elements of a product were inessential, the substitute product may consist of the same product minus the asbestos element (e.g., a kitchen hot pad with thick cotton padding but no asbestos); or the same product redesigned to eliminate the need for asbestos; or a similar product which uses different fibres (e.g., a hot pad made of glass fibre); or a similar product made of what the EC describes as "classic materials" (e.g., a trivet made of cast iron, ceramic or plastic). The physical correspondence between the two classes of products is therefore considerably weaker than Canada has assumed. Canada has failed to show that asbestos and asbestos-containing products and the substitutes have the same "properties, nature and quality". The known severe adverse human health effects of asbestos are another reason why asbestos-containing products are not "like" the substitutes for which adverse health effects have not been demonstrated. The substitute fibres differ considerably in physical structure and properties from chrysotile asbestos and thus cannot be considered "like products." For example, while chrysotile is a naturally occurring mineral which is crystalline in nature, the man-made mineral fibres (MMMF) are amorphous (non-crystalline) silicates which are produced from a liquid melt of different starting materials (e.g., slag, natural rock, glass, clays). Furthermore, unlike chrysotile asbestos, MMMF do not split longitudinally into smaller fibrils of smaller diameter, but may break transversely into shorter segments.[123]

(iii) Article XXIII:1(b) of the GATT

4.66 The United States argues that Canada has failed to meet the special burden imposed by Article 26.1 of the Dispute Settlement Understanding on parties making claims of non-violation nullification or impairment. The United States has been one of the strongest proponents of the non-violation remedy, as an essential safeguard for bargained-for market access rights against frustration by government actions. But the requirements of the non-violation remedy are not satisfied here. As the EC have noted, the text of Article XXIII:1(b) establishes three elements that a complaining party must demonstrate in order to make a cognisable claim under Article XXIII:1(b): (i) application of a measure by a WTO Member; (ii) a benefit accruing under the relevant agreement; and (iii) nullification or impairment of the benefit as a result of the application of the measure. Canada, as the complaining party, has the burden of presenting detailed evidence in support of all three elements. In the present case, there is no dispute that the French Decree is a measure of a Member. The question is simply whether Canada has a legitimate expectation of benefits accruing to it. The precedents are clear that for expectations to be legitimate, they must take into account all measures of the party making the concession that could reasonably have been anticipated at the time of the concession.

[122]BISD 18S/102, para. 18.

[123]*Man-Made Mineral Fibres*, IPCS Environmental Health Criteria 77, 1988, pp. 11-12; *Man-Made Mineral Fibres and Radon: Monographs on the Evaluation of Carcinogenic Risks to Humans*, Vol. 43, IARC, 1988, pp. 39-53; *Asbestos and Other Natural Mineral Fibres*, Environmental Health Criteria 53, IPCS, 1986, pp. 22-24.

4.67 The United States considers that, as a matter of principle, the Panel should reject the possibility of a finding of non-violation nullification or impairment with respect to health and safety regulations that respond to the development of scientific knowledge concerning health risks. Members do not have a legitimate expectation that regulatory measures will stay static in the face of expanding scientific knowledge concerning health risks, and changing societal decisions concerning the level of acceptable risk. Canada is also in a poor position to argue that an asbestos ban was unforeseeable at the time it negotiated the tariff concessions on asbestos. The dangers posed to human health by asbestos are notorious and have been so for many years. Pliny, the ancient Roman author, described the "diseases of slaves" as including exposure to the textile processes of preparing and weaving asbestos, and even referred to the use of a transparent bladder skin as a respirator to avoid inhalation of dusts by slaves.[124] As of the time of the first GATT negotiating round in 1947, asbestosis had already (in the 1920s) been identified as a distinct condition caused by asbestos.[125] By 1935 asbestosis was widely recognized as a mortal threat affecting a large fraction of those who regularly worked with the material.[126] In addition, by the mid-1940s there were indications that exposure to asbestos in animals and humans was associated with lung tumours.[127] Thus Canada should have reasonably expected subsequent regulatory action (such as a ban) by a GATT contracting party as a result. As of the Dillon Round of 1960-61, Canada had even more reason to foresee the possibility of restrictive regulations of asbestos. An international symposium of experts on the pathogenesis of lung cancer in 1953 published its conclusions and recommendations in a journal which editorialised: "[I]t seems to be beyond discussion that cancer of the lung is sometimes caused by occupational exposure to asbestos."[128] In addition, two major studies had been published in 1955 on cancer in the textile industry demonstrating the relationship between asbestosis and lung cancer.[129] Since the early 1960s, the hazards posed by asbestos - and particularly chrysotile asbestos - have become even more widely known and documented.[130]

(b) The Agreement on Technical Barriers to Trade

4.68 With respect to Canada's arguments that the French ban on asbestos is inconsistent with a number of provisions in the Agreement on Technical Barriers to Trade (TBT), the United States argues that Canada has misread the relevant TBT articles. The interpretation of the TBT Agreement on which Canada's arguments are based attempts to read into the Agreement obligations that do not exist. The United States urge the Panel to reject that interpretation. The EC, on the other hand, have argued that the French Decree is not a "technical regulation" because it is a categorical ban on asbestos and products containing asbestos. They have argued that general bans, and specifically this product ban, are not "technical regulations" because they allegedly do not "lay down product characteristics or their related processes and production methods" within the meaning of paragraph 1 of Annex 1 of the TBT Agreement. The United States disagree with the EC's view on this point. In this instance, the Decree lays down "product characteristics […] with which compliance is mandatory". The characteristics in question are that the product may not contain any asbestos if it is to be marketed, offered for sale, imported, exported, etc. in France. Compliance with the exclusion of asbestos is mandatory except if the French Government has accorded a derogation, in which case adherence to the terms of the derogation is mandatory. In any event, the French Decree is a technical

[124]Castleman B. I., *Asbestos: Medical and Legal Aspects*, 4th ed., 1996, p. 1.

[125]Lilienfeld, D. E., *The Silence: The Asbestos Industry and Early Occupational Cancer Research - A Case Study*, 81 American Journal of Public Health 791, 792 (1991).

[126]Castleman B. I., *Asbestos: Medical and Legal Aspects*, 4th ed., 1996, p. 39.

[127]Lilienfield, D. E., *The Silence: The Asbestos Industry and Early Occupational Cancer Research – A Case-Study*, 81 Am. J. Pub. Health 791, 794 (1991); Castleman B. I., *Asbestos: Medical and Legal Aspects*, 4th ed., 1996 pp. 53-65, 135.

[128]Castleman B. I., *Asbestos: Medical and Legal Aspects*, 4th ed., 1996 pp. 94, 95.

[129]Ibid. pp. 97, 98.

[130]See *IPCS Environmental Health Criteria 203 – Chrysotile Asbestos,* WHO, 1998, and sources cited therein.

regulation within the meaning of the TBT Agreement and is subject to the substantive rules of the TBT Agreement. The EC's interpretation of Annex 1 would open up a loophole of potentially huge dimensions in the TBT Agreement. Measures having a very significant impact on trade - for instance, regulations limiting the characteristics of spreadable butter or wool - could simply be redefined as product bans. Similarly, the EC argument would mean that a regulation on the safety of infant toys that excluded any parts below a certain size (to prevent choking) would not be a "technical regulation" nor would regulations excluding water from being added to ham. The provisions of the TBT Agreement would then be rendered a nullity. Such a reading of the TBT Agreement is impermissible as a matter of treaty interpretation, and undesirable as a matter of trade policy. This does not mean that the French Decree does not satisfy the requirements of the TBT Agreement, however. As discussed below, although the TBT Agreement applies to the French Decree, Canada has failed to make a case that the French Decree violates any of the provisions it has cited.

(i) Article 2.1 of the TBT Agreement

4.69 The United States argues that, for the reasons discussed in relation to Article III of the GATT, these products are not "like products." Furthermore, since the ban is applied without discrimination as to the source of the product, discrimination between foreign sources is not an issue.

(ii) Article 2.2 of the TBT Agreement

4.70 The United States notes that Article 2.2 provides a key element of the disciplines in the TBT Agreement. From the standpoint of the United States, certain aspects of Article 2.2 are particularly important with respect to health and safety regulation. The first sentence of Article 2.2 is important because it recognizes that in certain circumstances, technical regulations may create necessary obstacles to trade, and the creation of such necessary obstacles is consistent with the TBT Agreement. We note that the "legitimate objectives" enumerated (non-exhaustively) in Article 2.2 specifically include protection of human health or safety. Article 2.2 also recognizes that in assessing the risks that may arise from non-fulfilment of a legitimate objective, a government may consider a number of elements, including available scientific and technical information, related processing technology or the intended end-uses of a product.

4.71 The obligation in Article 2.2 that technical regulations are not to be more trade restrictive than necessary to fulfill a legitimate objective should be interpreted in a manner similar to Article 5.6 of the Agreement on Sanitary and Phytosanitary Measures (SPS).[131] Such a reading is supported by the sixth clause of the Preamble to the TBT Agreement, which provides that: "[R]ecognizing that no country should be prevented from taking measures necessary … for the protection of human, animal or plant life or health, [or] of the environment […] at the levels it considers appropriate […]." The United States argues that the preamble is part of the context of Article 2.2 in the sense of Article 31 of the Vienna Convention on the Law of Treaties, and provides an authoritative indication of the TBT Agreement's object and purpose for the purposes of treaty interpretation. Thus, in order for a Member to show that a government's technical regulation is more trade-restrictive than required, it would need to show that there is another measure that is reasonably available, fulfils the regulating Member's legitimate objectives, and is significantly less restrictive to trade. Accordingly, the complaining party should be required to identify a specific alternative measure that is reasonably available - as a Member is not required to do what is unreasonable. Furthermore, the alternative measure must make a significant difference from a trade perspective. There should be no need to adopt an alternative measure if it makes only an insignificant difference in terms of trade. Most

[131]Article 5.6 provides in relevant part "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".

importantly, the complaining party must demonstrate that the alternative measure fulfils the government's objectives. Canada has failed to demonstrate that its preferred alternative to the French ban – i.e. "controlled use" of asbestos and asbestos products – fulfils the French Government's stated "legitimate objective" of protection of human health.

4.72 Canada alleged that the Decree does not address the "true problem" of asbestos in France which Canada identifies as the flocking of asbestos. Yet it is not for Canada to determine what France's "true problem" is. It is up to France to determine what level of protection to afford its citizens. Second, Canada alleges that the French Decree violates Article 2.2 because it fails to acknowledge the "scientific reality" that chrysotile encapsulated in a matrix is harmless. Yet as discussed above and as demonstrated by the EC, encapsulated asbestos is not harmless at all, as the encapsulation can easily be breached, and is likely to be breached during the product's life cycle, resulting in release of fibres and elevated risk to human health. Canada alleges that the French Decree violates Article 2.2 because it replaces use of chrysotile – an allegedly harmless product – with substitutes whose health risks are unknown. The United States fundamentally objects to this reading of the TBT Agreement. Canada is implicitly arguing that any regulatory action negatively affecting trade in a product has to be tested against the hypothetical risks engendered by use of likely alternative products. This test has no basis whatsoever in the TBT Agreement.

(iii) Article 2.4 of the TBT Agreement

4.73 Canada has asserted that Article 2.4 requires a panel to determine: (i) whether a technical regulation on chrysotile is required; (ii) whether there are international standards concerning chrysotile, (iii) whether the international standards are effective and appropriate to achieve the objective; and (iv) whether the Decree is based on international standards. Under this analysis, Canada concludes that France adopted the most restrictive measure possible despite the fact that the international community has developed standards representing a less restrictive approach (i.e., controlled use). This analysis misreads Article 2.4. First and fundamentally, Article 2.4 does not contemplate that a panel determine whether a technical regulation is or is not required. The burden of proof is on Canada to demonstrate that international standards exist and are relevant. In regard to the ILO standard, both the ILO Convention 162 and Recommendation 172 allow participating countries to choose the approach they find to be appropriate to protect workers from asbestos hazards. Indeed, the Provisional Record to the 72nd Session of the International Labour Conference, which adopted Convention 162, states concerning Article 10 of Convention 162 (which Canada now claims to condition a ban on a finding concerning the risk posed by product substitutes): "The Government member of Canada saw nothing in Article 10 that would prevent any country from doing whatever it wanted with respect to asbestos." [132]

4.74 The United States argues that Brazil's interpretation of Article 2.4 of the TBT Agreement ignores the fact that climate, geography and fundamental technological problems are listed as examples, not an exhaustive list, of reasons that an international standard may be an "ineffective and inappropriate means" of achieving a Member's legitimate objective.

C. ZIMBABWE

1. Introduction

4.75 As an important producer and exporter of chrysotile (white) asbestos fibre and products containing chrysotile asbestos and also as a developing country in need of foreign exchange, Zimbabwe argues that it has a substantial interest in the outcome of this proceeding. In fact, the

[132]International Labour Conference Provisional Record, 72nd Session, Geneva, 1986, 29/1: Fourth Item on the Agenda: Safety in the Use of Asbestos, pp. 29/8.

present dispute is of such importance to Zimbabwe's asbestos industry and indeed its whole economy that the Government of Zimbabwe has decided, for the first time ever, to have recourse to the dispute settlement mechanism of the WTO. Zimbabwe is of the view that the ban of chrysotile asbestos and products containing chrysotile asbestos by France is unjustified and contrary to relevant rules of the World Trade Organization (WTO). The ban should therefore be lifted without delay. Zimbabwe believes that it is not incumbent upon it as a third party to this dispute to set out in full the case against the responding party, i.e. the EC. Accordingly, Zimbabwe will limit itself in this submission to the Panel to addressing a number of factual and legal aspects of this dispute that it feels are of particular importance to the outcome of this proceeding. Zimbabwe argues that the complaining party in this case, i.e. Canada, has made a compelling case with respect to both the factual and legal issues in dispute as to why the ban on chrysotile asbestos and products containing chrysotile asbestos is inconsistent with relevant WTO rules and must be withdrawn immediately.

2. Factual Aspects

4.76 **Zimbabwe** asserts that the chrysotile asbestos industry is of great economic importance to its economy. Zimbabwe ranks among the world's largest producers of chrysotile asbestos. In Africa, Zimbabwe is the number one producer of chrysotile asbestos. It produces a high-quality chrysotile asbestos fibre and has sufficient underground reserves for at least another 25 years and infrastructure to continue operations for many more years to come. Chrysotile asbestos currently accounts for about 18 per cent of Zimbabwe's mineral production index of volume and value. Crocidolite (blue) and amosite (brown) asbestos are not mined in Zimbabwe. As a developing African country, Zimbabwe relies primarily on natural resource products and other primary products for much of its export revenue. In terms of the revenue it generates, chrysotile asbestos is second only to gold as far as the mining sector is concerned. As much as 95 per cent of the country's total asbestos fibre production is exported. In 1998, for example, 150,000 tonnes of chrysotile asbestos were exported out of a total production of some 175,000 tonnes, generating foreign exchange in excess of ZW$1.5 billion. In addition to the export of chrysotile asbestos fibres, more than 7,500 tonnes of asbestos-cement products, valued at over ZW$30 million, were exported. Zimbabwe's sole producer of chrysotile asbestos fibre is African Associated Mines. The European Union in general, and Spain and France in particular, have traditionally been important export markets for African Associated Mines.

4.77 Zimbabwe argues that African Associated Mines suffered a dramatic (more than 50 per cent) drop in its sales to France in 1996. The setback suffered by African Associated Mines in the French market is directly attributable to the French Government's actions. It should be pointed out in this connection that in mid-1996 the French Government announced its intention to ban asbestos. Before that, i.e. towards the end of 1995, the French Government had already announced a programme to reduce the risks associated with exposure to asbestos. There is therefore clear evidence that the French ban on asbestos and products containing asbestos has had a direct and damaging impact on Zimbabwe's asbestos industry. The significance of the asbestos industry to Zimbabwe cannot be overstated. The country has immensely benefited from its existence. African Associated Mines directly employs about 6,000 people in Zimbabwe, which amounts to about 20 per cent of total employment in the mining industry. The industry indirectly sustains more than 70,000 people in and around the mining towns of Zvishavane and Mashava. There are no other industries in these towns, meaning that a decline of the asbestos industry would cause dislocation with all its attendant social consequences. It should be borne in mind in this context that the Zimbabwean economy has faced considerable difficulties in the past decade and has not been able to create a sufficient number of new jobs. Out of a labour force of 5 million people, only 1.4 million people are gainfully employed. Apart from generating revenue for the Government of Zimbabwe, the asbestos industry has injected dynamism into the country's economy. In addition to the salaries and wages paid by the companies engaged in the mining and marketing of asbestos and asbestos products, the asbestos industry's more than 300 suppliers of goods and services receive payments of around ZW$600 million each year,

including over ZW$150 million for the state-owned Zimbabwe Electricity Supply Authority (ZESA) and the National Railways of Zimbabwe.

4.78 It is apparent from the foregoing that a ban on asbestos would have severe repercussions for the Zimbabwean economy. In fact, as has been demonstrated, the ban on asbestos by France has already impacted negatively on the Zimbabwean economy. It must be mentioned in this connection that Zimbabwe views with great concern the potentially wider implications of the French ban on the use of chrysotile asbestos. While it is true that most countries, including the United States, still do not generally prohibit the use of chrysotile asbestos or products containing chrysotile asbestos, there is the probability that other governments may be tempted to follow the French example if the French measure were upheld by the WTO. Indeed, the European Union has just announced - without awaiting the outcome of a WTO ruling - that it will move to ban the use of chrysotile asbestos in all its member States.[133] Zimbabwe wished the WTO to be aware of the wider implications of the decision it would render in this dispute.

4.79 Zimbabwe argues that the risks involved in the use of chrysotile asbestos can be adequately controlled. It appears that the concerns that governments have with respect to the use of chrysotile asbestos relate to airborne asbestos dust or respirable asbestos fibres, as they may have an effect on human health. For this reason, the United Nations Environment Programme (UNEP), the International Labour Organization (ILO), and the World Health Organization (WHO), within the Framework of an Inter-Organization Programme for the Sound Management of Chemicals, commissioned a Task Group of international experts to make an evaluation of the risks for human health from exposure to chrysotile asbestos and to make recommendations for health protection and further research. The report of the Task Group was published in 1998.[134] One of the Task Group's main conclusions was that "[e]xposure to chrysotile asbestos poses increased risks for asbestosis, lung cancer and mesothelioma in a dose-dependent manner".[135] The Group acknowledged, however, that it was not possible to provide quantitative estimates of risks to humans given the dearth of information and data.[136] Furthermore, the Group cautioned that there was a need for further epidemiological studies of populations exposed to pure chrysotile so as to clearly and reliably be able to distinguish between chrysotile and amphibole exposure.[137] In other words, there is a possibility that the available data may actually overestimate the risks to humans from exposure to chrysotile asbestos.[138] What is quite clear from the Task Group's conclusion - and this is crucial - is that the risks to humans are conditional on exposure as well as on doses or concentrations.[139] The key objective for any responsible government must therefore be to reduce exposure. This said, it should be borne in mind that chrysotile asbestos is a natural product. It is present in the air we breathe and in the water we

[133]This information is based on a report by Reuters News Agency, dated 6 May 1999.

[134]WHO, *IPCS Environmental Health Criteria 203 - Chrysotile Asbestos*, Geneva, 1998.

[135]Ibid., p. 144.

[136]Ibid., pp. 7 and 144. Zimbabwe notes that, in this regard, it is misleading for the EC to cite the 1998 Task Group report for the proposition that there is an international consensus that no threshold of exposure can be identified below which no risk to humans exists. The Task Group in fact merely stated that it could not identify any such threshold on the basis of the available data. See WHO, *IPCS Environmental Health Criteria 203 - Chrysotile Asbestos*, Geneva, 1998, pp. 7 and 144.

[137]Ibid., p. 145.

[138]Zimbabwe notes that this is especially true of applications of chrysotile-containing products in industries such as construction, on which the EC has placed great emphasis in its Submission, because "studies have not been in general able to distinguish between chrysotile and amphibole exposure". See WHO, *IPCS Environmental Health Criteria 203 - Chrysotile Asbestos*, Geneva, 1998, pp. 122 and 112.

[139]According to Zimbabwe, the EC confirms this when stating: "[L]es principales données qui ont été présentées illustrent le caractère ubiquitaire de l'amiante en milieu de travail qui peut, à des niveaux d'exposition suffisamment élévés, entraîner de nombreux cas de maladies mortelles".

drink. Exposure is therefore inevitable, and no ban can change that.[140] With these facts at hand, the question arises as to whether the French ban of asbestos is justifiable given the information within the public domain. Zimbabwe believes that what is at the heart of this dispute is the risk of occupational exposure to cement containing chrysotile asbestos. This is because prior to 1997, i.e. before the French ban was implemented, around 90 per cent of French imports of chrysotile asbestos fibres were used for the production of asbestos-cement.

4.80 It is the submission of Zimbabwe that transportation and storage of imported chrysotile asbestos fibre do not entail a risk of exposure provided that there is proper packaging. Another possible activity involving a risk of exposure is the production of chrysotile asbestos-cement itself. In Zimbabwe, this risk has been contained, as demonstrated by the monitoring done by a group of independent experts for Turnall Fibre Cement Company Limited, which is a Zimbabwean company engaged in the manufacture of chrysotile asbestos-cement. The focus of the research has been on the health hazards related to asbestos during the process of manufacture. This research has been going on for more than ten years and so far there have been no reported cases of risks to human life. It should be mentioned here that the EC has adduced as relevant evidence a very recent study by the U.K. Health and Safety Commission which is alleged to demonstrate that notwithstanding the application of control measures, "primary users" of chrysotile asbestos fibres, i.e. workers in asbestos-cement factories, showed a higher mortality rate in relation to asbestos-related lung cancer and mesothelioma. Zimbabwe views this study with considerable scepticism in view of the fact that there are long latency periods involved in the above-named diseases and that the current "cases" go a long way back to a time when the control measures implemented were far less sophisticated than they are now.

4.81 Zimbabwe asserts that a risk of exposure may also be incurred by workers or any person, for that matter, during installation, maintenance and repair of asbestos-containing products. The risks involved in the use of asbestos-containing products can be adequately controlled, even taking into account France's high level of protection against health risks, thus making a ban unnecessary.[141] In fact, the 1998 Task Group report supports this conclusion when stating that "[n]on-friable products and appropriate technological controls greatly reduce fibre release.[142]" It can thus be said that the risk of occupational exposure (i) is a function of the nature of the product and (ii) the risk inherent in that product can in any event be further reduced through appropriate control measures. Regarding the products at issue, i.e. products made from asbestos-cement, the first thing that should be noted is that asbestos-cement does not contain friable asbestos. Moreover, and equally importantly, products made from asbestos-cement are products of high density and thus chrysotile asbestos fibres are firmly blended into the final product. This reduces to a minimum the likelihood of fibres being released into the air and thereby posing a health hazard to human beings. The ILO came to the same conclusion in a report released in 1985: "[l]a manipulation de produits contentant de l'amiante dans lesquels les fibres d'amiante sont solidement fixées dans un liant de telle sorte qu'il ne puisse pas se former de poussières ne présente pas de danger pour la santé.[143]"

4.82 It emerges therefore that when products made from asbestos-cement are used and handled properly, the risks associated with their use are minimal. The recommendation of the 1998 Task Force was to the same effect. It recommended that appropriate control measures be

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[140]WHO, *IPCS Environmental Health Criteria 203 - Chrysotile Asbestos*, Geneva, 1998, pp 2 and 129 et seq.

[141]For a more detailed discussion of this point, see Zimbabwe's arguments with respect to GATT Article XX .

[142]WHO, *IPCS Environmental Health Criteria 203 - Chrysotile Asbestos*, Geneva, 1998, p. 28.

[143]Bureau International du Travail, *La sécurité dans l'utilisation de l'amiante*, Conférence internationale du Travail, Rapport VI (1), 71ème session, 1985, Genève, p. 29.

implemented wherever occupational exposure might occur.[144] Among the control measures which might be used to minimize exposure to chrysotile asbestos are engineering controls, special work practices (including workplace hygiene), and protective equipment, such as technical appliances which eliminate or minimize the formation of asbestos dust, as well as protective respiratory equipment or special protective clothing. That risk control is in fact an effective means of dealing with chrysotile asbestos-related health concerns is borne out by the following passage taken from the report of the 1998 Task Group: "[d]ata from industries where control technologies have been applied have demonstrated the feasibility of controlling exposure to levels generally below 0.5 fibres/ml. Personal protective equipment can further reduce individual exposure where engineering controls and work practices prove insufficient."[145] In light of the foregoing, it is the contention of Zimbabwe that the combined use of high-density products made from asbestos-cement, which inherently are low-risk products, coupled with adequate risk control measures minimize the risk of exposure to asbestos dust. Whatever residual risk may remain does not, in Zimbabwe's view, justify an outright ban on chrysotile asbestos.

3. Legal Aspects

4.83 It is the submission of Zimbabwe that the French ban of chrysotile asbestos is contrary to WTO rules and should be lifted without any delay. It is the view of Zimbabwe that the French Decree constitutes a technical regulation within the meaning of the Agreement on Technical Barriers to Trade. As such, it must be in accordance with Article 2.2 of the TBT Agreement and hence must not be "more trade-restrictive than necessary to fulfil a legitimate objective". By totally banning the import of chrysotile asbestos, the French legislation contravenes the express language of this Article. Furthermore, in the event of the French Decree being found to fall outside the ambit of the TBT Agreement, the Decree contravenes the provisions of GATT Article III:4, as it discriminates against imported asbestos in favour of other like products which are used in France for the same purpose. In the same vein, the French Decree cannot be justified under the terms of GATT Article XX(b), as claimed by the EC.

(a) The Agreement on Technical Barriers to Trade

4.84 Zimbabwe disagrees with the view of the EC that the Decree does not fall within the scope of the TBT Agreement. For a mandatory measure to come within the scope of the TBT Agreement, it must be a "technical regulation". The Decree clearly is a mandatory measure. Notwithstanding the EC's claim to the contrary, it is the submission of Zimbabwe that the Decree, to the extent that it applies to products containing chrysotile asbestos, qualifies as a technical regulation within the meaning of Annex 1 of the TBT Agreement. The argument of the EC that for the TBT Agreement to be applicable, the Decree should have specified which particular products were covered by the ban is without any merit. It is the view of Zimbabwe that such an interpretation is overly restrictive. Annex 1 of the TBT Agreement talks about "product characteristics" in general. Nowhere does it state that the national legislator should adopt only product-specific regulations. Even ignoring this point, Zimbabwe fails to understand why a Member should be precluded from laying down horizontal rules applicable to a group or groups of products which call for the same regulatory approach. In fact, it appears that there would be little merit in forcing Members to specifically enumerate all products covered by a particular regulation when it is in the nature of things that new products would regularly have to be added to the list due to, for example, technological developments. From a public policy perspective, this would seem to be a rather inefficient and costly approach to adopt.

4.85 Zimbabwe argues that the second reason advanced by the EC in support of its argument that the TBT Agreement is not applicable in this case is also without any merit. According to the EC, the

[144]WHO, *IPCS Environmental Health Criteria 203 - Chrysotile Asbestos*, Geneva, 1998, p. 144.
[145]Ibid., p. 144.

ordinary meaning of the noun "characteristic" supports the view that, for the TBT Agreement to be applicable, product characteristics must be positively defined. Applying this reading of the TBT Agreement to the present case, the EC argues that "not containing chrysotile asbestos" should not be seen as the equivalent of a product characteristic. Zimbabwe finds this reasoning of the EC very tenuous. According to the Shorter Oxford English Dictionary, the noun "characteristic" designates a "distinguishing quality or peculiarity".[146] Zimbabwe believes that, without doing injustice to these terms, a product's "distinguishing quality or peculiarity" can lie in the fact that it does not contain asbestos. The absence of any trace of asbestos clearly sets apart a product in terms of its qualities from another product which contains asbestos.[147] In any event, Annex 1 does not actually require positive product characteristics. Zimbabwe submits that its interpretation of Annex 1 is also in conformity with the relevant context of Annex 1 of the TBT Agreement. All the Agreements annexed to the WTO Agreement are part of the relevant context.[148] Thus, Article 2(f) of the Agreement on Rules of Origin obliges Members to ensure that "their rules of origin are based on a positive standard". From this it follows that where Members wanted to give a special meaning to a term - in this case, to the term "standard" - they used appropriate language to reflect their intention. Members did not adopt that approach as far as Annex 1 of the TBT Agreement is concerned.[149]

4.86 Given the object and purpose of Annex 1 of the TBT Agreement, Zimbabwe wonders what would be the rationale of a rule which compels Members to define product characteristics positively when all they care about is a negative characteristic. Why, for example, should France have to positively define the characteristics of a host of products when its only regulatory concern is with the asbestos contained in those products? It is the submission of Zimbabwe that its interpretation is also in conformity with the jurisprudence of the WTO Appellate Body. Thus, according to the Appellate Body, the term "measure" as it appears in various WTO agreements is to be understood to include a government's failure to act.[150] In other words, a "negative" measure, i.e. a failure to act, counts as a measure no less than a "positive" measure. By token of the same reasoning, the term "characteristics" should encompass negative characteristics. In view of the above reasons, Zimbabwe joins Canada in believing that the general term "product characteristics" lends itself to an interpretation which includes negative characteristics.

4.87 Having demonstrated that the Decree qualifies as a technical regulation under the TBT Agreement to the extent that it bans products containing chrysotile asbestos, Zimbabwe now turns to show that the same is true also with respect to the Decree's ban on the use of chrysotile asbestos fibres as such. The EC has expressed the view that the French ban on the production and importation of chrysotile asbestos fibre is not a technical regulation within the meaning of Annex 1 of the TBT Agreement because, just like the ban on asbestos-containing products, the ban on asbestos fibres is general (rather than specific) and lays down negative characteristics (rather than positive ones) or, for that matter, does not lay down any characteristics. As the issues of specificity and of "positive vs. negative standards" have already been discussed, the following submissions will focus on whether or not the French Decree lays down product characteristics with regard to the ban on asbestos fibres. Zimbabwe contends that the matter is more complex than the EC makes it out to be. To be sure, an independent and isolated ban on sales, say, of all cigarettes would not normally be considered

[146]The Shorter Oxford English Dictionary on Historical Principles, Oxford, 1993.

[147]In this connection, Zimbabwe notes that it is a truism that it is often easier to define objects negatively than to come up with an exact and exhaustive positive definition.

[148]Panel Report, *Japan – Measures Affecting Agricultural Products*, adopted on 19 March 1999, WT/DS76/R, para. 8.111.

[149]"A treaty interpreter is not entitled to assume that [the use of different words in different places] was merely inadvertent on the part of the Members who negotiated and wrote that Agreement". See *EEC - Measures Concerning Meat and Meat Products (Hormones)*, Appellate Body Report, adopted on 13 February 1998, WT/DS26/AB/R, WT/DS48/AB/R, para. 164.

[150]See *Guatemala – Anti-Dumping Investigation Regarding Portland Cement From Mexico*, Appellate Body Report, adopted on 25 November 1998, WT/DS60/AB/R, footnote 47.

a technical regulation. Yet the situation as it presents itself in this dispute is quite unlike that. As Canada rightly pointed out, unlike cigarettes, asbestos fibres *per se*, i.e. as products in their own right, serve no useful purpose. It is the products containing asbestos fibres which have commercial use and value. By necessary implication, when it comes to dealing with the health hazards of asbestos, the concern of policymakers and the law should be with products containing asbestos fibres, not with asbestos fibres, *per se*. If the products containing asbestos disappear, so will asbestos fibres.

4.88 Zimbabwe considers that the Decree is fully consistent with this straightforward principle. The EC does not contest this. On the contrary, the EC sets out the objective of the Decree as follows: "[l]'interdiction de l'amiante, en France et dans d'autres pays, n'a pas pour objectif de supprimer les quelques 0,0002 fibres/ml qui existent 'naturellement' dans l'air. L'interdiction vise simplement à protéger l'ensemble des travailleurs et des utilisateurs de l'amiante qui sont souvent exposés à des valeurs très supérieures [...] pour des opérations courantes d'intervention sur des matériaux contenant de l'amiante-ciment."[151] The EC explains the rationale of its asbestos-control policy in the following terms: "[l]a politique adoptée en France en 1996 vise en tout premier lieu au remplacement des matériaux contenant de l'amiante par d'autres matériaux sans danger [...]".[152] It clearly emerges from these two quotes that the Decree aims at asbestos-containing products, not at asbestos fibres *per se*. The inference that can be drawn from this is that the import ban - just like the corresponding ban on domestic production - does not perform an independent function, but a subsidiary one. Indeed, the EC expressly states that nothing would change if the import ban - and, by implication, the ban on domestic production - were lifted. Imported and domestically produced asbestos fibres could still not be sold on French territory - because no products containing them could be sold. The following sentence pinpoints this underlying logic of the French ban: "[l]e but est donc bien d'arrêter la diffusion d'amiante le plus en amont possible".[153] The ban on asbestos fibres is thus based on considerations of administrative efficiency, which is arguably only a secondary objective pursued by France. Again, this is confirmed by the EC: "[l]'interdiction d'importation a simplement pour but de rendre plus efficace, en termes de contrôle, l'interdiction d'utilisation [which is France's primary goal]".[154]

4.89 Zimbabwe asserts that, for the foregoing reasons, it should be readily apparent that the ban on chrysotile asbestos fibre is very closely related to the ban on asbestos-containing products. Assuming the ban on chrysotile asbestos fibres could be viewed in isolation, it could possibly be argued that it does not, *stricto sensu*, lay down product characteristics. As Zimbabwe has demonstrated, however, such a line of reasoning is unwarranted and misses the point. The ban on asbestos fibres is an integral part of the Decree. In fact, it is part and parcel of the same Article of the same Decree. Zimbabwe therefore submits that for purposes of this proceeding there is one single, indivisible regulatory package - the Decree - whose consistency the Panel needs to examine with the TBT Agreement. Zimbabwe is of the view that the Decree falls within the ambit of the TBT Agreement. This view is buttressed by the reasoning of another Panel which faced a comparable situation. In the *Kodak/Fuji* film case, the Panel had to decide whether a measure that had not been directly brought up under Article 4 of the DSU could nevertheless be within the Panel's terms of reference. The Panel found that such a measure was not within the Panel's terms of reference, unless it was "subsidiary" or "closely related" to the measure that was properly before the Panel.[155] By way of analogous reasoning, Zimbabwe argues that the French ban on asbestos fibres is "subsidiary" and "so closely related" to the ban on asbestos-containing products - which, as shown, qualifies as a technical

[151]See Section III.B of this Report.
[152]Ibid.
[153]See Section III.C of this Report.
[154]Ibid.
[155]*Japan - Measures Affecting Consumer Photographic Film and Paper*, Panel Report, adopted on 22 April 1998, WT/DS44/R, para. 10.8.

regulation within the meaning of the TBT Agreement - that it can reasonably be found to form an integral part of the latter, and thus constitute a technical regulation in, and of, itself.[156]

4.90 Zimbabwe further submits that treating the ban on asbestos fibres and the ban on asbestos-containing products as separate and "unrelated" could give rise to unreasonable results. Such a situation could in fact arise in the present case. It could be envisaged, for instance, that the ban on asbestos fibres might be found to be consistent with the provisions of the GATT, while the ban on asbestos-containing products might be found to violate the provisions of the TBT Agreement because - to use but one example - it is more trade-restrictive than necessary to fulfil a legitimate governmental objective. Zimbabwe submits that such an outcome would be unreasonable and could undermine the practical effectiveness of the TBT Agreement. Taken to its logical conclusion, such a situation would imply, on the one hand, that France could not produce asbestos-containing products domestically as a result of the ban on imported or domestically-produced asbestos fibres. On the other hand, France would be required to lift its ban on imports of asbestos-containing products and adopt instead a less trade-restrictive measure which, in practice, would mean that a certain quantity of asbestos-containing products would cross the border into French territory. France would thus have no choice but to idly sit and watch as other countries take advantage of the business opportunities offered by the French domestic market. Zimbabwe is of the view that the drafters of the TBT Agreement did not and could not have intended such a result.

4.91 It is therefore the submission of Zimbabwe that the TBT Agreement applies to the French Decree in its entirety, i.e. with regard to the ban on asbestos-containing products as well as the ban on asbestos fibres. The French legislation does not meet the requirements of Article 2.2 of the TBT Agreement, as amply demonstrated by Canada. Zimbabwe adopts the arguments presented by Canada in this connection and would like to support the views expressed therein by also relying on the arguments presented below on whether or not the French measure is necessary within the meaning of GATT Article XX(b).

(b) The General Agreement on Tariffs and Trade

(i) Article III of the GATT

4.92 Zimbabwe argues that, in the alternative, and in addition to the claimed violations of the TBT Agreement, the Decree violates GATT Article III:4. Zimbabwe submits that chrysotile asbestos fibres and, at a minimum, cellulose fibres, aramid fibres and glass fibres are "like products" within the meaning of Article III:4. The EC confirms that cellulose and aramid fibres count among those fibres which are most frequently used to substitute asbestos fibres in the manufacture of cement.[157] Cellulose, aramid and glass fibres are all produced in France.[158] Whereas they may lawfully be sold in that country, the importation and sale of asbestos fibres is prohibited. There is thus no doubt that

[156]Zimbabwe believes that its interpretation of the TBT Agreement also finds support in Article 1.6 of the TBT Agreement. This Article states that "[a]ll references in this Agreement to technical regulations […] shall be construed to include any amendments thereto and any additions to the rules or the product coverage thereof, except amendments and additions thereof, except amendments and additions of an insignificant nature". This provision clearly establishes that the term "technical regulation" as used in the TBT Agreement is not to be given a narrow reading, but one which promotes the Agreement's effectiveness.

[157]Zimbabwe notes that, with regard to glass fibres, this follows from the definition of HS tariff position 68.11.

[158]In Zimbabwe's view it does not matter for the purposes of an inquiry under Article III:4 whether domestic production of the "like product" is substantial or small. Nowhere does Article III:4 lay down a requirement that domestic production needs to be substantial.

asbestos fibres are accorded "less favourable treatment" than cellulose, aramid and glass fibres, despite the fact that they are "like products".[159]

4.93 Zimbabwe notes that the EC contests that asbestos fibres, cellulose, aramid and glass fibres are "like products" within the meaning of Article III:4. It is well established in WTO jurisprudence that the determination of whether or not products are "like products" must be made in accordance with such criteria as the products' physical characteristics and the products' end-use.[160] It is equally clear from WTO jurisprudence that any such determination can only be made on a case-by-case basis, i.e. taking into account the specific and unique circumstances of each case.[161] Regarding the first criterion, i.e. physical characteristics and properties, the EC claims that cellulose, aramid and glass fibres are not sufficiently similar to asbestos fibres in that their chemical composition is different. In this connection, Zimbabwe wishes to recall that the EC has acknowledged that the chemical composition of all varieties of asbestos fibres is different as well. This did not preclude the EC, however, from concluding that chrysotile asbestos fibres and amphibole asbestos fibres were "like products". Zimbabwe submits that the same logic applies and extends to cellulose, aramid and glass fibres.

4.94 Even ignoring the inconsistency in the reasoning of the EC, Zimbabwe does not believe that the differences pointed out by the EC are significant enough to make the relevant products "unlike" within the meaning of Article III:4. Zimbabwe wishes to recall, first of all, that "likeness" does not require that products be "identical in all respects".[162] The second thing that should be noted is that the significance that is attached to differences in physical characteristics depends on the particular circumstances of each case. In this case, as has previously been stated, the starting-point of any analysis must be the fact that chrysotile asbestos fibres, as products in their own right, serve no useful purpose.[163] Chrysotile asbestos fibres are predominantly used as "inputs" in the manufacture of fibre-cement products. It follows that substitute fibres like cellulose, aramid or glass fibres, on the one hand, and asbestos fibres, on the other hand, should not be compared to each other as products in their own right. Instead, asbestos fibres and the relevant substitute fibres should be compared to each other as products incorporated into cement. It is obvious that if this approach is adopted, as it should be, the differences identified by the EC become minor ones and irrelevant. The EC essentially makes the point that cellulose and aramid fibres are, on average, less fibrillose and larger in diameter than asbestos fibres and that only asbestos fibres are internationally recognized as "category I" products, i.e. as products that have been shown to cause cancer. With regard to these alleged varying degrees of health risk associated with the fibres at issue, it should be noted that whatever differences exist between the relevant products become far less relevant when the fibres are blended with other materials to produce cement and other related products.[164] As explained by Zimbabwe, any remaining risks arise from improper handling and manipulation of cement-products and not from the cement-products themselves. Beyond that, Zimbabwe is not convinced that much significance should be

[159]Zimbabwe considers that the Decree falls obviously within the scope of Article III:4 inasmuch as it is a regulation which affects the internal sale of asbestos fibres.

[160]*Japan – Taxes on Alcoholic Beverages*, Appellate Body Report, adopted on 1 November 1996, WT/DS/8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, p. 20.

[161]Ibid., p. 20.

[162]*Japan – Taxes on Alcoholic Beverages*, Report of the Panel, adopted on 1 November 1996, WT/DS/8/R, WT/DS10/R, WT/DS11/R, para. 6.21

[163]This is precisely why, in the view of Zimbabwe, the different tariff classification of chrysotile asbestos fibres, on the one hand, and of cellulose and aramid fibres, on the other hand, cannot provide any useful guidance for purposes of determining "likeness" in this case. The Appellate Body has in fact confirmed in its report on *Japan – Taxes on Alcoholic Beverages*, adopted on 1 November 1996, WT/DS/8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, p. 22, that the value of tariff classification as a criterion for establishing "likeness" must be assessed on a case-by-case basis.

[164]According to Zimbabwe, it should be borne in mind in this context that diameter and fibrillosity are in any event relevant only to the extent that these characteristics correlate with health risks to humans.

attached to the fact that only asbestos fibres are listed by the WHO as a "category I" product. In fact, even the EC concedes that there is a lingering uncertainty about the risks involved in the use of alternative fibres. Zimbabwe submits that the fact that there are to date no known negative effects on human health from the use of alternative fibres does not necessarily mean that they are risk-free.[165] Zimbabwe notes that the EC shares that view, for it expressly acknowledges that "… un risque indétectable n'est pas égal à une absence de risque".[166]

4.95 With regard to the second criterion, i.e. commonality of end-uses, Zimbabwe submits that asbestos, cellulose, aramid and glass fibres serve "substantially identical end-uses".[167] Their chemical resistance and reinforcing capabilities make them almost perfect substitutes for asbestos fibres. It is therefore not the case that chrysotile asbestos fibres are unique products, as the EC would have the Panel believe. As previously noted, the EC, in fact, acknowledges that cellulose and aramid fibres are commonly used substitutes for asbestos fibres.[168] Moreover, like Canada, Zimbabwe believes that the structure of the Decree is at least suggestive of the substitutability of asbestos fibres with other fibres. This becomes clear if the French Decree is seen in terms of the functioning of the political process. If very close substitutes had not been available to the principal users of asbestos fibres at the time the Decree was signed into law, it is reasonable to assume that they would have lobbied the French Government and in all likelihood would have secured a broader exception (allowing the continued use of asbestos fibres) than the one that is now in the Decree.[169] In light of the foregoing considerations Zimbabwe believes that asbestos fibres and cellulose, aramid and glass fibres should be regarded as "like products" within the meaning of GATT Article III:4.

(ii) Article XX of the GATT

4.96 Zimbabwe argues that the Decree is not justified under paragraph (b) of Article XX because it is not "necessary to protect human […] health".[170] More particularly, the Decree does not satisfy the necessity requirement. GATT 1947 case law has established that a measure qualifies as "necessary" within the meaning of Article XX if there is "no alternative measure consistent with the General Agreement, or less inconsistent with it, which [a Member] could reasonably be expected to employ to achieve its […] policy objectives".[171] Zimbabwe believes that it is sufficient for it to establish that - even assuming that asbestos fibres posed more of a health risk to humans - there are less trade-restrictive measures available to France to achieve its health objective. The EC claims that in order for France to achieve its health policy objective there was no measure reasonably available to it other than an outright ban on chrysotile asbestos fibres. In particular, the EC submits that control measures used to minimize exposure to chrysotile asbestos fibres are not sufficient to ensure that France reaches its high level of protection. It also argues that control measures are impracticable in the case of the large group of "secondary users" of asbestos fibres, i.e. those workers and do-it-yourself people who, in the absence of control measures, may be exposed to chrysotile asbestos dust during installation, maintenance and repair of products containing chrysotile asbestos. The

[165]Zimbabwe notes that this is all the more true in view of the fact that the kind of diseases at issue here involve long latency periods.

[166]See Section III.B of this Report.

[167]*United States – Taxes on Petroleum and Certain Imported Substances*, adopted on 17 June 1987, BISD 34S/136, para. 5.1.1.

[168]According to Zimbabwe, the same is true for glass fibres.

[169]Zimbabwe notes that the fact that there is an additional and special temporary exemption in Article 7 of the Decree for certain used and agricultural vehicles precisely suggests that no equivalent and affordable substitutes existed at the time the Decree was signed into law and that the sectors concerned successfully lobbied the Government to provide for a temporary exemption.

[170]Zimbabwe notes that the question to be answered by the Panel here is whether it was necessary for France to discriminate between asbestos fibres and "like" domestic fibres in order to protect human health.

[171]*Thailand - Restrictions on Importation of and Internal Taxes on Cigarettes*, Panel Report adopted on 7 November 1990, BISD 37S/200, para. 75.

problem is compounded, according to the EC, by the fact that in many instances "secondary users" do not have any information as to whether they are dealing with products that contain asbestos. The EC submits that even if they were given that information, control measures are costly and turn what would otherwise be a simple operation into a costly, complicated and awkward one. Furthermore, the EC believes that "une fois mis sur le marché, il n'existe plus aucun moyen raisonnable de contrôler l'usage de l'amiante et, en particulier, de contrôler des opérations banales (découpage, sciage …) que de nombreuses personnes peuvent être amenées à réaliser".[172]

4.97 Zimbabwe is not convinced by the arguments of the EC. First of all, regarding the effectiveness of control measures, Zimbabwe believes that the observance of certain work practices and the use of technical appliances in accordance with the ISO standard 7337, for example, would be sufficient to meet the maximum exposure level acceptable to France. The EC argues that, even where special technical equipment is used when high-risk activities are undertaken, peak exposure levels to asbestos would still exceed the French maximum level. What the EC fails to mention, however, is that, as argued by Canada, the wearing of protective respiratory equipment and humidification of the materials during those activities could significantly reduce the exposure - so much so, in fact, that the respect of the French maximum level of exposure would be ensured. Regarding the argument of the EC that mandatory control measures are impracticable because they are too costly, Zimbabwe contests the relevance of such considerations. After all, whether or not these costs are too high, is a matter to be left to the dictates of the market. If the producers of asbestos-cement face insufficient demand for their products because of expensive control measures imposed on their customers, they will go out of business or diversify into the production of cement using alternative fibres. Likewise, Zimbabwe does not see any merit in the argument that control measures make certain work procedures complicated and awkward. Where certain practices are imposed by law, the question of whether they are appreciated by those who must follow them becomes meaningless.[173] It certainly does not in itself provide a rationale for trade-restrictive measures.

4.98 While Zimbabwe recognizes that it may not be readily apparent to an inexperienced person whether or not he/she is handling a product containing asbestos fibres, it is by no means justification for instituting a far-reaching ban on products which might contain asbestos fibres. It is the contention of Zimbabwe that it would be possible under the WTO legal framework for Members to impose a disclosure requirement, which would enable purchasers to make informed decisions as to whether or not they purchase products containing asbestos fibres. Where the materials have already been installed or incorporated, say, in a building, Zimbabwe does not see why there could not be, for instance, an asbestos warning message next to the evacuation instructions on a notice board of that building. Moreover and specifically with respect to the work of plumbers, electricians and the like, Zimbabwe does not see why the owner of an installation or building could not be required to make available some sort of map which would document in which parts of the installation asbestos is present.[174] With reference to the concern of the EC that the use of asbestos-containing products cannot sufficiently be controlled, especially when it comes to "secondary users" of such products, Zimbabwe again does not think that banning all imports of such products would solve the problem. In fact, it would raise more problems than it would solve. To begin with, if indeed the French Government is so concerned about do-it-yourself users of asbestos-containing products, it could have

[172]See Section III.C of this Report.

[173]Zimbabwe notes that, by way of analogy, it might be added here that many people think that the wearing of seatbelts in cars makes driving more "complicated" and awkward. Yet many countries made the wearing of seatbelt a legal requirement.

[174]In this connection, Zimbabwe recalls that a tenant or house owner who wants to drill a hole in a wall to hang up a painting, for instance, also needs to know exactly where the electrical wiring and installations are, lest he/she wants to put his/her life at risk.

easily banned the sale of such products in all do-it-yourself outlets.[175] Furthermore, as a supporting measure, it could have also restricted the handling of asbestos-made products to certified experts, thus eliminating contact with asbestos by inexperienced people.[176] The protection of workers, such as electricians and plumbers, could also have been ensured relatively easily. The French Government could have, for example, required certification, which would only be bestowed upon an individual once he/she had successfully followed information and training courses on the use and handling of asbestos-containing products. The French Government could also have laid out the precise work practices and technical appliances that must be used in all contacts with asbestos-containing products. To ensure compliance, the regulations could authorize the imposition of heavy fines or a custodial sentence in the event of a wilful disregard of the government's regulations. Needless to say, it is also open to a Member to run information campaigns, so as to raise awareness among workers of the risks of asbestos fibres and the procedures to be observed in all contacts with such fibres. It is clear from the foregoing that the French Government had a number of alternative measures at its disposal which would have interfered less with trade and at the same time would have assisted in realizing its overriding objective of protecting the health and safety of its citizens.

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[175]Zimbabwe notes that, after all, in most countries, drugs cannot be bought in supermarkets, but only in pharmacies upon production of a doctor's prescription.

[176]To give another analogous example, Zimbabwe notes that in many countries the installation of ceiling lamps and other electrical appliances may only be carried out by certified electricians.

V. PANEL'S CONSULTATION WITH SCIENTIFIC EXPERTS

A. DETERMINATION OF THE PROCEDURE

5.1 The **Panel** noted that the dispute before it raised scientific and technical issues. At the first substantive meeting, the Panel informed the parties of its intention to seek the opinion of individual scientific experts except where, in the light of the parties' written rebuttals, it concluded that such a procedure was not necessary. The areas in which the Panel wished to obtain information included the circumstances of exposure to chrysotile asbestos and the associated risks, as well as the effectiveness of the controlled use of chrysotile. The Panel invited the parties to submit their comments to it in writing, particularly regarding the areas on which the experts were to be consulted, the possible approaches to such a procedure and the international or other bodies that could usefully be consulted in order to identify suitable experts.

5.2 In a letter to the Panel dated 14 June 1999, **Canada** proposed, in regard to the possible approaches to a procedure for consultation with individual experts, that five requirements should be met, each one intended to ensure observance of the right of the parties to be heard at all stages of the procedure: (i) the Panel should consult the parties on the choice of scientific experts; (ii) the Panel should seek the opinion of the parties concerning the formulation of the questions to be put to the experts; (iii) the Panel should provide the parties with an opportunity to make written comments on a draft report by each of the experts; (iv) the parties should be able to question each of the experts on the content of his final report at a meeting with the Panel; (v) the parties should be given the possibility to make written comments on the conclusions set out in the final report of each expert and their legal implications. Like the Panel, Canada also believes that the areas on which the scientific experts should be consulted ought to include the circumstances of exposure to chrysotile asbestos and the risks associated with present applications as well as risk management by the controlled use of chrysotile asbestos. The experts should also be consulted in two other areas, namely the comparative toxicity of the different types of asbestos fibres and substitute fibres, and risk assessment methods, including the question of whether there are exposure thresholds below which the risk is undetectable in practice. In Canada's opinion, there are four specializations that in one way or another cover the above-mentioned areas and from which the experts should be drawn. These are toxicology, epidemiology, risk analysis and occupational health. Given the scientific characteristics of the dispute, Canada would wish that each question be submitted to more than one expert, and that each expert submit an individual report. As regards the international institutions that could usefully be approached in order to identify suitable experts, Canada believes that they should be consulted in order to come up with a sampling of experts in the above-mentioned domains. The main selection criteria and hence the best guarantee of impartiality should be that experts must have conducted recognized and independent research into chrysotile asbestos. The international organizations that could be approached included the World Health Organization, the International Labour Office and the International Organization for Standardization. Once a list of prospective candidates has been drawn up with the help of the international organizations, the parties should then be able to submit their own list of names of specialists who could act as scientific experts in the areas mentioned above.

5.3 In a letter dated 14 June 1999, the **European Communities** were of the opinion that the scientific issues raised in this dispute were simple and clear. The DSU rules on the burden of proof also provided the Panel with sufficient guidance in dealing with the factual and scientific issues raised by the parties to the dispute. With respect to the general selection procedures and criteria, the European Communities believed that the Panel's use of experts for obtaining scientific and technical advice should respect the general principles of law. In particular, it should be transparent, avoid conflicts of interest, reinforce the integrity of the dispute settlement mechanism and foster public confidence in the outcome of the dispute. In the view of the European Communities, the Panel can in this case establish only an expert review group under the terms of Appendix 4 to the Dispute

Settlement Understanding. Indeed, the measure at issue in the present dispute is one that must be examined strictly in terms of the GATT 1994, to the exclusion of the Agreement on Technical Barriers to Trade. Article 13:2 of the DSU provides as follows: "… With respect to a factual issue concerning a scientific or other technical matter raised by a party to a dispute, a Panel may request an advisory report in writing from an expert review group. Rules for the establishment of such a group and its procedures are set forth in Appendix 4". The establishment of an expert review group is the only option provided under the DSU for panels wishing to obtain information on scientific matters. The first sentence of Article 13:2 applies only to situations in which a Panel wishes to obtain factual or technical but not scientific information. In their context, the ordinary meaning of the terms, as well as the object and purpose of Article 13:2, first and second sentences, clearly lead to the conclusion that panels are not authorized to deviate from the procedure laid down by Appendix 4 to the Dispute Settlement Understanding. Whether the request comes from a party or arises at the initiative of the Panel itself makes no difference. Strictly scientific matters cannot be resolved by means and/or procedures other than those envisaged in Appendix 4 to the Dispute Settlement Understanding. The *chapeau* to Appendix 4 to the Dispute Settlement Understanding also confirms this interpretation by providing that the rules and procedures set forth in the Appendix "… shall apply to expert review groups established in accordance with the provisions of paragraph 2 of Article 13", that is, regardless of whether the Panel bases itself on the first or second sentence of that Article. This interpretation is supported by the fact that, if the Agreement on Technical Barriers to Trade (TBT) should be applicable (which is not the case), Article 14:2 of that Agreement explicitly prescribes that panels establish only a technical expert group (which is equivalent to an expert review group). In such a case, the procedural rules set forth in Annex 2 to the TBT Agreement must apply. Annex 2 to this latter agreement and Appendix 4 to the Dispute Settlement Understanding are almost identical. Moreover, by virtue of Article 1:2 and Appendix 2 to the DSU, only Article 14:2 of the TBT Agreement is applicable.

5.4 The European Communities also point out that the previous cases in which panels requested the opinion of scientific experts all came under the Agreement on the application of Sanitary and Phytosanitary Measures, which is not applicable in this case. Those previous cases are therefore irrelevant to the present dispute. The dispute concerning *Shrimp* is the only other case for which the opinion of scientific experts was requested under the GATT 1994. But this example *per se* is not enough to set a valid precedent applicable to all cases, especially because the parties to the *Shrimp* dispute apparently did not request the exclusive application of Appendix 4 to the Dispute Settlement Understanding. The result is that, in the present case, should the Panel decide to seek the scientific opinion of external experts, it can do so only under Article 13:2, second sentence of the Dispute Settlement Understanding or under Article 14:2 of the TBT Agreement.

5.5 According to the European Communities, Appendix 4 to the DSU and/or Annex 2 to the TBT Agreement lay down almost identical rules on the establishment of an expert review group. These rules must all be observed in this dispute. Moreover, to ensure that the aforementioned principles are respected, the European Communities believe that the Panel should observe the following specific criteria when choosing scientific experts: (i) the experts should not be citizens of the parties to the Dispute; (ii) the Panel should select scientific experts in different areas of specialization in order to ensure coverage of all the areas identified by it. These areas are: the human health hazards posed by asbestos, especially chrysotile asbestos; the inapplicability of a threshold; the circumstances of exposure and the question as to whether what is known as "controlled use" can eliminate the potential hazards to human health; (iii) the European Communities believe that if the Panel decides to request information, it should consult at least five experts so that more than one expert will have the requisite expertise and provide answers to the questions in the various areas identified by the Panel. In the light of the number of experts that the Panel should consult, only scientists with proven expertise in the realm of asbestos should be selected; (iv) the experts should be drawn mainly if not exclusively from the International Agency for Research on Cancer (IARC), a specialized agency of the WHO. The IARC has studied asbestos from all possible angles and should

therefore be well placed to propose experts covering all the areas in which questions could be posed. The Panel should also explore the possibility of consulting the International Labour Office (ILO) in the event that the IARC is unable to cover all the areas in question; (v) the experts chosen must have no link whatsoever, present or past, with the industry producing asbestos or substitute products. They must furthermore clearly demonstrate the lack of any conflict of interest. The parties should receive at the outset the *Curricula Vitae* of all the candidates proposed and should have at least ten working days in which to verify the skills, expertise and possible conflicts of interest of the candidates; (vi) the Panel should also request the opinion of the parties as to the aim of the consultation with experts, the type and nature of the questions to be put to them; (vii) the aim of the consultation should be to further the knowledge of the scientific considerations germane to this dispute. Therefore, and in accordance with the provisions of the Dispute Settlement Understanding, the questions to be put by the Panel must have a direct and strict bearing only on the scientific aspects of the case. The questions may not relate to legal problems nor to any problem of interpretation of any WTO Agreement under examination.

5.6 Having taken cognizance of the comments from the parties, the **Panel** decided to consult the experts on an individual basis, pursuant to paragraphs 1 and 2, first sentence, of Article 13 of the Understanding on Rules and Procedures Governing the Settlement of Disputes. The Panel convened the parties to a meeting on 10 July 1999 to acquaint them with the procedure it intended to follow and to give them the opportunity to state their opinions on the matter. The Panel recalled Article 13 of the Dispute Settlement Understanding which, among other things, provides that:

> "Each panel shall have the right to seek information and technical advice from any individual or technical body which it deems appropriate." […]
>
> "Panels may seek information from any relevant source and may consult experts to obtain their opinion on certain aspects of the matter."

5.7 At that meeting, the Panel told the parties that, in its opinion, Article 13 of the Dispute Settlement Understanding empowered it to seek such information and technical advice as it deemed fit in a given matter; in particular, a panel was free to determine whether it was necessary or appropriate to establish an expert review group. In the case at hand, the consultation of experts acting in their own right seemed to it to be the most appropriate form of consultation. The Panel intended to seek information concerning the circumstances of chrysotile exposure and the attendant hazards. In the circumstances, the Panel indicated that it would structure its questions around the following main topics: the pathogenicity of chrysotile, the relative pathogenicity of amphiboles, chrysotile and substitute products; the assessment and management of risks associated with the use of chrysotile; the effectiveness of controlled use of chrysotile.

5.8 The Panel then presented to the parties the procedure that it intended to follow, which is the same used by previous panels that had consulted experts selected on an individual basis:

- The experts will be placed under the authority of the Panel. They will be consulted on a personal basis and not as representatives of a government or organization. Their opinion will be strictly in the nature of advice; it will not be binding on the Panel;

- the number of experts to be chosen by the Panel will be decided depending on the number of matters on which an opinion will be sought, as well as the number of matters on which each expert can give an opinion;

- the Panel intends to request names from the World Health Organization (WHO), the International Labour Organization (ILO), the International Programme on Chemical

Safety (IPCS), the International Agency for Research on Cancer (IARC), the International Organization for Standardization (ISO), and from the parties;

- the Panel does not intend to appoint experts who are citizens of one or other of the parties to the dispute, unless the parties consent to their appointment or the Panel believes that it would otherwise be impossible for it to secure the specialized scientific advice needed;

- the Secretariat will request the persons suggested to submit a *curriculum vitae*. The *curricula vitae* will be transmitted to the parties. The parties may not establish contact with the experts suggested;

- the parties will have an opportunity to make comments and to state any major objections they may have to any expert under consideration. The Panel will inform the parties of the experts it chooses;

- the experts will receive all the relevant elements of the communications on a confidential basis;

- the Panel will prepare draft questions for the experts. They will be communicated to the parties. The parties will have the opportunity to comment on the questions proposed or to suggest additional questions before they are sent to the experts. The Panel will then draw up a definitive list of questions which will be sent to the experts and simultaneously to the parties;

- each expert will receive all the questions. He will be requested to reply to the questions falling within his sphere of competence and, if necessary, to indicate the areas on which he does not feel competent to reply. The experts will be invited to provide written answers; copies of those answers will be transmitted to the parties. The parties will have an opportunity to make written comments on the replies from the experts and the replies will be included in the Panel's final report;

- should the Panel deem it fitting, either on its own initiative or at the request of a party, a meeting may be held with the experts immediately before the second substantive meeting. Before the meeting, the Panel will ensure that: (i) experts are made privy to the parties' comments on their replies; (ii) the experts each receive the replies of the other experts to the Panel's questions;

- the minutes of the meeting with the experts will be submitted to the parties and to the experts so that they may make corrections. The corrected version will be attached to the Panel's final report.

5.9 The Panel gave the parties the opportunity to transmit their written comments to it.

5.10 In a letter dated 19 July 1999, **Canada** recalled all the points that it had notified to the Panel in its letter of 14 June 1999. Canada agrees with the Panel as to the nature of the information and advice that it intends to seek from the scientific experts. It nevertheless believes that the experts best qualified to reply to the Panel's questions concerning the circumstances of exposure to chrysotile and the associated hazards are to be found in the areas of toxicology, epidemiology, risk assessment and occupational safety. In addition to the opportunity given to the parties to make written comments on the experts' replies, the Panel should also provide for the possibility of a final written submission by the parties following the second substantive meeting. As regards the stipulation that the scientific experts may not be citizens of any of the parties to the dispute, Canada believes that this procedural

rule, established in Appendix 4 to the Dispute Settlement Understanding, normally applies only to the establishment of an expert review group. In the *Hormones* case, the Appellate Body stated in that connection: " … once the Panel has decided to request the opinion of individual scientific experts, there [was] no legal obstacle to the Panel drawing up, in consultation with the parties to the dispute, ad hoc rules for those particular proceedings".[1] As the agreement of the two parties to the dispute is required if the selection of citizens of one of the parties is to be allowed, Canada is surprised at the refusal of the European Communities to allow the selection of their citizens. Canada is prepared to consider the selection of experts who are citizens of the European Communities despite the refusal of the European Communities to consider experts from Canada. In this dispute, if the citizens of the parties are automatically excluded, the Panel risks facing a situation in which it will be unable to select the experts with the best scientific knowledge considering the nature of the advice being sought. Canada therefore requests the European Communities and the Panel to reconsider their decision with regard to the non-participation of citizens of the parties.

5.11 Moreover, Canada cannot accept that, as demanded by the European Communities, the experts must clearly demonstrate the absence of any conflict of interest. It is not incumbent upon a prospective expert to prove his impartiality, instead he is merely required to fill out a disclosure form concerning his interests, relationships and any matters that may affect his independence. This form is provided for in the document entitled *Rules of Conduct for the Understanding on Rules and Procedures Governing the Settlement of Disputes*.[2] Once the persons approached as potential experts have filled out their disclosure forms, the parties to the dispute may oppose any candidate who has disclosed an interest, relationship or matter that may place him in a situation of conflict of interest. The Panel is empowered to decide whether the information disclosed in the form really places a candidate expert in a situation of conflict of interest and to uphold a party's objection to an expert's candidature. The approach taken by the Panel in the *Shrimp* case should be followed in this instance. Having noted that in their disclosure forms three of the experts approached had disclosed what might be considered as potential conflicts of interest, the Panel nevertheless decided to confirm their appointments "being of the view that the disclosed information was not of such a nature as to prevent the individuals concerned from being impartial in providing the scientific information expected of them. The Panel has also taken into account the disclosed information when evaluating the answers provided. The Panel underlined that, in making its choice, it had been guided primarily by the need to gather expertise of the best quality and covering as wide a field as possible. In [the circumstances specific to this case], it was difficult – if not impossible – to reconcile this need with an agreement by all the parties to the dispute on each and every individual concerned".[3] Canada is surprised at the European Communities' insistence on the absence of any link between the experts and producers of chrysotile asbestos but not between the experts and anti-asbestos pressure groups. No one opposes the principles of independence and impartiality of experts or the observance of the rules on conflicts of interest. The single pertinent consideration remains the way in which these principles should be applied in this particular instance.

5.12 In a letter dated 19 July 1999, the **European Communities** took note of the Panel's decision to consult individual scientific experts pursuant to Article 13:1 of the Dispute Settlement Understanding. The European Communities contest the legal basis of the Panel's decision. Under the international customary principles of treaty interpretation, a systematic interpretation of Articles 13:1 and 13:2 of the Dispute Settlement Understanding suggests that as far as scientific matters are concerned, the preferred option in the Dispute Settlement Understanding is the establishment of an expert review group. The term "scientific matter" appears only in the second sentence of Article 13:2

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[1] *EC Measures Concerning Meat and Meat Products (Hormones)* Report of the Appellate Body, WT/DS26/DS48/AB/R, adopted on 13 February 1998, para. 148.

[2] WT/DSB/RC/1, of 11 December 1996.

[3] *United States – Import Prohibition of Certain Shrimp and Shrimp Products,* Report of the Panel, WT/DS58/R, adopted on 6 November 1998, para. 5.7.

of the Dispute Settlement Understanding, which envisages only the constitution of an expert review group. The drafting history of the WTO Agreements also confirms this interpretation.[4] The three previous cases in which panels sought the opinion of scientists in their own right all had to do with matters arising under the SPS Agreement, Article 11:2 of which expressly mentions "scientific" matters and envisages the possibility of consulting experts individually.[5] Canada furthermore requests that the TBT Agreement be applied to the measure at issue here. It is worth noting that Article 14.2 of the TBT Agreement provides only for the possibility of consulting a technical expert group. This Agreement contains no provision equivalent to Article 13:1 of the Dispute Settlement Understanding or to Article 11:2 (first sentence) of the SPS Agreement. The very terms of Article 14.2 of the TBT Agreement are therefore different from Articles 13:1 and 13:2 (first sentence) of the Dispute Settlement Understanding and from Article 11:2 of the SPS Agreement. This difference is not accidental.[6] It denotes the clear intention of the WTO Members to settle scientific or technical matters in the framework of the TBT Agreement only by establishing an expert review group. The decision of the Panel to consult experts on a personal basis is also contrary to Article 1:2 of the Dispute Settlement Understanding, which provides as follows:

> "To the extent that there is a difference between the rules and procedures of this Understanding and the special or additional rules and procedures set forth in Appendix 2, the special and additional rules and procedures in Appendix 2 shall prevail."

5.13 As explained above, there is a clear difference between Article 13:1 and 13:2 (first sentence) of the DSU, invoked in this case by the Panel, and Article 14:2 of the TBT Agreement. The special rules and procedures mentioned in Appendix 2 to the DSU, namely Article 14:2 of the TBT Agreement, which provides for the establishment of a technical expert group, should thus be applied in the present case, should the Panel judge the TBT Agreement to be applicable.[7] Therefore, the European Communities consider the Panel's decision contrary to the letter, object and purpose of Article 14:2 of the TBT Agreement (if the latter is applicable), in conjunction with Article 1:2 of the DSU, and to Article 13:2 (second sentence) of the DSU. Besides, from a systematic point of view, the Panel's decision renders useless and obsolete the provisions of the Dispute Settlement Understanding and of the TBT Agreement regarding expert review groups, which are clearly the option preferred by WTO Members and the only one for which rules of procedure have been drawn up in the WTO for the settlement of "scientific" questions.[8] At this stage, the European Communities are therefore obliged to reserve all their rights on this issue. They would also request the Panel, in keeping with current WTO practice and for the sake of transparency and due process, to state in writing the criteria and the reasons for its decision to call on individual scientific experts and the reasons for which is has not entertained the arguments put forward by the European Communities, and to communicate this information to the parties to the dispute.

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[4] According to the European Communities, confirmation can also be found in the *chapeau* to Appendix 4 to the Dispute Settlement Understanding which provides that "[the following rules and procedures] shall apply to expert review groups established in accordance with the provisions of paragraph 13", that is, regardless of whether it is the first or the second sentence of this Article that is being used by the Panel.

[5] That also explains the Appellate Body's reasons for its finding on that matter in the *Hormones* case. See the report AB/1997-4, para. 147.

[6] As the Appellate Body found in *Hormones* (para. 164), "a treaty interpreter is not entitled to assume that such usage was merely inadvertent on the part of the Members who negotiated and wrote that Agreement".

[7] The third sentence of Article 1:2 of the Dispute Settlement Understanding is not applicable in this case, as the GATT 1994 does not contain contradictory rules and procedures on this matter.

[8] The Panel's interpretation is also contrary to one of the corollaries of the general rule of interpretation set out in the 1969 Vienna Convention, which is that the interpretation must give meaning and effect to all the terms of a treaty. As held by the Appellate Body in the *Gasoline* case "an interpreter is not free to adopt a reading that would result in reducing whole clauses or paragraphs of a treaty to redundancy or inutility" (AB-1996-1, page 22). Specifically, the Panel has so far refrained from providing explicit substantive reasons for its choice of consultation with individual experts over the establishment of an expert review group.

5.14 As regards the type of scientific background and specializations, the European Communities take the view that the experts should be cancer specialists, in particular in lung cancer and mesothelioma. They should also be epidemiologists experienced in the area of asbestos and cancer. The European Communities are not clear as to what type of scientific discipline would encompass those persons who would be required to provide advice regarding "risk evaluation and management in the use of chrysotile" and "the effectiveness of the controlled use of chrysotile", nor what type of technical expertise they should have. If such experts exist, they should be able to provide information about all the categories of persons who could come into contact with asbestos and asbestos-containing products, such as those working in maintenance, repair and construction (for example, carpenters, plumbers, heat repairers, workers in insulating materials, do-it-yourself enthusiasts, etc.). The European Communities believe that the scientists chosen should also have expertise in the inspection of houses, buildings and factories for the presence and possible removal of asbestos. Obviously, such experts cannot be allowed to have any link, whether direct or indirect, with the industries producing asbestos or those producing the equipment for reducing the risk of asbestos fibre inhalation. Such a link would seem particularly possible if the experts were to be designated by the ISO. The European Communities consider that at least two experts should be designated for each scientific domain and each area of questions. That is a minimum prerequisite for a balanced view and for not being entirely dependent on the views of just one person. At all events, the overall number of experts should not be less than six.

5.15 The European Communities have expressed their wish to receive copies of the letters to be sent by the Panel to the aforementioned institutions under this point and of their replies. The experts appointed should not be nationals or residents of the parties to the dispute. The European Communities consider that all the candidates must submit a detailed *curriculum vitae* in time so as to enable the parties to verify their scientific credentials, experience and independence. The candidates must therefore clearly indicate in their *curriculum vitae* whether in the course of their professional life they have worked for or provided advice, in whatever form, to the industries producing asbestos, asbestos-containing products and substitute products or to the industry producing "controlled use" equipment. In addition, the selected experts must complete a disclosure form concerning potential conflict of interest, pursuant to the *Rules of Conduct for the Understanding on Rules and Procedures Governing the Settlement of Disputes* adopted (WT/AB/WP/3, Annex II, page 16, 28 February 1997). The disclosure form must contain all the information indicated in the illustrative list appearing in Annex II to the *Rules of Conduct* mentioned above. It should also explicitly contain information as to whether the expert has done any type of paid or unpaid work (scientific research, consulting, expert advice, participation in the board of directors or board of management, etc.) for the enterprises engaged in the extraction, production, processing of or trade in asbestos, asbestos-containing products or substitute products, or for enterprises producing the equipment intended for "controlled use".

5.16 It is the opinion of the European Communities, that the Panel should, for example, request that the disclosure form further indicate: (i) the expert's professional situation (job in an enterprise or institute connected to the asbestos, substitute products or "controlled use" equipment industries); (ii) whether the expert is a member of the board of directors, board of management or any other supervisory body within an enterprise, association, institution or interest group linked with the industries producing asbestos, substitute products or equipment for "controlled use"; (iii) whether he has conducted scientific research or provided expert advice at the request of or under contract to an enterprise, association, institution or interest group connected with the industries producing asbestos, substitute products or a "controlled use" equipment.[9] If the aforementioned clarifications and

[9] As far as the European Communities are concerned, additional support for the proposition that the term conflict of "interest" should be interpreted as broadly as possible may be drawn from Article III.1 of the *Rules of Conduct* mentioned above, and in a systematic interpretation (by analogy) of the following provisions:

information are not given in the *curriculum vitae* and in the disclosure form, the parties will not be in a position to exercise their rights and make the type of comments being requested of them by the Panel. Therefore, the European Communities consider that the issue of the scientific credentials, experience and, in particular, that of the independence and impartiality of the experts, are of paramount importance and that they need to be reflected in the Panel's decision on the selection and consultation of scientific experts. They therefore wish to reserve their rights until completion of the selection procedures. The parties should be allowed sufficient time to enable them to make effectively known to the Panel their views on the above issues. Specifically, they should be given sufficient time to make known their views on the list of potential experts to be chosen by the Panel and to submit their comments on the written replies from the experts to the questions put to them by the Panel.

5.17 In a letter to the parties dated 2 August 1999, the **Panel** confirmed its intention to consult experts individually, in application of Article 13 of the DSU. The Panel carefully examined the arguments advanced by the parties concerning the expert consultation procedures, in particular, the European Community argument that Article 13.2 of the DSU Agreement requires the constitution of a technical expert group as envisaged in Appendix 4 to the DSU for the purposes of consultation with experts on scientific matters. Article 13 of the DSU provides, among other things, that "each Panel shall have the right to seek information and take advice from any individual or body which it deems appropriate" and that "Panels may seek information from any relevant source and may consult experts to obtain their opinion on certain aspects of the matter". In addition, Article 13.2 prescribes that panels "may" request an advisory report in writing from an expert review group specifically though not exclusively to examine a factual issue concerning a scientific matter. The Panel deems this text to allow for the establishment of such an expert group, while not ruling out consultation of experts on an individual basis, both with regard to a scientific matter "or other technical matter". This interpretation of Article 13:2 of the DSU seems to the Panel to be perfectly in line with the text of this provision, interpreted in accordance with Article 31 of the Vienna Convention on the Law of Treaties, and with the interpretation given by the Appellate Body that Article 13 of the DSU does not prevent panels from consulting with individual experts and leaves to the sound discretion of a panel the determination of whether the establishment of an expert review group is necessary or appropriate.[10]

5.18 The Panel also considered the European Community's argument that, if the measure at issue should be deemed to fall under the TBT Agreement, which the Communities contest, Article 14.2 of that Agreement would require the establishment of an expert review group for any scientific or technical matter, and the EC position that pursuant to Article 1:2 of the DSU, that provision would prevail over those of Article 13 to the DSU. Article 14:2 of the TBT Agreement is among the provisions mentioned in Appendix 2 to the DSU and which, under Article 1:2 of that Understanding, will prevail over the provisions of the Understanding to the extent that there is a difference between the two. The Panel notes, however, that it is only "to the extent that there is a difference" between the rules and procedures of the Understanding and a special or additional rule or procedure in Appendix 2 to the DSU that the latter will prevail. Yet, as stated by the Appellate Body, it is only where the provisions of the DSU and the special or additional rules of Appendix 2 cannot be read as complementing each other that the special or additional provisions will prevail over those of the DSU,

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Articles 8:2, 8:3 and 17:3 of the DSU, paras. 2 and 3 of Appendix 4 to the DSU, as well as paras. 2 and 3 of Annex 2 to the TBT Agreement.

[10] See the Reports of the Appellate Body in *European Communities – Measures Concerning Meat Products (Hormones)* (WT/DS26/26-DS48/AB/R), para. 147 (" … in disputes involving scientific or technical issues, neither Article 11.2 of the SPS Agreement, nor Article 13 of the DSU prevents panels from consulting with individual experts. Rather, both the SPS Agreement and the DSU leave to the sound discretion of a panel the determination of whether the establishment of an expert review group is necessary or appropriate") and *Argentina – Measures Affecting Imports of Footwear, Textiles, Apparel and Other Items* (WT/DS56/AB/R) para. 84 ("Article 13 of the DSU enables a panel to seek information and technical advice as it deems appropriate in a particular case, and (…) the DSU leaves 'to the sound discretion of a panel the determination of whether the establishment of an expert review group is necessary or appropriate'.").

that is, in a situation where the two provisions would be mutually incompatible.[11] In the present case, Article 14:2 of the TBT Agreement provides that a panel "may" establish a technical expert group. Like Article 13:2 of the DSU, this text envisages the possibility of establishing a technical expert group and lays down the procedures that would be applicable in the event. Nevertheless, it does not exclusively prescribe the establishment of a technical expert group, and this possibility, in our opinion, is not incompatible with the general authorization given under Article 13 of the DSU to consult with individual experts. The two provisions can be read as complementing each other.

5.19 The Panel believes that in this case the consultation of experts on an individual basis is the more appropriate form of consultation, inasmuch as it is the one that will better enable the panel usefully to gather opinions and information on the scientific or technical issues raised by this dispute. Considering in particular the range of areas of competence that might be required, it is appropriate in this case to gather information and different individual opinions rather than asking for a collective report on the various scientific or technical matters in question. In the light of the foregoing, the Panel wishes to underline that its decision to consult experts on an individual basis is without prejudice to the applicability of the TBT Agreement to the measure in question, on which the parties disagree.

B. SELECTION OF EXPERTS

5.20 The Panel has requested the assistance of five institutions in identifying experts. The institutions concerned are the World Health Organization (WHO), the International Labour Organization (ILO), the International Programme on Chemical Safety (IPCS), the International Agency for Research on Cancer (IARC) and the International Organization for Standardization (ISO). The parties have also submitted names to the Panel. The Secretariat then requested those of the proposed experts who were prepared to participate to submit to it a detailed *curriculum vitae*. Those *curricula vitae* were forwarded to the parties, who were able to convey to the panel their comments concerning the potential experts and to indicate, where appropriate, whether they had any major objections to any of them. Upon careful examination of the *curricula vitae* and the comments of the parties, the Panel accepted the following four experts, whose nominations were not opposed by the parties:

- Dr. Nicholas H. de Klerk, Senior Research Fellow, Department of Public Health, University of Western Australia, Australia;

- Dr. Douglas W. Henderson, Professor of Pathology, Head of the Department of Anatomical Pathology, Flinders Medical Center and The Flinders University of South Australia, Australia;

- Dr. Peter F. Infante, Director, Office of Standards Review, Health Standards Programme, Occupational Safety and Health Administration, Washington D.C., United States;

- Dr. Arthur W. Musk, Clinical Professor of Medicine and Public Health, University of Western Australia, and Physician, Department of Respiratory Medicine, Sir Charles Gairdner Hospital, Nedlands, Australia.

5.21 The experts were asked to acquaint themselves with the *Rules of Conduct for the Understanding on Rules and Procedures Governing the Settlement of Disputes*[12], paying special

[11] See the Report of the Appellate Body in *Guatemala – Anti-Dumping Investigation Regarding Portland Cement from Mexico* (WT/DS60/AB/R), paras. 65 and 66.

[12] WT/AB/WP/3, of 28 February 1997.

attention to Annex 2 (Illustrative list of information to be disclosed). No expert has disclosed any circumstance that could be considered as the potential source of a conflict of interest.

5.22 In consultation with the parties, the Panel prepared precise questions which it submitted to each expert individually. The experts were requested to answer only those questions that they considered to be within their domain(s) of competence. Written communications by the parties, transcriptions of their oral statements, as well as the references they submitted to the Panel were transmitted to the experts for their information. The written answers from the experts have been forwarded to the parties, who have had a chance to comment on them. The questions posed by the Panel and the answers given by the experts are contained in section V.C. The observations of the parties are reproduced in section V.D.

5.23 On 17 January 2000, the experts were invited to discuss with the Panel and the parties their written answers to the questions and to provide additional information. Annex VI to this report contains the minutes of the meeting.

C. QUESTIONS BY THE PANEL AND COMMENTS BY THE SCIENTIFIC EXPERTS

5.24 The Panel requested the experts to comment on the areas of difference between the parties highlighted in the first paragraph of each question, as well as to address the specific points listed. The Panel encouraged the experts to indicate, to the extent possible, key points on which they considered that (i) there is scientific proof, (ii) there is broad agreement among experts, (iii) there is uncertainty and/or a range of divergent opinions among experts.

1. Introductory Comments by Dr. Henderson

(a) Introduction

5.25 This introduction sets out a general summary of prevailing knowledge and uncertainties on asbestos-related disorders, with emphasis on mesothelioma and lung cancer, together with discussion of both the amphiboles and commercial chrysotile, patterns of exposure, and some brief details of *in vivo* and *in vitro* experimental studies.

5.26 This introduction has two purposes: (i) to provide a general background and broad perspective to the questions and answers that follow; and (ii) to correct some inaccuracies and errors in the documentation supplied already to the WTO. In so doing, I have tried to broaden the perspective beyond the classical Canadian studies on the Quebec chrysotile miners and millers, and beyond the INSERM Report. A number of the general discussions in this introduction have been truncated after the issue has been put into context, and some of these discussions are then continued and amplified in my specific responses to the questions. This has produced some iteration of some points, but I believe that the advantages - avoidance of the potential for distortion created by answers without adequate background information - outweigh any disadvantages. The division of my report into these sections also provides an opportunity to indicate the relative importance of epidemiological studies versus *in vivo* or *in vitro* experimental models in the formulation of my opinions and answers.

5.27 At the outset, I emphasize that Australia (including Western Australia) is no longer an asbestos producer. Production of crocidolite at the Wittenoom blue asbestos industry stopped in 1966. None has been produced or exported since. Crocidolite was used in asbestos-cement products in Australia until 1966 when its use was discontinued, but imported amosite was used in these products until 1984 [NICNAS 99][13]. The use of chrysotile in fibro-cement products was discontinued in 1987.

[13]For complete references, see Annex III to the Panel Report.

5.28 As stated repeatedly in the documentation provided to the WTO, asbestos has the capacity to induce at least five benign pleuropulmonary disorders, and two cancers: parietal pleural fibrous plaques; benign asbestos pleuritis with effusion; diffuse pleural fibrosis; rounded atelectasis; asbestosis; primary lung cancer; malignant mesothelioma. The essential characteristics of these disorders are discussed in the documentation submitted to the WTO and lie beyond the scope of this report; if further details are required, standard texts should be consulted [26-30]. There is no persuasive or compelling evidence that asbestos of any type causes cancers other than lung cancer and mesothelioma, with the arguable exception of cancer of the larynx. At this stage, it is sufficient to point out that: " ... there is an exposure-response relationship for all chrysotile-related diseases. Reduction of exposure through introduction of control measures should significantly reduce risks. Construction and demolition operations may present special control problems". [EHC 203, p 141].

(b) Malignant mesothelioma – Introduction and general observations on asbestos and mesothelioma

5.29 Malignant mesothelioma is a cancer of the mesothelial cells that line the serosal membranes of the major body cavities, namely the pleura, the peritoneum, the pericardium and the tunica vaginalis testis; the constituent neoplastic cells characteristically express the phenotype of a recognized pattern of differentiation of the mesothelium, whether epithelioid, sarcomatoid or both (biphasic), as revealed by conventional light microscopy, mucin immunohistochemistry, immunohistochemistry or electron microscopy, or a combination of these techniques [31-33]. Like other forms of cancer, mesothelioma has the capacity for local invasion of tissues such as the chest wall or lung, with confluent serosal spread in most cases but not all, and in some instances distant metastasis [31], with an almost invariably fatal outcome. Mesothelioma is resistant to conventional cancer therapies (e.g. radiotherapy or chemotherapy), but some long-term survivals have been recorded following radical surgery (pleuropneumonectomy) in patients in good physical condition and with early-stage disease [34-43]; radical surgery of this type is not a treatment option for the majority of mesothelioma patients.

5.30 Most mesotheliomas encountered in the 1990s are a consequence of prior occupational exposure to asbestos [24], including bystander exposure. The relationship between asbestos - especially one or more of the amphibole varieties - and mesothelioma is accepted by virtually all authorities as causal. In this respect, asbestos fulfils all *The Bradford Hill Criteria* for the establishment of causality (e.g. please see Stolley and Lasky [44]).

5.31 The following points about asbestos and mesothelioma are worth emphasis:

(i) Inhalation of asbestos fibres represents the overwhelming cause of mesothelioma in industrialized societies, so much so that the incidence of mesothelioma is usually considered to be an index of those societies' past usage of asbestos.

According to Peto *et al.* [24]:

> "The great majority of mesotheliomas are caused by asbestos, and the much higher incidence in men indicates that most are due to occupational rather than environmental exposure. The incidence continues to rise approximately as the third power of time since first exposure to asbestos for many decades after exposure has ceased (Peto *et al.*, 1982), and most patients are men first exposed 30 or more years ago. A country's mesothelioma rate is therefore a quantitative indicator of its population's past exposure — mainly occupational — to asbestos." [p 666].

5.32 Boffetta [15] claims that:

> "Asbestos is the only established risk factor of mesothelioma. Because of the rarity of the disease and the specificity of the causal association, all cases occurring among asbestos-exposed workers are attributed to this exposure." [p 476; please see following discussion].

4.33 The asbestos exposure may take the following forms: (i) direct or indirect occupational exposure (including bystander exposure); (ii) domestic exposure: e.g. household contacts of asbestos workers, such as wives who washed the asbestos-contaminated work clothes of their husbands [45-47]; (iii) environmental exposure: this category includes those who lived downwind of asbestos industries or in townships contaminated by asbestos [45-47]. For example, ≥ 27 mesotheliomas have been recorded among those who lived at Wittenoom as children (the roads, airstrip and school yards were surfaced with crocidolite tailings from the mine, and children often played in the mine tailings).

> "The tumor [mesothelioma] is more often seen in workers who have only moderate or small amount of asbestos in their lungs, and who show little, if any, clinical or radiologic evidence of pulmonary fibrosis. This amount of asbestos may be inhaled not only by professional asbestos workers, but also by those who handle products containing only a small proportion of asbestos, those who do not handle asbestos at all but merely work alongside asbestos workers such as craftsmen employed in the building industry — carpenters, electricians, etc. — those who have relatives who carry asbestos home in their workclothes and those who live close to asbestos plants." [47] [p 295].

5.34 No history of asbestos exposure is obtainable in about 15-25 per cent of mesothelioma cases [31, 48]. Nonetheless, absence of a history of exposure does not equate to absence of exposure, and evidence indicates that many of these mesotheliomas are in reality attributable to asbestos inhalation — e.g. remote, brief or forgotten exposure, or alternatively, the individual may be unaware that he (the male:female ratio is about 8:1) was in fact exposed to asbestos: (i) from my own series of mesotheliomas, 79 per cent of the request forms that accompanied the biopsies on which the diagnosis was made gave a positive history of past asbestos exposure; clinical review of the remaining 21 per cent yielded a history of asbestos exposure in a substantial proportion, including some for whom the original history stated that there was no exposure, so that my estimate of the proportion for whom a positive history of exposure was eventually obtained is ≥ 85-90 per cent. This estimate is in reasonable agreement with figures in the 1999 Report for the Australian Mesothelioma Register [AMR 99], where 85 per cent of mesotheliomas had a history of asbestos exposure; (ii) Leigh *et al.* [49] found measurable asbestos fibre levels (> 200,000 fibres per gram dry lung tissue) in 81 per cent of the 28 per cent of Australian mesothelioma cases that had no history of occupational or environmental exposure to asbestos.

(ii) Putative or possible factors other than asbestos implicated in the induction of mesothelioma

5.35 In the reply to Question 3 from the European Communities, Canada makes the following statements:

> "... Canada wishes to inform the European Communities of the considerable body of evidence contradicting their statement that asbestos in all forms (amphiboles and chrysotile) is the only known factor that can cause mesothelioma or pleural cancer. ... A number of studies suggest other potential risk factors that may have been under-estimated in epidemiological studies in industrialized countries. ... A number of artificial fibres cause mesothelioma when they are injected into the pleura and peritoneum of laboratory animals. Note also that the International Agency for Research on Cancer (IARC) has classified refractory ceramic fibres as probable carcinogens, partly because of instances of mesothelioma induced by inhalation and injection in animal experiments. The SV40 virus readily induces mesothelioma when injected into animals; studies suggest that the virus contaminated anti-polio (poliomyelitis) vaccines from 1955 to about 1963 and may induce mesothelioma with or without the help of asbestos fibres. Some studies of humans report the presence of the simian SV40 virus in the biological tissue of mesothelioma victims. Ionizing radiation used in cancer therapy and perhaps occupational exposure to radiation have induced mesothelioma. ... [E]rionite has been shown to be even more toxic than crocidolite in causing mesothelioma; it has killed large numbers of villagers in

Turkey. Erionite is a mineral fibre but does not belong to the asbestos family."

5.36 Possible factors other than asbestos implicated as contributory or causative for rare mesotheliomas are tabulated below:

TABLE 1: PUTATIVE OR POSSIBLE RISK FACTORS AND MEDIATORS OF RISK OF MESOTHELIOMA OTHER THAN ASBESTOS

Factor	Comments
Erionite	Very high incidence of mesothelioma due to environmental exposure in Turkey (restricted geographic localization only).
Chronic inflammation	Pleural scars (tuberculosis, pleurisy, therapeutic pneumothorax, familial Mediterranean fever); see following discussion.
Radiation	Single cases after Thorotrast injection or radiotherapy; causality unproven. One case in atomic bomb survivor.
Beryllium	Two doubtful cases described.
Vegetable fibres	No proof in humans.
Hereditary factors	Familial cases (explicable by common asbestos exposure ± unidentified genetic susceptibility factors, including association with other cancers in first-degree relatives).
Immunological factors	Rapidly progressive cases in patients with HIV infection; very rare — single case(s) only.
Dietary factors	Provitamin A, β-carotene may decrease the risk (unproven).
Viruses	Mesotheliomas in animals. Simian virus 40 (SV40) DNA sequences reported in mesotheliomas; see following discussion

Modified from Hillerdal [20].

5.37 There are anecdotal reports of mesothelioma following radiation, including radiotherapy for childhood cancer such as Wilms' tumour [50-56]. In addition, excess rates of mesothelioma have been reported among both Danish and German patients exposed to radioactive thorium dioxide (Thorotrast) for radiological procedures [57, 58], although a similar but smaller Japanese study found no such excess [59]. Neugut *et al.* [60] investigated women with breast cancer and patients with Hodgkin's disease, many of whom had been treated by radiotherapy (RT):

> "The authors performed a retrospective cohort study utilizing 251,750 women registered with breast carcinoma in the Surveillance, Epidemiology, and End Results Program of the U.S. National Cancer Institute from 1973-1993, 24.8% of whom received RT as part of their initial management, and 13,743 people with Hodgkin's disease, 50.6% of whom received RT as part of their initial management. RESULTS: Six cases of malignant pleural mesothelioma were found: two in breast carcinoma patients treated with RT and four found in women not treated with RT. No cases occurred in the patients with Hodgkin's disease. The overall estimated relative risk for malignant pleural mesothelioma after RT was 1.56 (95% confidence interval, 0.18-5.63). CONCLUSIONS: To the authors' knowledge, this is the first controlled study to investigate thoracic radiation exposure and malignant pleural mesothelioma, and no association was found." [abstract].

5.38 I am also aware of at least one mesothelioma in a patient with HIV infection (AIDS) [61]. Other mesotheliomas have occurred many years after chronic inflammatory lesions of the pleura — e.g. chronic empyema or packing of the pleural cavity with leucite spheres as treatment for tuberculosis [62, 63], and there are a few reports of an association between familial Mediterranean fever (FMF) and mesothelioma (about eight cases only; possibly related to recurrent FMF serositis [64-67]). However, cases of this type are exceptional and most cases of "post-inflammatory" mesothelioma with a short interval between inflammation and tumour (e.g. $\leq$ 2-3 years by analogy with the criteria for the diagnosis of benign asbestos pleuritis [33, 68, 69]), are probably

mesotheliomas that presented with a burst of inflammatory activity, followed by a period of quiescence [70].

5.39 In addition, background asbestos exposure represents a confounding factor for some cases associated with radiation and immunodeficiency: (i) in one report on mortality among 260 plutonium workers, all six mesotheliomas occurred in individuals who had also sustained asbestos exposure [71]: "... no apparently elevated causes of death except for six cases of mesothelioma and six cases of astrocytoma glioblastoma multiforme. The mesothelioma cases had a documented occupational exposure to asbestos ..." [extract from abstract]; (ii) in one of my own cases, the patient had been treated for Hodgkin's disease by mantle radiotherapy 10 years before the diagnosis of his primary pericardial mesothelioma, but he also had a background of occupational exposure to asbestos; (iii) in another case — a pleural mesothelioma in a renal transplant recipient — the patient had also sustained earlier occupational exposure to asbestos.

(iii) Erionite and mesothelioma in Turkey

5.40 Erionite (a fibrous zeolite) represents a naturally occurring fibrous mineral implicated in the induction of mesothelioma in certain villages (notably Karain and Tuskoy) in the Cappadocian region of Turkey [72, 7 3], and in Turkish emigrants [74]. So far as I am aware this represents a restricted geographic pocket of mesothelioma cases induced by erionite used as stucco or whitewash in buildings, so that the inhabitants were exposed to high concentrations of erionite fibres from birth. Erionite has no relevance to the broader mesothelioma problem in Western Europe, North America, and Australia. Nonetheless, in its physical properties erionite has similarities to the amphibole varieties of asbestos and it has been suggested that its greater mesotheliomagenicity is related to a greater surface area (200 m^2 per gram) than crocidolite (8-10 m^2 per gram), due to the presence of pores in the crystal lattice (see Roggli and Brody [75]); such differences in surface topography might correlate with differences in free radical generation at the surface of fibres.

(iv) Simian virus 40 (SV40) and mesothelioma

5.41 Recently, a voluminous literature has grown rapidly on the detection of SV40 DNA in up to 60 per cent of human mesotheliomas [76-87] and some other tumours, such as papillary carcinoma of the thyroid [88], osteosarcomas and brain tumours [83, 89-91]. These observations followed an initial finding that SV40 could induce mesothelioma in hamsters when injected into the pleural cavity [92], and the later demonstration that SV40 could inactivate the tumour suppressor genes p53 and the retinoblastoma gene (Rb) via the large T antigen (TAG) [80, 82, 93, 94]. For humans, early poliomyelitis vaccines contaminated with SV40 were a potential source for the SV40 DNA [82-84]. The following points on this interesting association are also worth emphasis:

- It has been suggested that the presence of SV40 might explain: (i) why mesothelioma only develops in a relatively small proportion of asbestos-exposed individuals (usually < 10 per cent); and (ii) why no history of asbestos exposure is obtainable on a sizeable minority of mesotheliomas [95]. However, almost all the mesotheliomas in which SV40 DNA has been found were asbestos-associated; to the best of my knowledge, there is no reported case-control analysis of SV40-associated mesotheliomas where asbestos fibre counts were not elevated above reference values, with the exception of a recent study by Mayall *et al.* [96] (please see following discussion). Therefore, the existing data do not adequately address either (i) or (ii): there are many other possible explanations for these observations.

- In other studies, SV40 or TAG could not be detected within mesotheliomatous tissue [97-99]. Galateau-Sallé *et al.* [100] found that SV40 was present not only in mesotheliomas but also in benign inflammatory disorders of the pleura and non-

neoplastic lung tissue. In an as yet unpublished investigation carried out in collaboration with Prof. Alec Morley in the Department of Haematology-Oncology at the Flinders University, we have also identified SV40 in mesotheliomas, and in non-neoplastic pleural lesions, normal tissues and colon cancers, casting doubt on the specificity of the association.

- Two epidemiological studies have shown no increase in the incidence of bone or brain tumours — or mesotheliomas — 30 years after the use of polio vaccines contaminated with SV40 [101, 102], although in a later study using SEER data[14], Fisher *et al.* [103] reported an increased frequency of these tumours in subjects who had received SV40-contaminated poliomyelitis vaccines.

- The evidence so far only points to SV40 as a possible co-factor for asbestos in the genesis of mesothelioma [96]. For example, Mayall *et al.* [96] detected SV40 sequences in five of seven asbestos-associated mesotheliomas, but none of four mesotheliomas that were not asbestos-related (investigated by fibre burden analysis of lung tissue, using electron microscopy). However, the evidence in favour of SV40 as a co-factor for mesothelioma induction is still inconclusive and non-persuasive, and in humans the SV40 may represent an innocent bystander or passenger: the criteria for causality [44] have not been fulfilled.

  "It remains to be shown whether the presence of SV40 contributes significantly to malignant transformation or whether certain human neoplasms provide a microenvironment that favors viral replication in humans with latent SV40 infection." [91] [last sentence of abstract].

5.42 The point of these comments is that the evidence for a role of SV40 in the development of mesothelioma is inconclusive, and most of SV40-associated cases still represent asbestos-associated mesotheliomas. Although the literature contains anecdotal reports of mesothelioma following radiation, some of these cases (e.g. among plutonium workers) are complicated by coexistent asbestos exposure and it is worth emphasizing that these cases are rare: together they add up to only a small fraction of 1 per cent of the total burden of mesotheliomas in industrialized societies, for which asbestos remains the overwhelming cause. As emphasized already, there is general agreement that the incidence of mesothelioma in various nations is a reflection of the past usage of asbestos by those societies.

5.43 Hillerdal [20] comments along similar lines:

"... SV40 might be a cofactor to asbestos in some patients with mesothelioma, but the [findings] have not been confirmed and are still disputed. ... In summary, then, as far as is known today, factors other than mineral fibres can only explain a very small proportion of mesotheliomas, and can for practical purposes be disregarded [i.e. when approaching the causation of mesothelioma among large cohorts or populations]. Thus, a malignant mesothelioma can be regarded either as caused by asbestos or belonging to a normal background level — that is a spontaneously occurring tumour." [p 506].

(v) Male: female ratio for mesothelioma

5.44 Asbestos-induced mesothelioma affects males more often than females in a ratio of about 8:1, as a reflection of occupational exposure.

(vi) Anatomical distribution of mesothelioma

5.45 With the exception of one series in which 44 per cent of mesotheliomas were peritoneal [104],

[14]The National Cancer Institute's Surveillance Epidemiology and End Results program.

there is general agreement that primary asbestos-induced mesothelioma affects the pleura more often than the peritoneum, in a ratio of at least 3:1 or even up to ≥ 11:1 [31, 33] (see also AMR 99). In Australia, ≥ 91 per cent of mesotheliomas arise in the pleural cavities, whereas about 7 per cent represent primary peritoneal mesotheliomas and ≤ 1 per cent affect the pericardium or tunica vaginalis testis [33]. This predominance of pleural mesotheliomas in comparison to the peritoneum appears to correlate with gender differences in the frequency of occupational exposure to asbestos (the same high ratio of pleural to peritoneal tumours is also encountered in the United States). In females, a smaller proportion of mesotheliomas arises in the pleura, and in one study of Swedish insulation workers, all seven mesotheliomas arose in the peritoneum [105] (please see following discussion).

5.46 One report [106] that included cases notified to the Australian Mesothelioma Register from 1986 through 1988 gave figures for the anatomical sites affected in men and women: 676 of 723 men had a pleural mesothelioma (93 per cent), whereas 38 were peritoneal tumours (5 per cent) and nine occurred in other sites (1 per cent). In contrast, 84 mesotheliomas in 101 women were pleural in location, whereas 17 per cent had a peritoneal mesothelioma.

5.47 Presumably, this difference in anatomical distribution between sexes is a reflection of different rates of occupational exposure to asbestos. On theoretical grounds, one would expect mesotheliomas entirely unrelated to asbestos to occur with about equal frequency in the pleura and peritoneum, or more often in the peritoneum because of the greater surface area of the peritoneal cavity.

5.48 A partial list of the factors that might explain the higher proportion of peritoneal mesotheliomas in some series and in women includes the following [33]:

- The high proportion of pleural mesotheliomas in men is presumably a reflection of asbestos exposure, with deposition of asbestos fibres in lung tissue, followed by translocation of the fibres to the pleura; on this basis, asbestos inhalation appears to skew the proportional distribution of mesothelioma towards the pleura in comparison to other sites. In contrast, fibres presumably follow a more circuitous route from the lung to the pleura, across the diaphragm and into the peritoneal cavity, to induce peritoneal mesothelioma; higher inhaled doses of asbestos might be necessary for the requisite number of fibres (whatever that is) to reach the peritoneum via the pleura, in order to induce peritoneal mesothelioma.

- The high proportion of peritoneal tumours in some series may be a consequence of patterns of referral for cases that constitute problems in diagnosis, because the diagnosis of peritoneal mesothelioma is, in general, more difficult than for pleural mesotheliomas. This may explain the higher proportion of peritoneal mesotheliomas among cases referred to the US-Canadian Mesothelioma Panel [107], because many of these represented problems in diagnosis, whereas the Australian Mesothelioma Surveillance Program (AMSP) captured all mesotheliomas throughout Australia [48].

- Genuine biological differences in the inhaled dose, deposition or transport of different asbestos fibre types in some groups of workers, notably insulation workers [108] and former Wittenoom workers [109] — as a consequence of heavy occupational exposure — and in women [106, 110].

5.49 In answer to questions posed by the European Communities (Question 3, see Annex II), the following comment is made:

> "... malignant diffuse mesothelioma is a cancer of the mesothelial cells of the pleura, the pericardium and the peritoneum. Furthermore, peritoneal mesothelioma is an even more typical result of exposure to amphiboles than pleural mesothelioma."

5.50 From the preceding discussion on the proportions of mesotheliomas arising in the pleural cavities versus the peritoneum, it is evident that this proposition is not correct: use of the term typical in this context is inappropriate. In reality, pleural mesothelioma is a more typical or usual outcome of asbestos exposure, whereas asbestos-induced peritoneal mesotheliomas are usually associated with more prolonged and heavier exposures than pleural mesotheliomas, so that the proportion of patients with asbestosis is higher than for pleural mesothelioma [111]. It has also been claimed that peritoneal mesotheliomas are almost always a consequence of amphibole exposure (as opposed to chrysotile only) [112]. Nonetheless, although some of the peritoneal mesotheliomas in my own series of cases followed high-dose exposures to asbestos that included one or more of the amphiboles, a few followed lower cumulative exposures, and Neumann *et al.* [111] have reported peritoneal mesotheliomas as a consequence of exposure in the building trades and metal industries, in addition to asbestos industries; Rogers *et al.* [3] recorded peritoneal mesotheliomas in whom only chrysotile fibres were detected on lung fibre analysis (see Table 9, paragraph 5.137).

(vii) Latency intervals (lag-times)

5.51 In all reported studies, mesothelioma is a disease of long latency between exposure to asbestos and the subsequent diagnosis of the mesothelioma. In the AMSP [48], the mean latency interval (lag-time) was 37 years, with a reported range of 4-75 years; the lag-time was reported to be < 10 years in only four of 499 asbestos-associated mesotheliomas (0.8 per cent). Many authorities set a minimum lag-time of 10 years (e.g. The Helsinki Criteria [113]), and for most patients the lag-time is in the range of 20-40 years, When the lag-time is < 10 years, it is likely that the proximate exposure was coincidental, and that there were one or more earlier exposures.

(c) Spontaneous or background mesothelioma: does it exist?

4.52 The rare occurrence of mesothelioma in childhood and even as a congenital malignancy supports the existence of a background of spontaneous mesotheliomas unrelated to asbestos (in addition, mesothelioma has been reported in fish (trout) [114], where inhalation of airborne asbestos fibres cannot be invoked). However, in epidemiological studies on adult populations, it is virtually impossible to separate spontaneous mesotheliomas from those that are arguably attributable to environmental exposure to asbestos [70, 115]. The incidence of mesothelioma in women is sometimes used as an index of the background or spontaneous rate: the crude incidence rate for women in Western Australia is about 2.6 per million person-years at age ≥ 15 years [115]. The incidence rate in other populations is listed in Table 2 (following page).

5.53 In the answer to the WTO Panel's questions to Canada (Question 9, see Annex II), the following statement is made:

> "Recent analyses of Canadian data on mesothelioma in Canada, British Columbia and Quebec all agree that the incidence rate of mesothelioma has been stable among women of all age groups since 1984. The rates are 70% higher in Quebec than in the rest of Canada, presumably as a result of more frequent and more intense exposure in the workplace."

5.54 The statistics for Australia differ on this point (Table 2): mathematical modelling of Western Australian data suggests that the incidence rate in women has risen about two-fold from the 1970s until the 1980s, which might be explicable by increased general environmental exposure to asbestos, plus some occupational exposures among women [70, 115] (please see also AMR 99 — i.e. the graph for the Age Specific-Incidence Rates of Malignant Mesothelioma in Australia Women, 1986-1995, especially for ages 50-64 and 65-79). This increased incidence among women

presumably reflects direct or indirect occupational exposure, domestic exposure or environmental exposure [115]; in this respect, it is worth emphasizing that domestic (household contact) exposure to asbestos — e.g. among wives laundering the dust-laden workclothes of an asbestos-exposed husband — is not necessarily low-level exposure, and analysis of the asbestos fibre content of the lungs in a small number of such patients indicates that this type of exposure can approach occupational levels [116].

TABLE 2: INCIDENCE OF MORTALITY OF MESOTHELIOMA IN VARIOUS COUNTRIES AND AREAS OVER TIME, 1960S TO 1994 (PER MILLION INHABITANTS PER YEAR)

Country or area	Year	Males	Females
United States	1968-81	2.1	0.8
North America	1972	2.8	0.7
Texas	1976-80	5.8	2.1
Selected cities, United States	1970s	4.4-11.1	1.2-3.8
United States	1986	7-13	1-2
Nantes-Saint-Nazaire, France	1956-74	5.2	0.2
Nantes-Saint-Nazaire, France	1975-84	17.2	0.8
Nantes-Saint-Nazaire, France	1985-92	19.4	4.0
Great Britain	1968-71	8.4	2.3
Great Britain	1972-76	12.6	2.8
United Kingdom	1983	17.5	3.2
Great Britain	1968-71	20.7	4.3
Great Britain	1982-86	30.5	4.9
Great Britain	1987-91	44.0	6.4
Australia	1982-88	28.3	3.3
Australia	1994	49.9	4.8
Denmark	1978-80	14.7	7.0
Barcelona, Spain	1983-90	8.3	4.7
Finland	1990-94	10	2.9

Modified from Hillerdal [20].

5.55 The often-cited background or spontaneous rate of mesothelioma of 1-2 per million person-years [10, 117], has in part also been derived from backward extrapolation of the incidence rates in men, to the point where the estimated incidence rates for men and women diverged from each other (i.e. linear extrapolation to the point where the sex ratio = 1:1) [117] . Hillerdal [20] suggests that this incidence probably represents a high estimate and comments in the following terms:

> "... there seems to be a small spontaneous basal or background incidence of the tumour [mesothelioma] ... However, it is of course possible that some of these background cases might in fact be due to occupational, domestic, or even environmental exposure, unknown to (or forgotten by) the patients themselves. ... There are authors who claim that the presumed background levels must be very low, and retrospective searches for the tumour in the medical literature reveal no convincing cases of mesothelioma before 1946, although such negative evidence is of questionable value.[15] McDonald and

[15]Mark and Yokoi [118] have called into question the existence of mesothelioma in the absence of asbestos exposure, pointing out that the early descriptions of pleural tumours may have dealt with localized fibrous tumours of the pleura (four of the five tumours reported by Klemperer and Rabin [119]) or secondary carcinoma. Thus, mesothelioma might represent a new disease consequent upon the industrial use of asbestos (analogous to AIDS) and it may disappear upon withdrawal of the causative asbestos from the environment (analogous to smallpox). In support of this proposition, these authors cited the records of the Massachusetts General Hospital, where no examples of mesothelioma were diagnosed before 1946, in contrast to 100 autopsy cases thereafter, in a total of 47,000 autopsies. They also referred to the Henke-Lubarsch *Handbuch der*

> McDonald, in a recent review, estimated the background level to be 1-2/million per year; they came to this figure by extrapolating backwards from epidemiological studies from various countries. ... It is nevertheless possible that there is a background level of mesothelioma, — that is, that the tumour can occur even in the complete absence of asbestos (or erionite) fibres. However, the data reviewed here indicate that if so, this background level must be very low — probably much < 1 case/million people/year. This figure comes from studies of industrialized countries, where background exposure to asbestos is unavoidable. What the true figure is can only be guessed ... ". [p 507].

5.56 De Klerk [115] and Comin *et al.* [70] have commented that in the absence of specific exposure to asbestos, the final estimated rate for both men and women in Australia is 2.6 per million person-years — higher than the equivalent figure of 1.6 for Los Angeles [115]. This difference may lend some support to the proposition that general environmental exposure to asbestos may have produced an increase in the mesothelioma rate in Western Australia [115]. However, it is difficult or impossible in general to draw firm conclusions from differences between different studies, because of variation in the accuracy of diagnosis and differences in the ways that data are collected.

5.57 In response to questions from the WTO Panel (Question 9, see Annex II) the Canadian document also observes that:

> "The incidence of [mesothelioma] among men levelled off after 1984 in British Columbia ... and seems to have levelled off in Quebec after 1990 ... Finally, analysis of Canadian rates between 1973 and 1992 ... estimates that the risk is four times greater for men born before 1940 than for men born between 1951 and 1955. Those analyses therefore suggest that the incidence of mesothelioma has levelled off in Canada, is declining in British Colombia, and has levelled off in Quebec ..." .

5.58 In response to these observations, I emphasize the following: (i) the incidence of mesothelioma among Australian males shows little evidence of levelling off, and has continued to rise until 1994-1995 and thereafter (please see Table 2 and the 1998 and 1999 Reports for the Australian Mesothelioma Register); (ii) from the recent report by Peto *et al.* [24], it is also evident that the incidence of mesothelioma in Western Europe continues to rise, with particular emphasis on males born between 1945 and 1950 who used asbestos-containing products in the 1960s and the 1970s (and the early 1980s).

(d) Magnitude of the mesothelioma problem

5.59 Malignant mesothelioma continues to represent a major health problem within industrialized societies, and together with lung cancer it represents the most important occupational cancer among so-called blue-collar workers [121-124].

5.60 It has been estimated that across Western Europe, North America and Australia (combined population ~ 800,000,000), around 10,000 mesotheliomas and 20,000 asbestos-induced lung cancers occur annually, related mainly to occupational exposure (about one mesothelioma for every 200 tons of asbestos produced, taking into account the prolonged lag-times) [125]. Steenland *et al.* [126] estimate that approximately 9000-10,000 men and 900-1900 women develop lung cancer each year in

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speziellen pathologischen Anatomie und Histologie, wherein the four pages devoted to tumours of the pleura did not specifically acknowledge the existence of mesothelioma; the Henke-Lubarsch authors concluded that many cases described in the literature as primary pleural neoplasms were cases of lung cancer with spread to the pleura. I find the evidence for Mark and Yokoi's proposition to be underwhelming and unconvincing. The case reported in the 1920 paper by Du Bray and Rosson [120] is, I believe, a clear example of a mesothelioma, as is the fifth case of Klemperer and Rabin [119]. Failure to diagnose a tumour is hardly synonymous with its non-existence, and the pathological features of many tumours have been delineated in quite recent times. Pathological diagnoses follow prevailing evidence and fashions, and because the groundwork for modern concepts of mesothelioma was laid down in 1931 by Klemperer and Rabin, it is hardly surprising that the diagnosis became more widespread only after this time.

the United States because of past exposure to occupational carcinogens, and more than half of these lung cancers are related to asbestos (this overall estimate is considered probably to be conservative). Predictions of asbestos-related diseases in Australia (population ~ 18,000,000) indicate that about 13,000 cases of mesothelioma (range 8000-20,000), about 40,000 cases of lung cancer (range 30,000-76,000) and 1000 cases of asbestosis are likely to occur between the years 1987 and 2020 [70, 127].

5.61 More recently, Peto *et al.* [24] have predicted that about 190,000 mesothelioma deaths are likely to occur throughout Western Europe (Britain, France, Germany, Italy, the Netherlands and Switzerland) over the next 35 years. If one adds in lung cancer at a ratio of one lung cancer for every mesothelioma death, this figure would rise to 380,000 deaths, and if the ratio of lung cancers to mesotheliomas is 2:1 the figure rises to 570,000 deaths.

5.62 Overall, asbestos may have caused approximately 5,000,000 deaths across industrialized societies so far. When future deaths in so-called developing nations are added, the final toll is almost certain to be substantially higher, especially because occupational exposures in those countries are likely to be heavier (e.g. China). Estimates of this magnitude are likely to engender alarm among those who set social policy. Even so, it is important that this problem, like others (e.g. atomic energy), is approached with common sense, rationality and prudence, taking into account population-based risk estimates: it would be irrational to swap one risk for another higher risk if the two risks were equally serious.

(e) Some general observations on approaches to risk assessment on society and on epidemiological studies of asbestos-related cancers

5.63 The documentation supplied to the WTO includes estimates of risks from low-level exposure to chrysotile in proportion to various other risk factors in society: in fact, the relative risk of mesothelioma from low-level exposure to asbestos in place is the focus of considerable controversy. Clearly, detailed analysis of this issue is beyond the scope of this report, but the excess risk of mesothelioma from very low-level exposure to asbestos — e.g. simple occupancy of public buildings or schoolrooms where average asbestos fibre concentrations are about < 0.001-0.02 fibres per litre — appears to be very slight: about ≤ 5.5 mesotheliomas per million lifetimes of 80 years, or < 1 case per 10,000,000 per year.

5.64 The estimated mesothelioma risk for a 10-year exposure to low levels of airborne asbestos in schools (age start 7-8 years; fibre concentration 0.00065-0.001 fibre per ml[16] is in the range 6.6-20 per million lifetimes (0.0825-0.25 per million person-years). Estimates of this type are predicated on linear dose-response models with no threshold, and these have been the subject of argument and criticism. The occupational groups from which they were derived were exposed to mixtures of asbestos types, but one might expect the risk to be even less or "undetectably low" in nations where only chrysotile was used. At this point, it is sufficient to emphasize that - even if one accepts for a moment the no-threshold linear dose-response relationship - calculations indicate that a single asbestos fibre (the so-called "one fibre" hypothesis) would only have a 50-50 chance of producing a single excess mesothelioma among all the humans who have ever inhabited Planet Earth.

5.65 These observations on mesothelioma risk estimates for very low-level exposure to asbestos in buildings do not contradict the earlier suggestion in this report that Western Australian and Australian increases in mesothelioma incidence among females were a possible consequence of general environmental exposure to asbestos: the two-fold rise in incidence in Western Australia could be due to environmental fibre levels higher than those recorded in public buildings elsewhere.

[16]Given in various publications as fibres/ml, fb/ml, f/ml, f/mL and fibres/cm^3.

5.66 If it exists, the risk of mesothelioma from very low-level environmental exposure to asbestos needs to be considered in proportion to other risks of death in society. The lowest death-risk at any age occurs in girls aged 4-14 years and is ~ 100 per million per year, but the risk in late teenage increases by 300-400 per million per year — attributable largely to increased travel by motor vehicle. A 40-year-old man at risk of mesothelioma from low-level exposure to asbestos during childhood (excess mesothelioma risk < 1 per million person-years) has an annual risk of death from all causes of about 2000 per million. In 1990, de Klerk [128] had this to say on the subject:

> "In the US the acceptable (or possible litigation-proof) lifetime risk seems to be one per million. The FDA have this as a set policy; the EPA approximates to it, and other agencies seem to employ similar figures. In the UK the Royal Society has set a higher range with an annual risk of one per million considered negligible, with any form of control unjustified; one per 100,000 considered low ("very few would consider action necessary" — e.g. 16,000 km air or rail travel); one per 10,000 moderate (few would commit their own resources to reduce risk" — e.g. 16,000 km car driving, working as a coalminer); one per 1,000 high (e.g. age 30-39, 16,000 km motor cycling); and one per hundred unacceptable (e.g. age 55-59, smoking 20 cigarettes per day, heavy exposure to crocidolite)."

5.67 Within this context, one might ask what constitutes a negligible as opposed to an acceptable (or unacceptable) risk? In the context of the foregoing discussion, one might argue that a negligible risk is a statistical and scientific concept: a risk so slight that it does not require preventive or remedial steps in comparison to other risks in society (although some might argue about the dividing line between negligibility and unacceptability in this context). With acceptability or unacceptability other factors come into play: they include, for example, social, political and industrial considerations — and the likelihood of litigation over any situation wherein the theoretical or estimated risk is elevated to a background level, no matter how slightly. Accordingly, a risk, though slight or even negligible, might still be considered unacceptable in legal or sociopolitical terms.

5.68 Others may dissent from the acceptability of the Royal Society approach to low, moderate and high risks discussed above. Conclusions about the acceptability or unacceptability of risk will also vary according to the seriousness of the risk (e.g. the approach to a lethal risk such as mesothelioma would be quite different from a factor that caused a large proportion of the population to sneeze once or twice); these assessments will also vary according to the avoidability of the risk, the individuals making the assessment, and the question of informed consent by those at risk.

5.69 Furthermore, society abounds with inconsistencies and contradictions over the relativity of various risks. For example, some societies that regulate or propose a ban on chrysotile asbestos make extensive use of radioactive materials — e.g. in nuclear power stations and the production of radioactive isotopes for medical purposes. Even so, the use of fissionable materials for these purposes may be justified and justifiable within those societies, because: (i) the risk of morbidity or death from well-publicized mishaps at nuclear reactors is still substantially less than the risk of death from alternative energy sources (e.g. higher mortality rates among coalminers); and (ii) because the materials in question can be regulated and controlled so that they are accessible to only a small fraction of society (i.e. workers who can be trained in the controlled use of radioactive substances); and (iii) nuclear power does not contribute significantly to air pollution or greenhouse gas emissions in comparison to the burning of fossil fuels.

5.70 In addition, Nicholson [129] places the problem into the perspective of voluntary versus involuntary risks:

> "Rather than compare asbestos risks with voluntary risks (smoking, school football) or risks that remain high despite expenditures of substantial public and private money (aircraft and highway accidents), it is worthwhile to compare them with other involuntary environmental risks that are controlled by regulatory agencies (pesticide exposures, drinking water contamination). In a review of regulatory actions taken by the FDA ... and the EPA it was found that for estimated population risks exceeding one

> death/year, the individual lifetime risks were usually regulated if they exceed 1/1,000,000 for a lifetime exposure. Only eight of 31 carcinogenic exposure circumstances that exceeded this level were not regulated. They involved saccharin, aflatoxin, formaldehyde and polycyclic organic matter ... " [p 81].

5.71 In fact, it is my view that over-reaction to the low risks produced by asbestos in place may lead to a greater risk — i.e. the carcinogenic risks imposed by asbestos removal programmes. Two mesotheliomas encountered in my own practice during 1999 occurred not in asbestos removal workers, but in others who sustained bystander exposure as a result of this activity: (i) pleural mesothelioma in a lecturer who had walked to and from her classroom at an Australian university each day over a period of weeks, through a building where an asbestos insulation removal programme was being carried out; (ii) pleural mesothelioma in a fireman who attended fires in buildings that contained asbestos-cement products and who participated in clean-up operations thereafter; about once a month for some years, he also attended and examined buildings where fire alarms had been activated by high atmospheric concentrations of asbestos fibres produced by removal programmes. (In addition, a recent survey in Finland found "occasional high fibre concentrations even inside personal protectors during asbestos removal work" [130]).

5.72 Two other important points are worth emphasis. First, because they usually focus on specific cohorts or groups of workers, epidemiological studies may fail to identify a small but real risk, because of low statistical power. In this respect, the documents submitted to the WTO state that it may be impossible to prove a negative (absence of risk), but one can also state that absence of proof does not constitute proof of absence. For example, a number of investigations have failed to identify a statistically significant increase in the relative risk (RR) of cancer among individuals with parietal pleural fibrous plaques. In an extensive review of asbestos and lung cancer, Henderson *et al.* [131] commented along the following lines in relation to pleural plaques and lung cancer:

> "Nurminen and Tossavainen [132] also emphasized the issue of statistical power; they calculated the RR for plaque-associated lung cancer in the general population to be as low as 1.1, given the prevalence of 4.6% among unlikely exposed and 13.0% among probably exposed men with an estimated twofold risk of lung cancer. Detection of this RR at a level of statistical significance would require a population sample of about 300 000." [p 102].

5.73 In a discussion of the Hughes-Weill study [133] on radiological asbestosis and lung cancer in New Orleans asbestos-cement factory workers — one of the three key investigations that proposed an obligate intermediary step of pulmonary fibrosis for the induction of lung cancer by asbestos — Henderson *et al.* [131] also commented in the same review:

> " ... the number of lung cancer cases [in the Hughes-Weill investigation] was small. What number of workers would be required in such a study to detect an increase in risk of, say 1.4, 1.56 or 2.0, as opposed to the risk in workers with chest x-ray opacities? ... person-years of follow-up equivalent to 20-50 expected cases would be required to have any reasonable chance of detecting RRs of 1.4 to 1.6 at a level of significance of 0.05. ... The power level for the actual sample of 420 ... to detect a risk of 1.5 would be about 40%. That is, a true effect would be falsely declared 'non-significant' 60% of the time. ... The low power of the Hughes-Weill study is exemplified by the fact that ... lung cancer risk was not significantly associated with duration of employment or cumulative exposure (there was a fairly restricted range of employment periods) and even the association of lung cancer with fibrosis was only marginally significant." [pp 93-94].

5.74 The point is that a low, non-significant or undetectable risk in a small cohort may nonetheless translate into a substantial body of disease when spread over a large population: e.g. an RR of 1.1 representing an increase in risk of 10 per cent may require a population size of 300,000 to be detectable at a level of statistical significance of 0.05, whereas this 10 per cent increase in a common disease such as lung cancer may amount to a substantial burden of disease when spread across a

population of, say, 1,000,000, 10,000,000, or 100,000,000. (Please see also later discussion on mesothelioma among brake mechanics: answer to Question 2.)

5.75 Another point is that a high frequency of a cancer such as mesothelioma in a small population may be overshadowed in absolute numbers by a lower occurrence rate for the same disorder spread over a large population. For example, among non-smoking former Wittenoom workers, mesothelioma is now the most common cause of death [70] (in most cohorts exposed to amphibole asbestos, < 10 per cent will develop mesothelioma). Nonetheless, mesotheliomas among the Wittenoom cohort contribute only 5-6 per cent of the total burden of mesothelioma across the Australian population [AMR 99]. For example, the 1999 Report for the Register records 189 mesotheliomas among the former Wittenoom population with only a single exposure to asbestos, in comparison to 187 mesotheliomas among carpenters/joiners with only a single exposure to asbestos; the point is that the lower risk of mesothelioma from asbestos exposure among carpenters has produced almost the same number of cases, because carpenters among the Australian workforce constitute a much larger occupational group than the entire Wittenoom cohort of about 6000.

5.76 This observation also applies to the numbers of mesotheliomas among chrysotile miners and millers in Quebec, in proportion to other cases among the general population of Quebec. Bégin *et al.* [134] divided Quebec mesotheliomas into three groups, as shown in the following Table:

TABLE 3: MESOTHELIOMAS IN QUEBEC, 1967-1990

Group	**Type of asbestos exposure**	**Number of cases**	**Average age**	**Average duration of exposure**
1	Chrysotile miners and millers, Thetford and Asbestos, Quebec	49	62 ± 8.1 yrs	30.5 ± 13.7 yrs
2	Manufacturing, industrial insulation, shipbuilding yards of Quebec	50	56.7 ± 8.6 yrs	21.4 ± 14 .5 yrs
3	General construction/ building maintenance industries of Quebec	21	57.7 ± 7.2 yrs	27.7 ± 7.2 yrs

From Bégin *et al.* [134].

5.77 In this study, Bégin *et al.* [134] also commented that "the incidence of pleural mesothelioma in chrysotile miners and millers, although not as high as in the crocidolite workers, is well above the North American male rate". They also observed that "asbestos exposures in Group 3, although difficult to quantify on the basis of the record, appear to be often very low intensity". Bégin *et al.* also commented in the following terms:

> "The present study documents an increasing incidence of malignant mesothelioma in chrysotile miners and millers of the eastern townships of Québec, with 49 cases in the last 23 years and a rate of 2.5 cases per year in the last 10 years in the primary industry, as compared with a rate of 0.3 per year in the years prior to 1969 ... To put these rates into perspective, a comparison of the incidence for the combined population of the Asbestos and Thetford townships of Québec of some 40,000 adult males or the maximal estimated workforce of 10,00-15,000 men [sic; surely this is a typographic error in the original, and it should be 10,000-15,000], 20 years ago and currently at risk, reveals that the incidence of mesothelioma in the chrysotile mining townships of Québec would give an annual incidence rate of 62.5 cases per million per year for the 1980-1990 period, or in chrysotile miners and millers of Québec, would give an incidence rate of 150-250 cases per million per year for the 1980-1990 period. These values are well below the annual incidence rate of the crocidolite mining townships of South Africa, estimated at 542 cases per million per year, and well above the rate for the North American population, estimated at between 2.5 to 13 cases per year per million adult males for the 1970-1980 period, and 14.1 cases per year per million adult males in 1984 and 15 cases per million for 1980 and projected to increase for the 1990s. ...

> Thus, our observations add information of interest to the on-going debate regarding the relative carcinogenicity of different types of asbestos fibers. Our data suggest that some of the cases of malignant mesothelioma in Québec chrysotile miners and millers may not be necessarily attributable to amphibole and could be chrysotile-induced. Lung tissue burden analyses, a better indication of exposure than tumour tissue burden, will be done on these cases to further investigate this point. ....
>
> Finally, our data strengthen the view that a substantial number of malignant mesothelioma cases have a relatively short asbestos exposure, particularly seen in Group 3. In our study, 25% of all cases are in such a category" ... [pp 539-541].

5.78 In one of the documents submitted to the WTO, it is argued that evaluation of, and actions on, risks should be based on probability rather than mere possibility. This proposition is open to dispute. For example, action is often taken to avoid the possibility of harm — by regulation or prohibition — even though the likelihood of injury is remote, because of the seriousness of the potential outcome. In medical ethics, this is the principle of first, do no harm (*primum non nocere*). Two examples follow: (i) the antibiotic chloramphenicol was known to be highly effective in the treatment of various infections, including typhoid fever, but on rare occasions it induced bone marrow aplasia; despite the low likelihood of this side-effect — about 1 in 250,000 — the use of chloramphenicol was restricted to only a few life-threatening infections (e.g. typhoid fever), and it is now almost never used because safer effective alternatives are available; (ii) over recent years, there has been a flood of publicity over global warming and greenhouse gas emissions. A causal or direct relationship between greenhouse gases (such as CO_2 and methane) and climate change is open to argument, and Earth undergoes repeated cycles of natural cooling and warming; in this respect, there is also evidence that melting of the Antarctic ice cap has been going on for some thousands of years, and global warming for over 100 years. Nonetheless, the consequences of inaction over greenhouse gas emissions are potentially so serious that strategies to reduce the release of these gases into the atmosphere are entirely appropriate, despite uncertainty over the link between them and global warming.

(f) General observations on induction of mesothelioma by asbestos, especially the amphibole varieties of asbestos such as crocidolite and amosite

(i) The linkage between the amphibole varieties of asbestos, and commercial chrysotile, and the subsequent development of malignant mesothelioma is well established and is not in dispute.

5.79 This link is generally accepted as causal; in this respect, asbestos fulfils all *The Bradford Hill Criteria* for the establishment of causality [44].

(ii) There is a dose-response relationship between cumulative exposure to asbestos and the subsequent incidence of mesothelioma in asbestos-exposed cohorts or populations; the incidence is also related to time since exposure, so that early exposures are more significant for mesothelioma induction than later exposures, other factors being equal.

5.80 This relationship is expressed by the Peto model and its various modifications:

$$I = K*F*(T^p - [T - D]^p)$$

where I = incidence; K depends on fibre type, mix, size and other site-specific variables; F = intensity of exposure in f/ml; and D = years of exposure. For the purposes of modelling, T can be replaced by (T – 10) to build in a minimum 10-year lag-time, and the cubic power of time (T^3) is often used, so that:

$$I = K*F*([T - 10]^3 - [T - 10 - D]^3)$$

An important aspect of this model is that early exposures are more significant for mesothelioma induction than later equivalent doses.

5.81 Of the variables D, F and K, it is D that is the most accurately measurable, whereas the values for K and F are often unknown, though some estimates of F can be made from the type of work activity. When there are multiple periods of employment for which the type of work is similar for each, one can assume that the value for each of F_1, F_2, F_3 ... F_n remains constant, which also applies to K_1, K_2, K_3 ... K_n, so that:

$$I \propto ([T - 10]^3 - [T - 10 - D]^3)$$

In practice, a simpler equation can be used: $I = ct^k$

where the constant c is dependent on exposure, usually taken as proportional to the intensity of exposure multiplied by its duration (i.e. cumulative exposure), with weightings for different fibre types; the power k remains about 3.5, or 3 for short periods of exposure. As de Klerk and Armstrong [135] state:

> "The model predicts that risk is increased after each increment of exposure by an amount proportional to the level of exposure and the cube of time after that. In terms of the multistage model of cancer, it implies that asbestos acts at the first stage of a 4-stage process. ... The model predicts that incidence is much more dependent on early or low levels of exposure and increases less rapidly as exposure continues to increase, depending mainly on time since first exposed." [p 232].

5.82 When one is faced with multiple exposures to asbestos, the following points emerge, specifically for mesothelioma induction, provided that the characteristics and time for each exposure are appropriate for a biological effect: (i) it is not valid to point to one exposure among the others and incriminate it as the sole cause of a mesothelioma, with exoneration of the other exposures; (ii) it is not valid to point to one exposure among the others and exonerate it from a causative role in the development of a mesothelioma, and to incriminate all the others; (iii) when there are multiple episodes of exposure as a background to a mesothelioma, it is often the case that each exposure in isolation would be sufficient for attribution of the mesothelioma to asbestos, with the provisos mentioned above (characteristics and times of exposures). When each exposure among others is appropriate for mesothelioma induction if the particular exposure occurred alone, it is not logical to state that this exposure — which could have a biological effect in isolation — has no effect when in combination. In such circumstances, it is not the presence or absence of an effect that is in question, but the magnitude of each effect in proportion to the others.

5.83 A dose-response relationship has been observed with both estimates of airborne exposure to asbestos [136], and quantitative and qualitative fibre burden analysis of the asbestos content in human lung tissue of mesothelioma patients [3, 25, 137, 138]: e.g. see Rogers *et al.* [3], and, more recently, Williams *et al.* [138], who noted in 1997 that:

> "It was shown there that while the relative risk of all three diseases [i.e. asbestosis, mesothelioma and lung cancer] increased with increasing exposure, the relative risk of malignant mesothelioma is greater at low levels of exposure when compared with the risk of asbestosis but is lower at very high levels of exposure." [p. 39].

5.84 In their study on the relationship between lung asbestos fibre type and the lung tissue concentration of asbestos versus the relative risk of mesothelioma, Rogers *et al.* [3] made the following comment:

> "Fiber content in the lung depends on both the amount of fiber deposited and the amount cleared. The amount deposited depends on duration and intensity of exposure in the occupational or general

environment. Clearance rate is thought to be dependent on the amount deposited at any point in time, i.e, clearance is exponential. Thus, the same fiber content in the lung at death or time of resection may be achieved from a high initial deposition, followed by absence of deposition and absence of clearance over a long period of time, or by a continuous deposition at a lower level, with or without clearance. Since detailed mechanisms of mesothelioma initiation and progression are not known, 'dose' as estimated by final lung fiber content may not relate to the 'dose' required to produce mesothelioma. It is thus possible that a high lung fiber content in a mesothelioma case may represent continuing accumulation of fibers after a lower level of fibers had produced malignant change. It is more likely, however, that the malignant change did not occur until the fiber content reached a sufficiently high level." [p 1913].

(iii) The dose-response relationship between the amphiboles and mixtures of asbestos types is linear at high exposures [15]

5.85 For example, please see EHC 203 and Table 4.

(iv) This dose-response relationship between asbestos exposure and the risk of mesothelioma has also been detected at low levels of exposure, which overlap with environmental exposures.

TABLE 4: INCIDENCE OF MESOTHELIOMA IN OCCUPATIONALLY EXPOSED GROUPS BY FIBRE TYPE AND TIME SINCE FIRST EMPLOYED

Fibre type	**Industry**	**Years since first employed**	**Rate per million person–years**
Mixed: crocidolite, amosite and chrysotile	Manufacture textiles and insulation	20-24 25-30 30+	1520 1710 3180
Mixed, mainly amosite	Insulation workers	20-24 25-29 30-34 35-39 40-44 45+	290 1550 2760 6300 6330 8110
Mixed: crocidolite and chrysotile	Fibrous cement manufacture	20-24 25-29 30-34	2700 6300 9600
Chrysotile, some crocidolite	Textile manufacture	20-24 25-29 30-34 35-39 40+	108 143 1156 493 1774
Amosite	Insulation manufacture	20-24 25-29 30-34 35+	744 2623 5078 1842
Mixed	Dockyards	20-24 25-29 30-34 35-40 40-44 45-49	120 410 220 370 1240 1510
Crocidolite	Mining and milling	20-24 25-29 30-34 35-39	900 2200 3000 7000

From de Klerk and Armstrong [135].

5.86 A recent case-control study [136] from France on the dose-response relationship between low levels of asbestos exposure and the odds ratio (OR) for mesothelioma showed a clear dose-response relationship between estimated cumulative asbestos exposure and the OR for pleural mesothelioma. In the final paragraph of the article, the authors stated:

> "We found a clear dose-response relation between cumulative exposure to asbestos and pleural mesothelioma in a population-based control study, with retrospective assessment of exposure. A significant excess of mesothelioma was observed for levels of cumulative exposure that were probably far below the limits adopted in many industrial countries during the 1980s." [last sentence of abstract].

Although some concerns have been expressed about this type of investigation [139], it is my opinion that these points were addressed in the original paper [136], and they are common and intrinsic to epidemiological studies of this type — e.g. see Camus *et al.* [140, 141]. This study [136] found an OR for mesothelioma of 4.2 [95 per cent CI 2.0-8.8] at estimated cumulative exposures of 0.5-0.99 fibre-year,[17] with elevation of the OR at about 0.5 fibre-year.

5.87 In a fibre burden study on mesothelioma patients, Rödelsperger [137] observed that:

> "A significantly increased OR [for mesothelioma] is obtained even within the very low concentration range of 0.1-0.2 F/µg [i.e. concentrations in the range of 100,000-200,000 fibres per gram dry lung tissue], which may be expected for about 5% of the population." [p lll] (which also corresponds to an estimated cumulative exposure in the range of about 1-2 fibre-years).

5.88 In a more recent study on mesothelioma cases (N = 66) and controls (N = 66), Rödelsperger *et al.* [25] found an OR for mesothelioma of 4.5 at fibre concentrations of 100,000 to < 200,000 per gram dry lung tissue (for fibres > 5 µm in length; 95 per cent CI 1.1-17.9). These authors also recorded an OR = 2.4 at concentrations of 50,000 to < 100,000 fibres per gram dry lung tissue (95 per cent CI 0.8-7.6). The controls for this study — surgical lung resections mainly for lung cancer — would be expected to bias the OR towards 1.0 (i.e. underestimate the effect) [25], and hence the OR of 2.4 probably represents a genuine doubling of risk or more at these low fibre concentrations.

> "Even within the concentration interval of 0.1-0.2 f/µg dry weight [i.e. 100,000 to 200,000 fibres per gram dry weight], a significantly increased odds ratio of 4.5 was obtained. Previously, the same method of tissue analysis was used to estimate a 95 percentile of the amphibole fibre concentration of 0.1 f/µg dry weight for persons without detectable exposure to asbestos at the workplace. Therefore, within the range of the normal background level [up to 300,000 fibres per gram dry lung in Germany], a positive dose response is observed." [p 191].

This study did not detect an increase in the OR for chrysotile or for other mineral fibres.

5.89 The risk detected by Rödelsperger *et al.* [25] appears to correlate reasonably well with the French case-control study reported by Iwatsubo *et al.* [136], which found an OR for mesothelioma of 4.2 at estimated cumulative exposures of 0.5-0.99 fibre-year, with elevation of the OR at about 0.5 fibre-year.

(v) No lower threshold (minimum) level of asbestos exposure has been delineated, below which there is demonstrably no increase in the risk of mesothelioma.

5.90 This observation is expressed by Hillerdal [20] in the following terms:

> "There is no proof of a threshold value — that is, a minimal lower limit below which asbestos fibres cannot cause the tumour [i.e. mesothelioma] — and thus it is plausible that even such low exposure can

[17]Fibre-year = concentration of airborne asbestos fibres (f/ml) x years of exposure.

> cause mesothelioma (even if the risk is extremely low). Patients with mesothelioma whose lungs show fibre concentrations within the normal range cannot be dismissed as background cases, — that is, not due to asbestos. ... The only way to prove such a hypothesis would be to compare the incidence of mesothelioma in a group with such background exposure with the incidence in a truly non-exposed group. This is not possible, as no such group can be found." [i.e. the lung tissue of virtually all mammals contains some asbestos fibres derived from natural, environmental or occupational sources] [p 510].

5.91 Points worth emphasis in Hillerdal's review [20] include reports of mesothelioma among school teachers (9/487 patients with mesothelioma in one reference), in jewellers, and in individuals exposed to asbestos insulation at home (6/262 patients with mesothelioma according to one reference). Hillerdal [20] also makes the point that low-level asbestos exposure "more often than not contains peak concentrations which can be very high for short periods" (e.g. airborne asbestos fibre concentrations of up to 78 f/ml from sweeping asbestos from the floor [New Caledonia]).

(vi) The dose-response relationship for commercial Canadian chrysotile and mesothelioma incidence is also linear at high levels of exposure.

5.92 For example, among the Quebec chrysotile miners and millers it has been noted that:

> "All the observed 38 cases were pleural with the exception of one of low diagnostic probability, which was pleuro-peritoneal. None occurred in workers exposed for less than two years. There was a clear dose-response relationship, with crude rates of mesotheliomas (cases/thousand person-years) ranging from 0.15 with cumulative exposure < 3530 million particles per m^3 (mpcm)-years (< 100 million particles per cubic foot (mpcf)-years) to 0.97 for those with exposures of more than 10 590 mpcm-years (> 300 mpcf-years)." [EHC 203, p 8].

(vii) So far as I am aware, there are no observational data on dose-response relationships between chrysotile only at low exposure levels and mesothelioma incidence; in this respect, estimates are based on extrapolation of a linear dose-response line from high exposures down to low exposures.

> "Overall, the available toxicological data provide clear evidence that chrysotile fibres can cause fibrogenic and carcinogenic hazard to humans. The data, however, are not adequate for providing quantitative estimates of the risk to humans. This is because there are inadequate exposure-response data from inhalation studies, and there are uncertainties concerning the sensitivities of the animal studies for predicting human risk." [EHC 203, p 7].

5.93 Because of the lack of such data, no definite threshold for chrysotile in relation to mesothelioma and lung cancer has been delineated: According to EHC 203 (p 144):

> "(a) Exposure to chrysotile asbestos poses increased risks for asbestosis, lung cancer and mesothelioma in a dose-dependent manner. No threshold has been identified for carcinogenic risks."

5.94 In summary:

TABLE 5: ASBESTOS-RELATED DOSE-RESPONSE RELATIONSHIPS FOR MESOTHELIOMA

	Amphiboles	**Chrysotile**
Heavy exposure	Dose-response effect; linear	Dose-response effect; linear
Low-level exposure	Dose-response effect	No data
Threshold	No threshold delineated	No threshold delineated

(viii) To the best of my knowledge, there are no observational data on the interactive effect of low (or for that matter, high) concentrations of inhaled chrysotile fibres only, when these are

superimposed later and separately upon a pre-existing amphibole ± chrysotile burden within lung tissue (?superimpositional additive or multiplicative effect).

5.95 For example, it has been estimated that up to 15-20 per cent of men in industrialized societies may have sustained occupational exposure to asbestos (chrysotile/amphiboles). Rödelsperger *et al.* [137] indicate that fibre concentrations of 100,000-200,000 amphibole fibres per gram dry weight lung tissue may be expected for about 5 per cent of the population in Germany. We do not know what the effect of subsequent chrysotile fibre inhalation on top of this type of amphibole burden might be.

> "Data were analysed on a case-referent basis, to relate relative risks of mesothelioma to dose of fibre, as measured both by lung content and estimated airborne exposure. Multivariate analysis of cases found a dose response relationship for lung fibre content of crocidolite, amosite and chrysotile and the development of mesothelioma. Either a multiplicative or additive model could be used to fit the relative risk/dose coefficients for the various asbestos types. A progressive increase in relative risk with increasing fibre content was reported for all fibres ... . Tests for trend were highly significant in all cases." [NICNAS 99, p 61].

(ix) There is a long lag-time between asbestos exposure and the subsequent diagnosis of mesothelioma (10 years as a minimum; usually in the range of 20-40 years). It follows that the mesotheliomas encountered in the 1990s and the incidence of mesothelioma in various nations are a consequence of exposures, especially occupational exposures, sustained from the 1940s through to the 1970s and even beyond.

5.96 Exposures from the 1940s through to the 1980s usually involved one or more of the amphibole varieties of asbestos. For example, asbestos-cement building products used in Australia usually contained one or more of the amphibole varieties of asbestos, namely crocidolite or amosite, or both, at different times; in this respect, the use of crocidolite in the products was discontinued in 1966, and amosite in 1984.

5.97 Peto *et al.* [24] make this point in the following terms:

> "The extraordinarily high mesothelioma incidence throughout Western Europe in men born around 1945-50 reflects the extent of asbestos use in the 1960s and 1970s at the beginning of their working lives. Annual raw asbestos imports to European Union countries peaked in the early to mid 1970s and remained above 800 000 tonnes per year until 1980, falling to about 100 000 tonnes by 1993 (European Commission, 1996). Increasingly stringent exposure limits were enforced in the manufacture of asbestos-containing products over this period, but exposure to users of such materials, particularly in the building industry, remained virtually uncontrolled in many countries. Chrysotile asbestos products are still widely used in several European countries, and maintenance or demolition work on older buildings may result in substantial exposure to amphiboles as well as to chrysotile. We have not included men born after 1955 in our projections, but the effects of asbestos exposure during the 1980s and 1990s, although not yet apparent, may prove considerable." [p 670].

(x) Properties of asbestos fibres that determine carcinogenicity

5.98 As indicated in the documents submitted to the WTO Panel, the properties of asbestos fibres implicated for mesothelioma induction (and, possibly, lung cancer and other disorders), can be summarized as the **three Ds**:

5.99 **Dose**: this issue is covered in the preceding sections [(f)(ii)to (vi)].

5.100 **Dimensions**: according to *The Stanton Hypothesis*, the carcinogenicity of asbestos fibres appears to reside primarily in long thin fibres (length > 5 μm and especially > 8 μm, and in the range of 10-20 μm, and diameters < 0.25 μm) — e.g. see Pott [142]. On the other hand, shorter fibres appear to be less carcinogenic, although data indicate that tremolite fibres > 4 μm in length

and < 1.5 µm in diameter produce malignant mesenchymal tumours when implanted into the pleural cavities of rats [2]. On the other hand, very short-length fibres appear to have little carcinogenic activity, although Churg [143] comments on fibre dimensions in the following terms:

> "There has been extensive investigation of the relation of mesothelioma induction and fiber size in experimental models. Using intrapleural inoculation of different types of fibers with different size distributions, Stanton *et al.* concluded that long, thin (i.e., high aspect ratio) fibres were much more powerful mesothelial carcinogens than were short, thick fibers and that fiber type was less important. The exact size of fiber that qualifies as long and thin is unclear: fibers ... longer than 8 µm and widths narrower than 1.5 µm are usually cited from Stanton's work, but the same experiments show that fibers with lengths greater 4 µm and widths less than 0.25 µm were also effective carcinogens. The Stanton hypothesis has been supported by animal inhalation experiments using size-separated fibers: few mesotheliomas were found with either amosite or chrysotile prepared to contain few fibers longer than 5 µm.
>
> Human data on the question of fiber length and mesothelioma are equivocal. The tremolite found as a natural constituent of chrysotile ore is a relatively short, thick fiber compared with commercial amosite or crocidolite, and if one attributes 'chrysotile-induced' mesotheliomas in man to the tremolite component, the differences in mesothelioma do correlate with fiber size. However, attempts to prove this proposition directly have produced equivocal results ... McDonald *et al*. concluded that the number of fibers longer than 8 µm explained most mesotheliomas and that chrysotile played no role. However, Rogers *et al*. found that fibers both longer and shorter than 10 µm, including chrysotile fibers, played a role, although long fibers were generally more important. The problem with both of these studies is that most patients with mesothelioma have had occupational asbestos exposure, and fibers in lungs from those with occupational exposure are always longer than fibers in the general population; thus the same result would have been obtained if the test group were exposed but had no disease or some disease other than mesothelioma. My colleagues and I have attempted to circumvent this problem by comparing fiber sizes in a chrysotile mining and milling cohort and a cohort with heavy amosite exposure, using exposed workers with no disease as the control group. In neither cohort could we show that fibers in mesothelioma cases were significantly longer and thinner than those in the other disease categories or even in the disease-free workers." [p 353].

5.101 In other words, it is possibly the bio-persistence of amphibole fibres that is important for mesothelioma induction, rather than precise fibre dimensions.

5.102 **Durability** (bio-persistence): the greater mesotheliomagenic (mesothelioma-producing) potency of the amphiboles in comparison to chrysotile is widely ascribed to greater persistence of the amphiboles in tissues, with significantly longer half-lives than chrysotile (please see later discussion, Section (g)(v)). On the other hand, it is conceivable that the same effect might be achieved by sustained inhalation of chrysotile over a prolonged time interval or, possibly, shorter, but more intense exposures so that the chrysotile fibres persist despite shorter half-lives than the amphiboles.

(xi) There is general though not universal agreement of a differential potency between the amphiboles versus chrysotile for mesothelioma induction

5.103 In this respect, the amphiboles are substantially more potent, with estimates ranging from 2-4X, to 10X, to 12X on a fibre-for-fibre basis, to 30X, to a 30-60X greater potency, or more (e.g. please see EHC 203). A minority view that the amphiboles in chrysotile have roughly equal mesotheliomagenicity is not supported by the prevailing evidence for humans. Although acknowledging the greater potency of the amphiboles for mesothelioma induction, some argue that chrysotile is of equal or greater importance overall, because chrysotile accounts for > 95 per cent of world asbestos production. According to this perspective, commercial chrysotile is a weaker carcinogen on a fibre-for-fibre basis, but this lesser potency is multiplied across a much greater tonnage, leading to an overall equivalent or greater effect [144].

(xii) Tobacco smoke plays no role in the development of mesothelioma at any anatomical site — unlike the synergy between asbestos and tobacco smoke for the causation of asbestos-related lung cancer (see section (i)(i) below).

(g) Commercial Chrysotile and Mesothelioma Induction

(i) There is general agreement that commercial chrysotile has the capacity to induce mesothelioma in experimental animals and humans

5.104 There is dispute, however, over which fibres in commercial chrysotile are implicated (i.e. the predominant chrysotile or the trace quantities of fibrous tremolite).

(ii) Canadian chrysotile contains trace amounts of tremolite, including fibrous tremolite, as a contaminant [2, 10, 13, 14, 145-148]

5.105 The amount of tremolite appears to vary from one sample to another, but is generally < 1 per cent (please see EHC 203).

(iii) It has been argued that the occurrence of mesotheliomas among the Quebec chrysotile miners and millers is a consequence — not of the chrysotile per se — but of the coexistent trace quantities of tremolite (a non-commercial amphibole).

5.106 Analysis of the asbestos fibre content of lung tissue from this cohort demonstrates disproportionately high concentrations of tremolite in comparison to chrysotile; this appears to represent a bio-accumulation phenomenon whereby chrysotile is cleared from lung tissue more rapidly than the tremolite, so that the tremolite not only persists but increases in proportional concentration. In this respect, the tremolite content of the lung tissue can be used as an index on the past chrysotile exposure and some claim that the incidence of mesotheliomas in the same cohort can be related directly to the tremolite content [13, 14].

(iv) It is known that fibrous tremolite has the capacity for mesothelioma induction

5.107 Mesotheliomas related to the use of tremolite in whitewash or stucco have been reported in Turkey, Greece, Cyprus and Corsica [149-152] (for additional references, see Hillerdal [20]).

> "Tremolite asbestos, a minor component mineral of commercial chrysotile, has also been shown to be carcinogenic and fibrogenic in a single inhalation experiment and an intraperitoneal injection study in rats. Exposure/dose-response data are not available to allow direct comparison of the cancer potency of tremolite and chrysotile." [EHC 203, p 6].

5.108 Tremolite has also been implicated in lung cancer and mesothelioma induction in a group of vermiculite miners in Montana [2, 16, 153, 154]. It appears that these miners were exposed only to tremolite-actinolite fibres. The group was shown to have a:

> " ... very high lung cancer incidence (standard mortality ratio [SMR] 285 ...), as well as four cases of mesothelioma and eight of pneumoconiosis. Examination of sputum samples from all but three (170/173) current workers demonstrated asbestos bodies (AB) in 75%, the numbers showing a close parallel with cumulative exposures in fibre-years." [2] [p 493].

5.109 Case [2] has extensively reviewed the biohazards of tremolite, including epidemiological investigations in humans and experimental data on animal models. In his review, he emphasized the pathogenicity of the tremolite found in Quebec chrysotile samples, especially at Asbestos and in the Thetford mine:

> "Tremolite was not identified in Montreal air, was just detectable (0.2 fibres/l) in Asbestos, and was one order of magnitude higher in Thetford mines (still only 1.5 fibres/l or 0.0015 fibres/cc ...)." [pp 496-497].

5.110 He also favoured the expression "chrysotile/tremolite" for Quebec chrysotile:

> "As to the separate issue of 'chrysotile vs. tremolite', few would dispute the abilities of both to produce lung cancer and asbestosis, again in sufficient exposure dose. The weight of epidemiological, animal, and, especially, lung internal-dose biomarker studies leads to the inevitable conclusion that it is the tremolite 'component' of Quebec chrysotile which causes mesothelioma [but please see later discussion in this report]. It is unfortunate that adequate terminology for tremolite-contaminated chrysotile has not been introduced: I for one would favour the simple compound phrase 'chrysotile/tremolite'." [p 500].

5.111 Case [2] also states:

> " ... it becomes important to know to what degree 'chrysotile-in-place' is really 'chrysotile/tremolite-in-place'. No easy answer can be expected: both bulk analyses and air sampling, even with analytical electron microscopy, can miss very low levels of tremolite. Studies in the Quebec mining district indicate that, at the very least, such low levels (roughly 0.0015 fibres/cc) can induce biological effects (i.e., pleural plaques). Unfortunately, only expensive *in vivo* animal bioaccumulation assay systems can truly answer the question: the alternative is to wait 40 to 50 years for the next wave of asbestos disease — which is likely to occur mainly among present-day asbestos abatement workers and to some degree in custodial personnel and other tradesmen" …. [p. 500].

(v) Clearance of chrysotile from lung tissue

5.112 It is well known that chrysotile fibres are cleared more rapidly than amphiboles, especially in long-term studies [145]. Clearance of amphibole fibres does occur and the clearance mechanisms appear to be more effective for short fibres (for both chrysotile and the amphiboles) so that the mean length of retained fibres increases over time. Churg and Vedal [155] calculated a half-life in lung tissue of about 20 years for amosite. Estimates of the tissue half-life for crocidolite fibres have been somewhat shorter (in the order of 5-10 years) [156-158], and de Klerk *et al.* [158] could find no difference between the clearance rates for long and short fibres. Oberdörster [159] estimates human clearance half-times to be about 90-110 days for chrysotile and 200-1500 days for crocidolite fibres > 16 μm in length, based on extrapolated rat and primate inhalation data.

5.113 It has been claimed that chrysotile is cleared from lung tissue within 28-48 hours of inhalation. This claim seems extraordinary and begs the question: why, if chrysotile is cleared from lung tissue so rapidly, is it still demonstrable in human lung tissue many years or decades after cessation of inhalation of commercial chrysotile (or mixtures of asbestos types)? For example, in one of my recent referral cases — an elderly man with lung cancer who sustained exposure from mixing loose asbestos and sweeping up dried insulation materials — an asbestos fibre analysis carried out on lung tissue resected 16 years after his exposure stopped showed a total asbestos fibre count of 8,440,000 fibres/gram dry lung (> 1 μm in length; aspect ratio ≥ 3:1), made up by 6,250,000 chrysotile fibres + 940,000 tremolite fibres + 940,000 anthophyllite fibres + 310,000 crocidolite fibres (the 24 year lag-time is enough for a carcinogenic effect).

(vi) The Quebec chrysotile cohort

4.114 In an analysis of mesotheliomas among the Quebec chrysotile miners and millers, up to 1997, McDonald *et al.* [13, 14] reported 38 mesotheliomas, and most of these occurred after prolonged and heavy exposure, especially at the mine where the greatest concentrations of trace tremolite occurred (Thetford). For example, these authors [13] recorded the breakdown of the mesotheliomas shown in Table 6 (below).

5.115 McDonald *et al.* [13] identify two main reasons for the low mesothelioma rate from the five smallest mines (1 case only among 6010 person-years, equivalent to 166 cases per million person-years): firstly, workers within this sub-group were younger than the remainder of the cohort; secondly, these mines had been opened recently so that "there were inadequate periods of latency". A single additional mesothelioma shortly after completion of the study would erase the difference in incidence rates between the five smallest mines and the main complex. McDonald *et al.* [13] go on to indicate that the other rates are "reasonably comparable". In comparison to the Thetford main complex, there were relatively few mesotheliomas among workers at the asbestos mine and mill (23 versus 8), despite nearly equivalent person-years of observation; in addition, asbestos fibre analysis on lung tissue demonstrated crocidolite and amosite in five out of the eight cases from the mine and mill at Asbestos and in two out of the five mesotheliomas from the Asbestos factory (Table 7, below). In focussing on the Thetford mines group, it was noted that most of the mesotheliomas came from the five central mines (Area A; Group C) as opposed to the 10 peripheral mines (Area B; Group P), so that the odds ratio for mesothelioma for Group C plus employees who had jobs in both Area A and Area B (Group M) was 2.50 (based on net service; 20 adjusted years), in comparison to an odds ratio of 0.80 for Group P.

TABLE 6: MESOTHELIOMAS AMONG QUEBEC CHRYSOTILE MINERS AND MILLERS, 1997

	Number of mesothelioma deaths	**Subject-years (000s)**	**Rate (per 100,000 subject-years)**
Thetford Mines:			
Main complex and the oldest of the smaller mines	23	65.14	35.3
The five smallest mines	1	6.01	26.6
Asbestos:			
Mine and mill	8	60.64	13.2
Factory	5	10.84	46.2

From McDonald *et al.* [13].

5.116 The clear implication of this complex and sophisticated study is that the risk of mesothelioma was related strongly to years of service in the central area at Thetford where geological factors "in Area A would probably result in tremolite, some in fibrous form, being mined with the ore". In addition, the mesothelioma rate for miners and millers was > 2.5 times higher at Thetford mines (excluding the smallest mines) than at Asbestos, and this difference was also attributed to differences in the amount of fibrous tremolite in the ores. Despite these differences within the cohort for the distribution of mesothelioma related to chrysotile and tremolite (and also to crocidolite and amosite at the Asbestos factory and the Asbestos mine and mill), the results indicate that Quebec chrysotile — on average contaminated by fibrous tremolite in small amounts — is capable of mesothelioma induction: the Abstract describes 25 mesotheliomas from the Thetford mines, representing a mesothelioma rate of 337 per million person-years, which is substantially (almost 20X) higher than the mesothelioma incidence rate of about 17 per million per person-years for men in British Colombia and the USA in 1982 and 1973-1984 respectively, and well above the background rate for spontaneous mesotheliomas of 1-2 per million person-years.

TABLE 7: ASBESTOS FIBRE CONCENTRATIONS IN LUNGS AT AUTOPSY FROM 21 MESOTHELIOMA CASES AMONG QUEBEC CHRYSOTILE MINERS AND MILLERS
(FIBRES PER µg: GEOMETRIC MEANS)

Place of employment	No. of cases	Chrysotile	Tremolite	Crocidolite	Amosite
Mines and mills					
Thetford Mines	14	12.8	104.1	0	0
Asbestos	5	4.3	7.5	1.7	0.3
Factory					
Asbestos	2	2.1	0.5	6.4	0.3

Table from McDonald *et al.* (1997): Table 2 in the original reference. See also Table 1 in the original.
In calculating geometric means, a zero count has been replaced by half the detectable limit.
For crocidolite and amosite, all counts were zero: i.e. below the detectable limit.
For fibre counts/g lung tissue, multiply the figures by 106.

5.117 In the final two paragraphs of the paper, McDonald *et al.* [13] comment as follows:

> "The tremolite hypothesis, if correct, has several important implications. First, it supports the widely but not universally held view that most, if not all, asbestos-related mesotheliomas are caused by amphibole fibres. This in turn points to fibre durability and biopersistence as critical factors in aetiology ... a point of even greater relevance in assessing the safety of man-made mineral fibres. Second, it implies that uncontaminated chrysotile carries very little risk of mesothelioma. In Asbestos, exposures were not to uncontaminated chrysotile, but also to some tremolite and crocidolite, yet among the miners and millers only five deaths from a total of over 3,300 can be confidently attributed to their work.
>
> At present-day levels of dust control the mesothelioma risk must be vanishingly small. Even so, it remains desirable to minimise, perhaps by screening, the contamination of commercial chrysotile by amphibole fibres, however difficult this may be." [p 718].

5.118 Despite the importance of this study by McDonald *et al.* [13], the following comments can also be made:

- The number of mesotheliomas in all groups except for the Thetford main complex was small (1, 8 and 5 mesotheliomas respectively; please see Table 6 above). In this respect, misdiagnosis or misclassification of the mesotheliomas according to the places worked could significantly affect the results, although there is no evidence that this happened; however, the probability for the diagnosis of mesothelioma also varied, with a high probability in 19 cases, moderate probability in 14, and a low probability (though considered more likely than not) in five; of these 38 cases, only 18 had been coded on the death certificate to ICD 163, and the rest to a variety of other diagnostic codes. Furthermore, in analysing the mesotheliomas according to Area A versus Area B at the Thetford mines (groups C, M and P), the numbers were 104 for group C, 69 for group P and 35 for group M; McDonald *et al.* noted that the odds ratio for group P was unstable as shown by the "very wide confidence intervals, and as the point estimate is well below unity it is quite unrealistic ".

- The low incidence of mesotheliomas in the Quebec chrysotile cohort appears to parallel similar low incidence rates for asbestosis and lung cancer for the same cohort

> [160, 161]; the incidence rates for lung cancer and mesothelioma appear to be different in other chrysotile-exposed cohorts.

5.119 For these reasons and because of the different rates of various asbestos diseases (asbestosis, lung cancer and mesothelioma) between the Quebec cohort and other groups of workers, I would be reluctant to recommend national policies from the findings in this cohort in isolation, and I would look for coherence of the evidence across different cohorts and studies.

5.120 In relation to the Quebec cohort, there is an important error in the Canadian reply to Question 4 (see Annex II) from the European Communities, where the following statement is made:

> "Regarding asbestos-related mesothelioma, a number of studies have demonstrated cogently that this type of cancer is almost exclusively linked to exposure to amphiboles. Cases of mesothelioma in chrysotile asbestos miners in Quebec are quite rare — in a cohort of 11,000 workers who were very carefully tracked (in the McDonald study), there were no more than 50 or so cases over several decades. Exhaustive research on their employment history revealed that most of the cases were related to short-term exposure to commercial amphiboles. For example, during World War II, some of the miners with mesothelioma had worked in plants manufacturing products for the Allied Forces and amphiboles imported into Canada had been used to make a variety of products, including gas masks, to assist in the War effort."

5.121 The statement that "most of the cases were related to short-term exposure to commercial amphiboles" is incorrect and misleading. As demonstrated in the study by McDonald *et al.* [13], most of the mesotheliomas occurred among chrysotile miners who worked at the Thetford main complex, without exposure to commercial amphiboles such as crocidolite or amosite. This is clearly shown in Table 7 (above), slightly modified from the paper by McDonald *et al.* [13] where fibre burden analysis on lung tissue from 14 mesothelioma cases from the Thetford mines showed both chrysotile and a high concentration of tremolite, with a zero count for the commercial amphiboles crocidolite and amosite. The point to be emphasized is that the mesotheliomas from the Thetford mines were not related to commercial amphiboles such as crocidolite or amosite, but to chrysotile with its content of fibrous tremolite.

(vii) As discussed earlier, a dose-response relationship between the incidence of mesothelioma and cumulative asbestos exposure has been demonstrated for commercial chrysotile.

5.122 Mesotheliomas have also been produced in experimental animals by implantation and inhalation of chrysotile (presumably also containing trace amounts of tremolite). Mesotheliomas can also be induced in rats by intraperitoneal injection of chrysotile, with evidence of a dose-response effect [1] (see also bibliography for EHC 203).

> "In non-inhalation experiments (intrapleural and intraperitoneal injection studies), dose-response relationships for mesothelioma have been demonstrated for chrysotile fibres." [EHC 203, p 5].

(viii) Chrysotile is also known to be toxic to a variety of cell lines in vitro, with induction of a variety of chromosomal alterations (e.g. please see EHC 203, pp 69-102).

(h) Other Chrysotile-Exposed Cohorts and Studies

5.123 In addition to the Quebec chrysotile miners and millers, mesotheliomas have also been reported among other workforces apparently exposed only to chrysotile, with no significant tremolite.

(i) Russia

5.124 Chrysotile from the Urals region (Uralasbest) in Russia [162, 163] is said to represent pure chrysotile. Although precise figures for the mesothelioma incidence in this area are difficult to procure, Kogan [164] makes the following comment in a recently-published textbook on occupational lung diseases:

> "In the Middle Ural mountains, the main asbestos mining region in Russia, only chrysotile asbestos is produced. In the 50 districts of this region, the mortality from mesothelioma over a 10-year period was six-fold higher than the average rate in the Sverdlovsk region, an area of negligible asbestos mining. Most with mesothelioma had worked at the asbestos mining and milling plants, or had lived in an adjacent town near old and very 'dusty' mills." ... . [p 251].

5.125 Because it is difficult to equate exposure levels in the Russian chrysotile industry with other industries (e.g. the airborne fibre concentrations at Uralasbest are usually expressed as gravimetric measurements), and I have been unable to ascertain the numbers of cases relative to exposure levels, I consider this evidence to be weak in comparison to other studies.

5.126 One might expect data on mesothelioma incidence in Central and Eastern European nations to be of interest, from an assumption that some of these countries would have imported mainly chrysotile from Russia until the breakup of the Soviet Union. Unfortunately, it is difficult to evaluate national mesothelioma statistics, because a number of these nations also imported amphibole asbestos. For example, in Slovenia, the total consumption of asbestos (1947-1995) was 580,000 tonnes, of which crocidolite accounted for 37,133 tons, until its use was stopped in 1992 [165]. Similarly, the annual usage of asbestos in Bulgaria during the 1970s and 1980s reached approximately 32,000 tons of chrysotile (mainly from Russia and Canada), together with about 1000 tons of crocidolite from Africa and 6000-7000 tons of Bulgarian amphibole material (anthophyllite and tremolite) [166]. In Poland, total consumption of asbestos for the manufacture of asbestos-cement products between the end of the Second World War until 1993 was about 1.4 million metric tons which included about 8500 metric tons of amosite and approximately 86,000 metric tons of crocidolite [167].

(ii) Germany

5.127 The former German Democratic Republic (GDR): Sturm *et al.* [5, 7] have published data on asbestos-related diseases and asbestos types in the German State of Saxony-Anhalt. These authors pointed out that:

> "All asbestos-based products were made from raw asbestos which was primarily imported from the former Soviet Union, particularly from the Kiembay mining area in the Ural mountains (said to represent pure chrysotile). Small quantities of long-fibred grades came from Canada (2,990 tonnes in 1989) and were mainly used for the manufacture of asbestos-cement pressure pipes free of amphibole asbestos. This was a share of approximately 7% in total imports. We never obtained any information about the Canadian mines from which the asbestos processed in the former GDR originated. ... However, several analyses carried out by the GDR Central Institute for Industrial Medicine confirmed that both the Canadian and the Russian asbestos were pure chrysotile. In addition to these imports of chrysotile asbestos, smaller quantities of amphibole asbestos were imported. For example, in the period from 1980 to 1985, some 90 tonnes of anthophyllite were imported annually from Mozambique. This anthophyllite was used exclusively by a Berlin manufacturer and was of acid-proof products, similar to the way crocidolite had been used in previous years to produce filters, seals and acid and lye-proof plastic materials. In Saxony-Anhalt, our region of work, these amphibole imports did not have any significance from the point of view of industrial medicine" ... [p 318/173].

5.128 Between 1960 and 1990, a total of 1082 mesotheliomas was recorded in Saxony-Anhalt, and these included 843 "proven asbestos-accepted mesotheliomas"; Table 8 from Sturm *et al.* [5, 7] gives

a breakdown of 812 cases for which adequate data were available: 67 were said to follow exposure to chrysotile only, and 331 were associated with "chrysotile; possible amphiboles".

(iii) Italy

5.129 Two mesotheliomas have now been recorded among more than 900 workers employed at the Balangero mine and mill in Italy [168, 169]. EHC 203 gives the following summary:

> "The cohort of chrysotile production workers employed at the Balangero mine and mill ... was almost exactly one tenth the size of the Quebec cohort. At the end of 1987, when 427 (45%) of the cohort had died, there were two deaths from pleural mesothelioma, both in men employed for more than 20 years with cumulative exposure estimated respectively at 100-400 and > 400 f/ml years. One diagnosis was confirmed histopathologically, and one was based on radiological findings and examination of pleural fluid. Fibrous tremolite was not detected in samples of chrysotile from this mine, but another fibrous silicate (balangeroite), the biological effects of which are not known, was identified in low proportions by mass (0.2-0.5%). At a comparable stage in the evolution of the Quebec cohort, mesothelioma accounted for 10 of 4547 deaths, a lower but not dissimilar proportion." [p 112].

TABLE 8: MESOTHELIOMAS ACCORDING TO TYPES OF EXPOSURES TO ASBESTOS IN SAXONY-ANHALT

	Amphiboles	**Amphiboles and chrysotile**	**Chrysotile; possible amphiboles**	**Chrysotile**	**Mean values**
Age at beginning of exposure	25	28	28	34	28
Duration of exposure	16	21	19	14	19
Lethal period (years)	40	40	41	31	38
Age of person dying of mesothelioma	65	68	69	65	66
Number of mesotheliomas	135	279	331	67	N = 812

Note: All types of application of asbestos with common addition of chrysotile fall under the heading "Chrysotile. Amphiboles possible" when previous admixture of amphiboles cannot be definitely excluded. From Sturm *et al.* [5, 7] .

(iv) China

5.130 At the XV International Scientific Meeting of the International Epidemiological Association (Florence, September 1999), Yano *et al.* [170] presented a paper on lung cancer incidence in a cohort of 515 male asbestos workers heavily exposed to chrysotile containing < 0.001 per cent tremolite, in Chongqin; two mesotheliomas over 11,850 person-years of observation occurred in this cohort (discussion to the paper; assuming this rate to be representative, it would amount to 170 mesotheliomas per million person-years).

5.131 In a retrospective cohort mortality study of 1227 men employed at a chrysotile mine in Hebei Province of China before 1972, Zou *et al.* found three deaths from mesothelioma (please see EHC 203, p 120).

(v) United States

5.132 Two mesotheliomas have also been observed among the cohort of South Carolina chrysotile textile workers — who used Canadian chrysotile — studied by Dement *et al.* [171, 172] (please see EHC 203, p 115).

(vi) Australia

5.133 There is also some indication of an increased frequency of mesothelioma among Australian brake mechanics who were potentially exposed only to chrysotile from grinding of brake blocks that contained Canadian chrysotile (please see later discussion on friction products, and NICNAS 99 and AMR 99).

(vii) Zimbabwe

5.134 One pathologically confirmed case of mesothelioma has been recorded in association with occupational exposures to asbestos in the Zimbabwe mines and/or mills, with one other case said to resemble mesothelioma radiologically (EHC 203, p 121).

(viii) Fibre burden studies on human lung tissue from mesothelioma patients

5.135 Fibre burden analyses also support the notion that some mesotheliomas occur in association with, or as a consequence of, inhalation of pure chrysotile.

5.136 Morinaga *et al.* [173] detected asbestos fibres in 19 of 23 mesothelioma studied; amphibole fibres were found in 13 cases, but six were found to have only chrysotile fibres (five pleural mesotheliomas and one peritoneal mesothelioma). Nonetheless, the methodology for this study seems unimpressive, with relatively small numbers of fibres analysed.

4.137 The 1991 paper by Rogers *et al.* [3] recorded a substantial number of mesothelioma patients in whom the only detectable type of asbestos was chrysotile (Table 9), with evidence of a dose-response effect as reflected in a trend to an increasing odds ratio (OR) at a relatively low fibre concentration of $\leq 10^6$ fibres per gram dry lung tissue ($\log_{10} = 5.5–6$; OR = 8.67).

TABLE 9: DISTRIBUTION OF FIBRE CONCENTRATION: TRANSMISSION ELECTRON MICROSCOPIC ANALYSIS, CHRYSOTILE ONLY (ALL LENGTHS)

		Mesothelioma cases		**Controls**		**Odds ratio**
		No.	Percent	No.	Percent	95% Cornfield Cl
f/g	0-200.000	12	48.0	26	83.9	
$\log_{10}$ (f/g)	5.3-5.5	1	4.0	2	6.5	**1.08** (0-17.95)
	5.5-6	7	28.0	3	9.7	**8.67**(1.77-48.14)
	6-6.5	3	12.0			
	6.5-7	1	4.0			
	7-8	1	4.0	$X^2_1 = 9.80$ (P<0.0005) (trend)		

From Rogers *et al.* [3]. Cl: confidence interval; f/g: fibres per gram of dried lung tissue.

5.138 Finally, fibre burden studies have demonstrated that both chrysotile fibres and amphibole fibres can translocate from lung parenchyma to reach the pleura; EHC 203 summarizes these findings in the following way:

"In a study of asbestos fibres in the lung parenchyma and the parietal pleura of 29 asbestos workers,

> Sebastien *et al.* (1980) found that chrysotile fibres predominated in the pleura and that amphibole fibres could not be detected. A similar result was reported by Dodson *et al.* (1990). Kohyama & Suzuki (1991) found short chrysotile fibres in pleural plaques and in mesothelial tumours. In contrast, Boutin et al. (1993) found 0.21 x 10^6 fibres per g of parietal pleura and 1.96 x 10^6 in samples of lung parenchyma. Fibre concentrations were higher in subjects with a history of asbestos exposure and most of the fibres were amphiboles. Churg (1994) reported detection of chrysotile fibres in the subpleural parenchyma in chrysotile miners and millers." [pp 64-65].

(ix) Other Observations

5.139 Nicholson and Raffn [8] analysed mesothelioma risk over 40 studies for which little or no exposure information was available, using the excess numbers of lung cancers as a measure of exposure and comparing the ratios of mesotheliomas to excess lung cancers across these studies. They suggested that:

> " ... the ratio of mesothelioma to excess lung cancer is the same for exposures to 100% chrysotile (presumably Canadian chrysotile), 97%+ chrysotile, 100% amosite, and mixtures of chrysotile, amosite and crocidolite, within statistical uncertainty. Only 100% crocidolite exposures appear to have a greater ratio, about two to four times that of predominantly chrysotile. This relatively small difference in the potential for crocidolite to produce mesotheliomas compared with other fibre exposure cannot explain the high risk seen in chrysotile exposures accompanied by a very small crocidolite exposure. The data speak strongly that much of the mesothelioma risk in predominantly chrysotile exposures is from the chrysotile." [p 402].

5.140 In other words, these authors appear to argue, like Smith and Wright [144], Stayner *et al.* [11], and Landrigan *et al.* [21] that although chrysotile may be cleared more rapidly from lung tissue than tremolite — and that tremolite can be used as an indicator of past chrysotile — it may not be valid to ascribe all the mesothelioma risk to the tremolite and to ignore the far more numerous chrysotile fibres. Nonetheless, I do not find Nicholson and Raffn's argument to be persuasive, taking into account the K values for different industries.

5.141 Therefore, it is my perception that epidemiological and experimental evidence clearly demonstrates that Canadian chrysotile with its trace amounts of fibrous tremolite has the capacity for mesothelioma induction. Although the tremolite may have a disproportionately large effect, it is my perception that the evidence does not allow one to conclude that the chrysotile has no effect on mesothelioma induction: there is evidence from other cohorts and studies that chrysotile per se can also induce mesothelioma, even when tremolite is undetectable, and in experimental models in animals, chrysotile is as carcinogenic as, and more toxic than, the amphiboles. However, there is also general agreement that in humans, chrysotile is substantially less carcinogenic for the mesothelium than the amphiboles, and my estimate is that it has a potency $1/10^{th}$ – $1/30^{th}$ the carcinogenicity of crocidolite, with amosite being less mesotheliomagenic than crocidolite but more carcinogenic than chrysotile on a fibre-for-fibre basis. Amosite is an important factor in the incidence of mesothelioma in the United States, because of its widespread use in insulation materials from the 1960s [155, 174-176].

(i) Abestos and Lung Cancer

5.142 Still the focus of some controversy, this subject has been reviewed by Henderson *et al.*: (i) Henderson DW, Roggli VL, Shilkin KB *et al.*, *Is Asbestosis an Obligate Precursor for Asbestos-Induced Lung Cancer?* In: Peters GA, Peters BJ, eds. *Sourcebook on Asbestos Diseases, vol 11*. Charlottesville: Michie; 1995;11:97-168 [177]; (ii) Henderson DW, de Klerk NH, Hammar SP, *et al.*, *Asbestos and Lung Cancer: Is it Attributable to Asbestosis, or to Asbestos Fiber Burden?* In: Corrin B, ed. *Pathology of Lung Tumors*, New York: Churchill Livingstone; 1997:83-118 [131]; (iii) Leigh J, Berry G, de Klerk NH, Henderson DW., *Asbestos-Related Lung Cancer: Apportionment*

of Causation and Damages to Asbestos and Tobacco Smoke, In: Peters GA, Peters BJ, eds. *Sourcebook on Asbestos Diseases, vol 13*, Charlottesville: Michie; 1996:141-66 [178]; (iv) Multiple authors. *Consensus Report: Asbestos, Asbestosis, and Cancer: the Helsinki Criteria for Diagnosis and Attribution,* Scand. J. Work Environ. Health 1997;23:311-6 [113].

5.143 Some salient features of asbestos-associated lung cancer include the following:

(i) Synergy between asbestos and tobacco smoke

5.144 Historically, most asbestos workers have also been cigarette smokers, and the lung cancer rate in virtually all cohorts is an outcome of the combined and synergistic effects of tobacco smoke and asbestos. Vainio and Boffetta [179] emphasize that asbestos and tobacco smoke are complex carcinogens that can affect multiple steps in the multistage process of cancer evolution, and that the combined effects will depend on the relative magnitude of each carcinogen at each stage; the interactive effect ranges from less than additive to supramultiplicative, but the model for insulation workers approximates a multiplicative effect (reviewed in Henderson *et al.* [131]). If the multistage model of carcinogenesis holds, and asbestos and smoking act at different stages, then a multiplicative relationship follows [180]. Leigh *et al.* [178] have reviewed various models for the apportionment of fractional contributions from cigarette smoke and asbestos towards the development of lung cancer.

(ii) Lung cancer incidence rates for asbestos-associated lung cancer vary greatly from one cohort to another

5.145 Please see following discussion.

(iii) Asbestos fibre type and lung cancer risk

5.146 The greater carcinogenicity of the amphiboles for the mesothelium in comparison to chrysotile appears not to extend to the induction of lung cancer [11]. In this respect, chrysotile is implicated in one of the lowest rates of asbestos-associated lung cancer (in Quebec chrysotile miners and millers), but also the highest rate (in South Carolina asbestos textile workers who used Canadian chrysotile) [171]. The reasons underlying this ≥ 30-fold difference in lung cancer risk remain unknown (reviewed recently by McDonald [161]; please see also EHC 203). The risk of lung cancer in other asbestos-exposed cohorts is intermediate between these two extremes [15].

(iv) Dose-response relationship

5.147 In most studies, there is a direct and linear relationship between the relative risk of lung cancer and cumulative exposure to asbestos, including chrysotile and the amphiboles.

5.148 Accordingly, EHC 203 gives the following account:

> "The slopes of the relationship between cumulative exposure to chrysotile and the relative risk of lung cancer are summarized in Table 23 for those studies that reported this information. These studies all expressed this relationship using the following linear relative risk (RR) model:
>
> RR = 1 + B x E
>
> where B is the slope and E is the cumulative exposure to chrysotile asbestos expressed in f/ml-years.
>
> The slopes from the studies of the mining and milling industries (0.0006 to 0.0017), the latter having been estimated on a subset of the cohort on which the former was based, and the friction production industries (0.0005 to 0.0006) are reasonably similar. Hughes *et al*. (1987) in a study of cement workers (section 7.1.2.1b) reported a similar slope (0.0003) in one plant (plant 1) that only used chrysotile, and

a nearly 20-fold higher slope (0.007) among workers only exposed to chrysotile in another plant (plant 2).

The slopes of 0.01 and 0.03 reported for the two studies of the chrysotile-exposed textile workers conducted on overlapping populations, as well as the slope of 0.007 from one of the two plants (plant 2) of cement workers in the study of Hughes *et al.* (1987), were an order of magnitude greater than those reported for the other cohorts. It should be noted that the two textile cohorts were identified from the same textile facility, but were based on different cohort definitions. Hence, it is not surprising that the slopes from these two studies were similar. The slopes in the studies of chrysotile-exposed textile workers are also remarkably similar to those reported in other studies of textile workers with mixed fibre exposures (Peto, 1980; McDonald *et al.*, 1983b; Peto et al., 1985). This similarity in findings provides some support for the validity of the slopes reported in the chrysotile-exposed textile cohorts.

The reason for the much higher slopes observed in studies of textile workers is unknown, although several possible explanations have been suggested. The first is that these differences might be attributed to errors in the classification of exposures in these studies. Particular concern has been raised about errors in the exposure assessment related to conversions from mpcm (mpcf) to fibres/ml that were performed, particularly in the mining and milling studies (Peto, 1989). Sebastien *et al.* (1989) conducted a lung burden study specifically designed to examine whether the differences in lung cancer slopes observed in the Charleston chrysotile textile cohort and the Quebec mining industries could be explained by differences in errors in exposure estimates. Lung fibre concentrations were measured in: (a) 32 paired subjects that were matched on duration of exposure and time since last exposure; and (b) 136 subjects stratified on the same time variables. Both analyses indicated that the Quebec/Charleston ratios of chrysotile fibres in the lungs were even higher than the corresponding ratios of estimated exposures. This finding was interpreted by the author as being clearly inconsistent with the hypothesis that exposure misclassification could explain the large discrepancy in the lung exposure-response relationships observed in the two cohorts." [pp 118-119].

5.149 Boffetta [15] expresses the relationship in the following terms:

"A large number of studies have been conducted on lung cancer risk following asbestos exposure. The interpretation of their results is complicated by several factors: (i) dose, geological type of fibres and industry are all important determinants of risk and are strictly correlated; (ii) the biologically relevant exposures occur 20 or more years before appearance of the disease, and their quantitative assessment is imprecise; and (iii) the role of potential confounders, in particular, tobacco smoking, can hardly be evaluated. In general, the risk of lung cancer is smaller in studies of miners and friction product manufacturers, is intermediate in studies of asbestos-cement and asbestos product manufacturers, and is highest in studies of asbestos textile workers. This likely reflects a stronger carcinogenic effect of individual, long and thin fibres, like those occurring in the textile industry, as compared to grouped, short and coarse fibres, like those occurring in mining.

Several cohort studies provide sufficient details to allow a quantitative evaluation of the risk of lung cancer from cumulative asbestos exposure. In all cohorts, the empirical relationship fits well a linear correlation with no threshold, which can be expressed as:

$RR_1 = 1 + K_1*CE$,

where RR_1 is the relative risk of lung, CE represents cumulative asbestos exposure, expressed as fb/ml-yrs, and K_1 is the industry-specific slope of the relationship (RR for the increase in 1 fb/ml-year of exposure) for lung cancer and varies across cohorts. Similarly, the risk difference (RD_1) can be expressed as

$RD_1 = K_1*CE*Exp$,

where Exp is the number of expected cases of lung cancer. In other words, the number of cases of (or deaths from) lung cancer attributable to asbestos exposure depends on the number of expected cases (deaths), the cumulative exposure, and the intrinsic carcinogenic potential of the exposure

> circumstance. The value K_1 varies from 0.05-0.01 in cohorts of insulation and asbestos textile workers to 0.001-0.0005 in friction manufacturers and miners, while cohorts with mixed exposure have, in most cases, intermediate values. ... While all estimated values of K_1 are positive, the type of asbestos does not seem to be correlated to lung cancer risk.
>
> In the interpretation of these results, however, one should consider several limitations. Most studies are based on a small number of cases or deaths: for example, the risk estimate of 100 fb/ml-yrs for the cohort of asbestos textile workers presented by McDonald and colleagues (RR 2.4) has a 95% confidence interval from 1.7 to 3.8. Another source of uncertainty, and possibly bias, relates to the estimate of cumulative exposure: in the same cohort of asbestos textile workers, the range of RRs based on the extremes of the distribution of possible exposure values is 1.3-6.7. For these reasons, several governmental and scientific committees have suggested to adopt an 'average' value of K_1, independent from fibre type and circumstance of exposure ...: the most widely accepted value is 0.01 which corresponds to an increase of 1% of the risk of lung cancer for each fb/ml-yr of exposure. ...
>
> Tobacco smoking is the main cause of lung cancer, and this applies also to the cohorts of asbestos-exposed workers. Despite the limitations of the available studies, which limit the precision of the estimates of the combined effect of the two carcinogens, the risk from tobacco smoking seems to act synergistically with that of asbestos exposure, according to a multiplicative model. ... The available data are consistent with the most widely accepted model of quantitative dose-response between cumulative exposure to asbestos and lung cancer risk, which assumes a linear relationship with no threshold. Alternative models, however, would also be consistent with the data. In particular, as no precise data are available for cumulative exposures below 1 fb/ml, a model with a threshold at low exposure cannot be rejected." [pp 473-475].

(v) Histological types of lung cancer

5.150 Although some studies have shown a relative excess of adenocarcinomas in proportion to other histological types of lung cancer, all of the major histological types occur among asbestos workers in proportions equivalent to, or only slightly different from, those in the general population [112]. Therefore, the histological type of a lung cancer has no value in ascertaining whether or not asbestos has contributed significantly to the genesis of the cancer (reviewed by Henderson *et al.* [131]).

(vi) Lobar distribution and the central versus peripheral distribution of asbestos-related lung cancer

5.151 Some studies have reported a reversal of the upper lobe:lower lobe ratio for lung cancers in asbestos workers, in comparison to a reference non-exposed population. Recently, Lee *et al.* [181] addressed the lobar distribution of lung cancer in asbestos-exposed individuals and found that the tumours were predominantly located in the upper lobe (i.e. they did not find a reversal of the upper lobe to lower lobe ratio). The lobe of origin for a cancer has no value in ascertaining whether the cancer is likely to be asbestos-related. The distribution of lung cancer between the central versus the peripheral airways does not differ significantly in asbestos workers from a control non-exposed population (please see Henderson *et al.* [131]).

(vii) Asbestos and lung cancer risk

5.152 Cumulative exposure versus fibrosis (asbestosis): as discussed already, most epidemiological studies dealing with lung cancer risk in asbestos workers have reported a direct correlation between the relative risk of lung cancer and cumulative asbestos exposure, although the slope of the dose-response line varies from one cohort to another. Most of the documents submitted to the WTO appear to agree on this relationship, the main area of uncertainty or dispute being the question of whether a threshold exists or not.

5.153 However, Canada's answers to questions from the Panel and the European Communities appear to resurrect the fibrosis-cancer hypothesis, which postulates that asbestos does not induce lung cancer per se, but only through an obligate intermediary step of pulmonary fibrosis (asbestosis), so that fibrosis becomes the determinator of lung cancer risk, not cumulative exposure:

> "1. Canada does not disagree that chrysotile causes lung cancer. However, the way in which exposure to chrysotile asbestos may increase the risk of lung cancer has not yet been fully explained; it could be just an indirect cause. ...
>
> 2. The risk may become detectable in cases of long-term exposure to high levels, but it is by no means certain that chrysotile acts as a direct carcinogen or that it acts in the form of pulmonary fibrosis, which would be a precursor to neoplasia. In other words, exposure must be intense and long enough to induce pulmonary fibrosis, which predisposes the pulmonary parenchyma to a high risk of cancer."

5.154 It is my perception that the fibrosis→cancer hypothesis represents a minority opinion: with some prominent exceptions, most authorities in this area reject the fibrosis→cancer theory and focus instead on the asbestos fibre burden in lung tissue as the main determinator for lung cancer risk, as discussed earlier in this report.

5.155 The fibrosis→cancer hypothesis is predicated upon three key but flawed studies:

- In the investigation reported by Kipen *et al.* [182], there was major problem with case selection (only 138 cases out 450 — 31 per cent — had a tissue specimen with sufficient non-malignant tissue for assessment of fibrosis); in addition, the histological criteria used for the diagnosis of asbestosis are unacceptable to most pathologists — i.e. no asbestos bodies in some cases; fibrosis restricted to the subpleural zone considered to be asbestosis — so that this study seems to have suffered from an over-diagnosis of asbestosis [183, 184].

- As discussed in Section (e) above, the Hughes-Weill study [133] on chest X-ray opacities related to lung cancer mortality in New Orleans asbestos-cement workers had low statistical power, so that it had only a 40 per cent chance of detecting a significant lung cancer standardized mortality ratio (SMR) of 1.5. Other studies based on X-rays have shown an increase in risk or mortality for lung cancer in the absence of radiological asbestosis (e.g. Wilkinson *et al.* [185], Finkelstein [186] and de Klerk *et al.* [187]).

- The autopsy study on South African crocidolite miners reported by Sluis-Cremer and Bezuidenhout [188] was also bedevilled by problems of selection (black people excluded; autopsies on 36.7 per cent of deaths only; autopsies on cases for which compensation was sought). Analysis of the findings indicates that the effect of duration of exposure (the most accurately measurable of the exposure variables) was still significant even after adjustment for the grade of asbestosis and other variables. This indicates that exposure to asbestos still had an independent effect on lung cancer mortality even after adjustment for the grade of asbestosis, as in the study reported by Wilkinson *et al.* [185]. In subsequent correspondence, Sluis-Cremer and Bezuidenhout [189] conceded that when they carried out a logistic regression analysis, allowing for the grade of asbestosis, years of exposure accounted for most of the variation, but the degree of asbestosis still emerged as a highly significant risk factor.

5.156 Recently, Case and Dufresne [190] have commented as follows:

> " ... Hughes and Weill go much further in stating that asbestosis is a prerequisite for lung cancer attribution in those with asbestos exposure. This statement goes beyond the known facts and relies on mechanistic speculation. The authors believe that asbestosis is produced by a mechanism or mechanisms that will also lead to lung cancer. Their hypothesis requires that the mechanism(s) always be intermediate in that lung cancer always follows asbestosis. Finally, the speculation requires that lung cancer occurring without asbestosis can never be caused by asbestos exposure alone (or in synergy with cigarette smoking) regardless of the level of that exposure, and that no mechanism can occur that does not involve intermediate fibrosis. The biological fallacy of this argument has been well documented ... one must remember that lung cancer originates in the large airways, while asbestosis is a disease of the lung parenchyma at and beyond the respiratory bronchioles. ... To ignore our knowledge of indices of exposure other than the simple presence or absence of asbestosis is simplistic and biologically naïve." [p 1118].

5.157 The case-control studies carried out on South Carolina asbestos textile workers by Dement *et al.* [171] clearly undermine the fibrosis→cancer hypothesis and, in this respect, they constitute Popper's *Black Swan* factor:[18] Dement and his colleagues clearly identified a lung cancer SMR > 2.5 at 2.7-6.8 fibre-years of exposure (well below the exposure level necessary for histological asbestosis in the same cohort [191]).

(viii) Non-occupational asbestos exposure in Quebec and lung cancer risk

5.158 The first written submission from Canada also refers to the study reported by Camus *et al.* [140] on non-occupational exposure to chrysotile asbestos in Quebec and the risk of lung cancer:

> "It is also interesting to note the work of Dr Camus *et al.* (see Camus, M., Siemiatycki, J. Meek, B., *Nonoccupational Exposure to Chrysotile Asbestos and the Risk of Lung Cancer*, (1998) 338, New England Journal of Medicine 1565). They published a vast study on women in chrysotile mining communities in Quebec, many of whom were exposed to very high levels of fibres between 1920 and 1975. These women were subjected to exposure of 0.0107 f/ml,[19] higher than the current exposure limits in France, and literally thousands of times higher than the levels measured in public buildings. Nonetheless, no excess in lung cancer was detected in this population. According to the study's authors, this is particularly important in the light of the current French situation. In fact, applying the risk model adopted by France for the exposure studied, results in a forecast of approximately 100 lung cancer deaths, while in reality there are none. Likewise, use of the French risk model would have resulted in estimates of approximately 250 and, at any rate, no less than 50 deaths from mesothelioma, while the preliminary results of the study in question show only 10 cases, some of which may be associated with exposure to amphiboles. Research continues, particularly with an analysis of the work history of each individual in order to determine the exact link, if any, between these cases of mesothelioma and on-the-job exposure, as well as exposure to amphiboles."

---

[18]"The philosopher of science, Sir Karl Popper ... coined the term 'falsification' to express the concept that scientific theories are not proven by repetition of results but rather survive because they successfully withstand refutation (falsification). His example of the black swan makes this point clearly. Suppose you have a hypothesis that all swans are white ... you observe, say, 10,000 swans and they are all white. Another scientist repeats your efforts and observes another 10,000 swans: they too are all white. So far the theory is standing up well. The repetition helped to strengthen it — but if only a single black swan is sighted, this falsifies the theory: it is no longer tenable. Popper asserted that scientific statements have to be formulated in a manner that subjects them to the possibility of falsification. One of the important demarcating criteria between science and nonscience, according to Popper, is this formulation of statements in a manner permitting falsification" [pp 18-19] [44].

[19]This figure is inconsistent with the former limit of 0.1 f/ml in France, and contradicts Case's claim that the Quebec women were exposed at up to 1 f/ml [192]; at a level of 0.0107 f/ml (a figure two orders of magnitude less than 1f/ml), a cumulative exposure of 5 fibre-years would require residence of > 150 years (adjusted for equivalence to an 8-hour working day) and > 750 years to reach 25.0 fibre-years (using the same adjustment).

4.159 In fact, Camus *et al.* [140] investigated the relative risk of death from lung cancer among 2242 deaths between 1970 and 1989 among women ≥ 30 years of age who lived in two chrysotile asbestos-mining areas that comprised eight towns of which three (Thetford mines, Black Lake and Asbestos) contained nearly all the asbestos mines and mills. Eighty percent of the women lived within 4 km of a mine or mill, and all lived within 10 km.

5.160 The estimated average cumulative level of exposure was 25 fibre-years (range 5-125 fibre-years) made up by neighbourhood exposure (16.0 fibre-years), household exposure of 7.8 fibre-years and occupational exposure of 1.2 fibre-years, making a total of 25.0. The authors of this study pointed out that:

> " ... The lower limit of 5 fibre-years per ml corresponds, for example, to 50 years of exposure to asbestos at a level of 0.1 fibre per ml (the actual mean ambient airborne asbestos level in the area in 1974); the upper limit of 125 corresponds for example, to 50 years of exposure to 2.5 fibres per ml — a relatively low exposure level in local asbestos-mining and asbestos-milling industries before 1960." [p 1568].

5.161 This investigation found a standardized mortality ratio of 1.0 in comparison to the reference population (i.e. no observed excess of lung cancer mortality). However, seven deaths from "pleural cancer" were observed (RR = 7.64; $p < 0.05$).

5.162 A few points about this study are worth emphasis:

- The Quebec chrysotile miners and millers have a low risk of lung cancer in comparison to other cohorts, such as the South Carolina chrysotile textile workers, for whom the frequency of lung cancer is at least 30 times higher. Therefore, it is not surprising that the low risk of lung cancer in the chrysotile miners and millers of Quebec extends across residents exposed environmentally to the same ore. In other words, the absence of a detectable increase in lung cancer mortality in female residents of this region of Quebec may not apply to other groups exposed environmentally to asbestos from other asbestos industries.

- The study reported by Camus *et al.* [140] stimulated considerable correspondence in the columns of the same journal (NEJM), and at least two of the correspondents (Churg [193] and Case [192]) emphasized that the seven-fold increase in mesothelioma mortality (seven cases) among the women was probably explicable by occupational exposure to amphiboles from manufacture of gas masks, repair of bags that contained imported asbestos, and, possibly in one case, domestic exposure to "tremolite brought home on miners' clothes".

  In his letter to the editor, Case [192] also pointed out that "[T]hese women were exposed to levels of chrysotile as high as 1 fibre per ml of air as recently as one month in 1984."

- I have some misgivings over the exposure estimates for this female population, and the figure of 25 fibre-years from environmental exposure in the general neighbourhood or vicinity of the Quebec chrysotile industry seems high in comparison to neighbourhood or environmental exposures from other industries. For example, ECH 203 (p 35) reproduces a Table of asbestos fibre concentrations in Quebec chrysotile mining towns, where the fibre concentration in 1984 is in the vicinity of 0.005 fibre/ml and the concentrations in 1973 and 1974 are given as 0.08 fibre/ml. In other words, Case's figure of 1 fibre/ml for one month in 1984 [192] may be doubtful, unless there were some catastrophic event in the industry, with

a burst of asbestos into the general environment. Unless earlier environmental airborne fibre concentrations were substantially above the 1973/1974 concentrations, it is difficult to see how a cumulative exposure of 25 fibre-years would come about; e.g. Camus *et al.* [140] state that residence in the area for 50 years at a mean fibre concentration of 0.1 fibre/ml would lead to the lower estimate of 5 fibre-years.

In addition, the estimate of 25 fibre-years seems high in comparison to data on environmental airborne fibre levels related to the Zimbabwean and Russian chrysotile industries. For example, EHC (p 47) states:

> "There are some data concerning fibre levels in the air close to chrysotile mines. Baloyi (1989) found fibre levels around the Shabani mine (Zimbabwe) to range from below the limit of detection of the method" (less than 0.01 f/ml) to 0.02 f/ml of air, assayed by PCOM. [PCOM = phase contrast optical microscopy].

Scherbakov *et al.* [163] also give a comparable environmental airborne fibre concentration in Asbest City of 0.1 mg/m^3 (comparative data for the same industry [194] suggest that the gravimetric measurement of mg/m^3 is very roughly equivalent to the same number of fibres/ml).

The point is that if the estimate of cumulative asbestos exposure in the Quebec female population is high, this would lead to underestimation of lung cancer risk or mortality. For example, no detectable increase in lung cancer mortality among the 2242 deaths would be expected at the low cumulative estimate of ≤ 5 fibre-years.

- In addition, in their reply to the Letters to the Editor, Camus and Siemiatycki [141] state that "[W]e agree ... that the study had low statistical power to detect small risks; this was conveyed by the wide confidence intervals for our risk estimates ...", although they go on to indicate that the Quebec study should have detected a risk of the magnitude predicted by the Environmental Protection Agency [EPA].

(ix) The Helsinki Criteria

5.163 This set of criteria deals with attribution of lung cancer to asbestos for the individual patient [113]:

> "Because of the high incidence of lung cancer in the general population, it is not possible to prove in precise deterministic terms that asbestos is the causative factor for an *individual* patient, even when asbestosis is present. However, attribution of causation requires *reasonable* medical certainty on a probability basis that the agent (asbestos) has caused or contributed materially to the disease. The likelihood that asbestos exposure has made a substantial contribution increases when the exposure increases. Cumulative exposure, on a probability basis, should thus be considered the main criterion for the attribution of a substantial contribution by asbestos to lung cancer risk." [p 314; emphasis in original].

5.164 The Helsinki Criteria set an exposure level of ≥ 25 fibre-years of exposure; however, it should be emphasized that this level of cumulative exposure is required for the individual patient as an index for an asbestos-attributable relative risk of lung cancer of ≥ 2.0 (which, in the individual patient, equates to a probability of causation or material contribution of ≥ 50 per cent — the civil standard of proof). Intended as a criterion for individual compensation, this exercise is clearly different from population-based relative risks relevant to the dispute before the WTO.

5.165 In summary:

TABLE 10: ASBESTOS-RELATED DOSE-RESPONSE RELATIONSHIPS FOR LUNG CANCER

	Chrysotile or Amphiboles
Heavy exposure	Dose-response effect; linear
Low-level exposure	Dose-response effect for South Carolina textile workers (chrysotile)
Threshold	No threshold delineated

(j) Some General Observations on Experimental Models of Asbestos Carcinogenesis, including *in vivo* and *in vitro* Systems

(i) In vivo experimental models

5.166 Although animal models of asbestos carcinogenesis - especially induction of mesotheliomas in animals such as rats - are of value to demonstrate the capacity of different fibres to induce tumours and to elucidate the mechanisms underlying carcinogenesis, they are not strictly comparable to carcinogenesis in humans, for a number of reasons:

- The airborne fibre concentrations to which experimental animals are exposed for inhalation experiments are substantially higher than in workplace or environmental situations for humans.

- The routes of administration of asbestos or other fibres - e.g. injection or direct implantation into the pleura or peritoneum - are not comparable to the human situation, with the exception of inhalation experiments.

- High concentrations of asbestos or other fibres are necessary to reduce latency intervals so that a reasonable yield of mesotheliomas or other cancers is obtainable within the life span of the animal used. In other words, the latency intervals are not comparable to the human model.

- There are known to be marked differences in the susceptibility of different species to asbestos carcinogenesis.

5.167 For example, in a review of asbestos and lung cancer, Henderson *et al.* [131] state the following:

> "The dose of asbestos delivered by inhalation or installation over a short time interval in experimental animals, the lag-times, and the histological spectrum of the tumors also make it difficult or impossible to extrapolate the findings from such models to humans. The exposure to asbestos in positive inhalation experiments seems to have been so high that fibrosis was an unavoidable association with an increased cancer risk (exposure to at least 100 f/ml, > 1,000 f/ml for some groups, 5 x 7 hours per week, up to 12 months or more). Wagner *et al*. remarked on a number of 'surprising' results in their study (e.g. no differences in carcinogenicity or fibrogenicity between chrysotile and the amphiboles). ...
>
> The sensitivity of humans to the carcinogenic effects of asbestos is about 100-fold greater than that of rats. ...
>
> ... Experimental studies of this type address asbestos inhalation in isolation, instead of asbestos combined with tobacco smoke [for the study of lung cancer]. Hence, they are of questionable relevance to most lung cancers in asbestos workers, for which tobacco smoke is an important co-factor.

For the reasons stated above, we consider that the existing literature on tumorigenesis by inhalation of asbestos in laboratory animals allows no conclusions on the asbestos-asbestosis-lung cancer controversy in humans." [p 96].

5.168 Davis [195] comments in the following terms:

"In experimental inhalation and injection studies, however, chrysotile has repeatedly produced as many mesotheliomas as other asbestos types. This finding probably indicates that the carcinogenic potential of chrysotile to cells is as high as the other asbestos types, and it is just sufficiently durable to exert its maximum effect in rats, although it is unable to survive long enough to do so in humans." [p 201; but see discussion in this report on chrysotile clearance from lung tissue, Section A.(g)(v)].

(ii) In vitro systems

5.169 It is obvious that the effects of asbestos and other fibre types on isolated cell lines used for *in vitro* studies are not comparable to the induction of mesothelioma or lung cancer in humans. *In vitro* studies of this type are of most value in showing that asbestos and other fibres can induce chromosomal injury, oncogene expression or mutations similar to those induced by other known carcinogens.

5.170 Detailed discussion of the voluminous literature on this topic lies beyond the scope of this report. Henderson *et al.* [131] give some details of the effects of asbestos on cell lines *in vitro*; more extensive reviews are given in EHC 203 (pp 69-102), Both *et al.* [196], and Mossman *et al.* [197-202], and Bielefeldt-Ohlmann [203]. Only a few recent studies on chrysotile follow:

- "In the study by Haugen *et al.* [204], chrysotile was about 10 times more cytotoxic than amosite or crocidolite (as assayed by inhibition of clonal growth rate) and > 100-fold more toxic than glass fibres; epithelial cells were 10-15 times more sensitive to the cytotoxic effects of asbestos fibres than bronchial fibroblasts from the same human. We can find no comparison with mesothelial cells in this paper [204], despite at least one claim to this effect [197] ... " [p 97].

- "Harrison *et al*. demonstrated synergy between the lung carcinogen N-nitrosoheptamethyleneimine (NHMI) and chrysotile in the production of hyperplastic epithelial lesions in the lungs of rats, with a dose-response relationship for NHMI, augmented by chrysotile. Neoplastic lesions (adenoma and adenocarcinoma) were found only in animals treated with both NHMI and asbestos, but the number of such tumours was small (N = 6 among 115 rats studied)" [p. 118; see Henderson *et al.* [131] for references].

- "Hei and Piao reported on malignant transformation of a human papillomavirus-immortalized human bronchial epithelial cell line (BEP2D) by a single 7-day treatment with chrysotile: the cells so treated evolved through a series of sequential steps to become tumorigenic, with the formation of progressively growing tumours in nude mice" [p. 118; see Henderson *et al.* [131] for references].

- In an investigation of the capacity of different asbestos fibre types to induce loss of heterozygosity [LOH] mutations in lymphocytes and diploid mesothelioma cells that were heterozygous for the HLA A2/A3 histocompatibility complex studied (in collaboration with Dr David Turner at the Department of Haematology-Oncology at the Flinders University), it was found that chrysotile was more toxic to the cell lines used so that few viable cells remained, making it difficult to evaluate LOH mutations, in contrast to UICC South African crocidolite.

- More recently, Dr. Turner and I have investigated the effects of UICC South African crocidolite injected into the peritoneal cavity of mice, for the investigation of somatic intrachromosomal recombinational events in mice that are transgenic for the gene that encodes the enzyme β-galactosidase; using PCR [the polymerase chain reaction], we detected a 5-fold reduction in SIR within only a few days of administration of the crocidolite. This finding parallels the results obtained with other carcinogens (e.g. cytotoxic drugs used for cancer chemotherapy) and may be explicable by a reduction of SIR because the asbestos produces an increase in other classes of mutation (e.g. point mutations or deletions), or because of impairment of DNA repair mechanisms.

5.171 The picture now emerging on asbestos carcinogenesis is a prolonged multistage parametric process [205], in which asbestos fibres may participate in both the initiation and promotion phases [196]. Some classes of mutation potentially inducible by asbestos - e.g. loss of heterozygosity mutations - are implicated in the initiation or progression phases of cancer development in humans, thought to be related to loss of tumour suppressor genes (e.g. retinoblastoma, astrocytoma, and colonic, gastric, prostatic and breast cancer) [206-211].

5.172 Free radicals — generated either from the surface of the fibres themselves [205, 212-215] or via macrophages [213, 216-218] — have been shown to have genotoxic or clastogenic properties [205, 212-214, 217, 219, 220], and are also implicated in asbestos carcinogenesis.

2. Questions by the Panel and Comments by the Scientific Experts

Question 1:

High-density chrysotile products (i.e. products where chrysotile fibres are bound in a matrix, such as chrysotile-cement, as opposed to "friable" products, such as flocking and heat insulation) represent the main use of chrysotile asbestos. The parties to this dispute disagree as to the circumstances of exposure to chrysotile and the risks to human health associated with such products. In this context, various questions arise with respect to the risks to human health associated with the use of high-density chrysotile products, in particular chrysotile-cement (of particular concern are installation, modification, repair, maintenance, demolition and disposal).

1.(a) Canada argues that workers who are at greatest risk of exposure to chrysotile asbestos are, in descending order: (i) chrysotile miners and workers employed in the processing (milling) industry; (ii) workers in the chrysotile textile industry; (iii) workers involved in the production of friction materials (such as brakes, clutches); (iv) workers involved in the manufacturing of chrysotile-cement products; (v) workers involved in the removal of asbestos from buildings; and (vi) workers involved in construction, renovation, maintenance and the heat insulation of buildings. Furthermore, according to Canada, the last two categories are likely to be exposed to amphiboles. On the other hand, the European Communities argues that, in France, the secondary users, which includes installation, maintenance, repair, insulation, waste management and "handyman" type persons, etc. are at the greatest risk of exposure and that they are mainly exposed to chrysotile asbestos, since, for some fifty years, chrysotile has represented about 97 per cent of asbestos consumption in that country. Could you comment on these contrasting views, with a special focus on current uses and products?

Dr. de Klerk:

5.173 This question is rather curious and is either irrelevant or the wrong words have been used: trying to elucidate an ordering of working groups according to their "risk of exposure to chrysotile asbestos". The risk of an event is the probability that it will occur. The event in question here is that a

worker will come into contact with chrysotile asbestos. It is certain that the workers in groups (i) to (v) are exposed to chrysotile so their risks are all the same and equal to 1.0. Workers in group (vi) may not come into contact with chrysotile so their risk of exposure is less. The more relevant question here is: who is likely to receive the most exposure and therefore have the greatest risk of disease? In general, workers in well-regulated industries, where government inspection is mandatory, where there is a long history of efficient industrial hygiene practices, will have less risk of disease than those in the smaller less well-regulated industries. A good example can be found with silicosis: the majority of cases now occurring in both the USA and Australia arising from small unregulated industries with no awareness of risks or hygiene practices. Similar examples from own experience are: witnessing (in 1992) use of Russian asbestos in an asbestos-cement factory in Czechoslovakia (as it was then) where all the warnings on the bags of asbestos were in English; passing by demolition in progress of an old asbestos cement factory building in Sydney last month where no observable precautions of any kind were being taken. (Note added later: It has struck me that the misunderstanding with this question could be due to the relative imprecision of the French language, where "de" means both "of" and "from", words with quite different meanings, especially in this context!)

Dr. Henderson:

5.174 In past historical terms, the Canadian proposition about the classes of workers at risk of exposure to chrysotile is correct — provided that this risk is expressed in terms of a numerical value for the risk per person-years of observation (e.g. per 100,000 or 1 million person-years). However, this situation has changed over recent years, as airborne fibre concentrations have been reduced in the mining and milling industries and during the production of friction products. As one example, NICNAS 99 points out that manufacture of friction products (brake linings and gaskets) in Australia is a completely closed operation, with low airborne fibre concentrations.

5.175 EHC 203 refers to this reduction in airborne fibre concentrations:

> "Based on data mainly from North America, Europe and Japan, in most production sectors workplace exposures in the early 1930s were very high. Levels dropped considerably to the late 1970s and have declined substantially to present day values. In the mining and milling industry in Quebec, the average fibre concentration in air often exceeded 20 fibres/ml (f/ml) in the 1970s, while they are now generally well below 1 f/ml. In the production of asbestos-cement in Japan, typical mean concentrations were 2.5-9.5 f/ml in 1970s, while mean concentration of 0.05-0.45 f/ml were reported in 1992. In asbestos textile manufacture in Japan, mean concentrations were between 2.6 and 12.8 f/ml in the period between 1970 and 1975, and 0.1-0.2 f/ml in the period between 1984 and 1986. Trends have been similar in the production of friction materials: based on data available from the same country, mean concentrations of 10-35 f/ml were measured in the period between 1970 and 1975, while levels 0.2-5.5 f/ml were reported in the period between 1984 and 1986. In a plant in the United Kingdom in which a large mortality study was conducted, concentrations were generally above 20 f/ml in the period before 1931 and generally below 1 f/ml during 1970-1979." [pp 2-3].

5.176 In contrast, the risk per million person-years of observation may be less in building construction, renovation and maintenance workers, but this smaller risk is spread across a substantially larger workforce (i.e. there are many more carpenters/joiners, builder's labourers, electricians, plumbers and other tradespeople in Western societies than the numbers of workers engaged in the mining, milling or production of high-density asbestos-containing materials such as asbestos-cement sheets and pipes or brake blocks).

5.177 According to EHC 203:

> "It should be recognized that although the epidemiological studies of chrysotile-exposed workers have been primarily limited to the mining and milling, and manufacturing sector, there is evidence, based on the historic pattern of disease associated with exposure to mixed fibre types in western countries, that

risks are likely to be greater among workers in construction and possibly other user industries." [EHC 203, p 9].

"Past uncontrolled mixed exposure to chrysotile and amphiboles has caused considerable disease and mortality in Europe and North America. Moreover, historical experience to mixed fibre types in European countries has clearly indicated that a larger proportion of mesotheliomas occurs in the construction trades than in production. Far larger quantities of chrysotile than of other types of asbestos were used in most construction applications. Epidemiological studies that contribute to our understanding of the health effects of chrysotile conducted to date and reviewed in this monograph have been on populations mainly in the mining or manufacturing sectors and not in construction or other user industries. This should be borne in mind when considering potential risks associated with exposure to chrysotile." [EHC 203, p 137].

"Few data on concentrations of fibres associated with the installation and use of chrysotile-containing products were available to the Task Group, although this is easily the most likely place for workers to be exposed." [EHC 203, p 138].

"There is potential for widespread exposure of maintenance personnel to mixed asbestos fibre types due to the large quantities of friable asbestos materials still in place. In buildings where there are control plans, personal exposure of building maintenance personnel in the USA, expressed as 8-h time-weighted averages, was between 0.002 and 0.02 f/ml. These values are the same order of magnitude as exposures reported during telecommunication switch work (0.009 f/ml) and above-ceiling work (0.037 f/ml), although higher concentrations have been reported in utility space work (0.5 f/ml). Concentrations may be considerably higher where control plans have not been introduced. For example, in one case, short-term episodic concentrations ranged from 1.6 f/ml during sweeping to 15.5 f/ml during cleaning (dusting off) of library books in a building with a very friable chrysotile-containing surface formulation. Most other values, presented as 8-h timed-weighted averages, are about two order of magnitude less." [EHC 203, p 139].

5.178 These points are also borne out by the 1999 Report for the Australian Mesothelioma Register [AMR 99], where the broad spread of prior occupations among mesothelioma victims is plain. For example, the number of mesotheliomas from the former Wittenoom blue asbestos industry (189 mesotheliomas related to a single exposure only; 25 additional mesotheliomas as a consequence of multiple exposures; total = 214) is less than the numbers of mesotheliomas as a consequence of asbestos exposure in different occupations (e.g. carpenters/joiners: 187 mesotheliomas from a single exposure; 33 additional mesotheliomas due to multiple exposures; total = 220; for builders/builders' labourers the corresponding numbers are 150 + 27 = 177). In other words, mesotheliomas among the former Wittenoom cohort constitute a relatively small number (214) in comparison to the aggregate numbers of mesotheliomas from asbestos exposures in other occupations (2585 – 214 = 2371 other asbestos-associated mesotheliomas; no exposure data for 717 cases, and no apparent exposure for 443; aggregate total = 3745).

5.179 NICNAS 99 makes the same point (p 59):

"Occupation/industry classification of the mesothelioma cases on the register are based on the Australian Bureau of Statistics 'Industry and Occupation Codes'. The percentage of overall cases of mesothelioma (January 1986 to March 1995) according to exposure category are: repair and maintenance of asbestos material (13%), shipbuilding (3%), asbestos cement production (4%), railways (3%), power stations (3%), boilermaking (3%), mining (Wittenoom) (5%), wharf labour (2%), para-occupational, hobby, environmental (4%) carpentry (4%), building (6%) navy (3%), plumbing (2%) brake linings (manufacture/repair) (2%) and combinations of the above (multiple) (12%) (Leigh *et al*., 1997). Leigh (1994) reported that the pattern of exposure is shifting away from the older traditional industries towards product, domestic and environmental exposure. An analysis of 16 years data in 1996 by Yeung *et al.* (1997) showed more cases (on a number of cases basis) in more recent years in the asbestos user industries and from occupations such as plumbers, carpenters, machinists and car mechanics."

5.180 Similar patterns of exposure — and resultant diseases (lung cancer; mesothelioma) — have been recorded in the United Kingdom (EHC 203, pp 123-124):

> "Based on analyses of mortality of workers with mixed exposures to chrysotile and amphiboles in the United Kingdom, by far the greatest proportion of mesotheliomas occurs in users of asbestos-containing products, rather than those involved in their production. ...
>
> 1. Asbestos exposure caused approximately equal numbers of excess deaths from lung cancer (749 observed, 549 expected) and mesothelioma (183 deaths) within the occupations covered by the 1969 and 1984 Regulations ...
>
> 2. Only a few (5%) of British mesothelioma deaths were among workers in regulated occupations (Peto *et al.*, 1995). The majority of deaths occurred in unregulated occupations in which asbestos-containing products are used, particularly in the construction industry. The risk was particularly high among electricians plumbers and carpenters as well as among building workers."

5.181 As shown by the literature cited in this discussion, it is my perception that there is broad agreement among experts on these patterns of exposure.

Dr. Infante:

5.182 The relative exposure categorization of the six job situations mentioned in the question depends on the nature of controls being used in each situation. In general, exposures are more easily controlled in manufacturing and more difficult to control in construction, maintenance, repair, demolition and disposal activities. Today, exposures would be more easily controlled in mining and milling because of awareness of the hazard and the clear identification of the operations as sources of asbestos exposure. Quite often workers involved in maintenance, repair and handyman type activities do not know whether asbestos is present or not. In the absence of such knowledge, workers usually do little, or nothing to protect themselves from exposures to asbestos in these situations. As a result, workers involved in these activities are most likely to be the most heavily exposed in the occupational setting today. These types of activities often result in asbestos being carried home on the workers' clothing. A typical scenario that comes to mind is a situation whereby a worker is in a crawl space and encounters asbestos insulation. There is no active supervision in this situation and the asbestos most likely is not labelled. Thus, the worker cuts through the insulation to get to the area needing to be repaired without knowledge of the hazard and without having the appropriate personal protective equipment. In the latter scenario, even when workers do wear respirators, they are often dust masks, which do not provide a proper face seal and the filter medium is not adequate i.e., HEPA filters are not part of the filtration material on these masks. In the repair trades particularly, it is common practice for workers to use dust masks that do not provide HEPA filtration. As a result, the respirator is inadequate for filtering out the fibres of dimensions that are thought to lead to cancer and other asbestos related diseases. Furthermore, even in situations where the appropriate respirators may be worn, comprehensive respiratory fit-testing programmes may not be included as part of the industrial hygiene programme and as a result, the respirators leak because of the inability to achieve a proper face seal. In situations where workers may be drilling, sawing, crushing, or sanding asbestos cement products the only appropriate respirator may be a supplied air respirator, but it may not be used because it is too cumbersome for the job situation. In my opinion, scenarios (v) and (vi) are usually the most dangerous in current times because the workers are not aware of the presence of asbestos and they are more likely not to have received training and education about the hazards of asbestos exposure.

5.183 The risk of exposure should be considered not only by level of exposure, but also by the extent of the populations exposed to chrysotile asbestos. The large number of mesotheliomas associated with secondary and tertiary users of chrysotile asbestos (maintenance workers, electricians, bystanders, etc.) is a reflection of the large number of individuals in the population exposed in these

situations. Thus, in terms of the risk of disease from chrysotile exposure, one must consider not only the intensity of exposure in the various work situations, but also the extent of the population exposed. One study (Begin *et al.*, 1992) reports that 33 per cent of mesothelioma cases identified among maintenance workers, electricians, bystanders, etc. were the result of exposure for less than five years, and that the incidence of these occasionally exposed cases was increasing more rapidly than in the primary industries (mines and mills), or in the secondary industries (manufacturing, daily handling of asbestos).

Dr. Musk:

5.184 The term "risk of exposure" is taken to mean who is most likely to receive the most exposure and therefore be at the greatest risk of developing asbestos-related disease. This would depend on the nature of the industry in the locality and the type of asbestos being produced or used or otherwise encountered. Those workers likely to receive the most exposure would be those in industries where regulations are most permissive or compliance with them is poorest from absence of supervision or means of personal protection. It would also depend on the conditions of work such as indoor versus outdoor etc. Canada's "argument" could be settled by monitoring of exposure! The "arguments" do not seem to be incompatible.

1.(b) Should we consider that the risk to human health associated with the various uses of chrysotile throughout its life-cycle is a workplace issue or does this risk affect a larger part of the population?

Dr. de Klerk:

5.185 The risk of disease from chrysotile affects everyone. The risk of disease depends on intensity of exposure, the duration of exposure and the time since exposure. The population who do not work with asbestos will still come into contact with it, albeit at a much lower intensity, however this population is much larger and hence the burden of disease may be greater. There are numerous examples of asbestos-related disease arising in people living in the vicinity of asbestos works or living with asbestos workers.

Dr. Henderson:

5.186 From my perspective, this is overwhelmingly a workplace issue (e.g. construction workers). The risk of cancer for the larger general population from exposure to asbestos in place has been discussed in an earlier part of this report (see above section C.1.(e)). Please see also my answer to the preceding question.

5.187 For example, asbestos-cement roofs are common in Germany where corrosion by acid rain represents a potential problem. Measurements carried out by Spurny *et al.* [221-224] on airborne asbestos fibre concentrations in the vicinity of such buildings consistently reveal levels in the order of 0.0002-0.0012 f/ml, in comparison to fibre concentration in other urban environments that range up to 0.1 f/ml (but generally $\leq$ 0.001 f/ml).

5.188 Measurements have also been made on airborne fibre levels related to asbestos-cement roofing in schools in Western Australia [128] , with only one asbestos fibre detected in each of two schools (air monitoring at 9 sites over 720 hours). Based on the findings, it was estimated that airborne fibre concentrations would be unlikely to exceed 0.002 f/ml and were likely to be < 0.0002 f/ml. These levels were considered to represent a negligible risk to health; the Western Australia Advisory Committee on Hazardous Substances that carried out this investigation considered that a greater risk to health would arise from: (i) unskilled attempts to clean up the

asbestos-cement roofs before application of protective coating; and (ii) trauma to the workers — e.g. falling from or through the roofs.

5.189 It is my perception that there is little or no dispute among experts on this issue.

Dr. Infante:

5.190 In general, workers are at relatively greater risk of exposure to chrysotile and disease, particularly those involved in maintenance, modification, demolition, repair and disposal activities as compared to those exposed in non-occupational situations. A large number of people from the general population, however, also will be exposed to chrysotile and elevated risk of disease when they engage in home repairs that involve manipulating or disturbing asbestos-containing products. (The latter individuals usually have little or no education about the hazards of asbestos, nor of the most appropriate means to handle it with the least amount of exposure.) These types of operations will also create some standby exposures (Ascoli *et al.* 1996). If appropriate controls are not used when handling asbestos insulation in buildings, the building can become contaminated and the occupants will become exposed. Therefore, the major problem with asbestos exposure is related to occupational situations though a much larger population is exposed beyond the occupational setting to relatively lower levels. Reports of cases of mesothelioma among non-occupationally exposed individuals document non-occupational exposures to asbestos causing disease. Family members of workers involved in the asbestos cement industry (Magnani *et al.* 1993) as well as children of miners and millers (McDonald and McDonald 1980) have been diagnosed with mesothelioma.

Dr. Musk:

5.191 It is my opinion that the risks resulting from exposure affects all exposed people and depends on the cumulative level of exposure. It is also my opinion that there is not an exposure threshold below which there is no risk. The risks to people not occupationally exposed to asbestos are likely to be much less than the risks to those with occupational exposure because the degree of exposure is likely to be less (though not necessarily always so). However, while the individual risks may be much less the total burden of disease in the community may not be because it is likely that there are many more people experiencing these risks (albeit lower). For example the burden of disease in the residents of the town of Wittenoom, Western Australia has been significant albeit less than that of the workers. The WA Mesothelioma Registry contains subjects whose only exposure was from neighbourhood industries. Similar cases have been documented in the Quebec areas.

1.(c) Can chrysotile-cement products (for instance in buildings) release fibres, through weathering, corrosion or general degradation, thus presenting a possible risk to human health? Can you quantify this risk?

Dr. de Klerk:

5.192 There is good evidence that both wind and rain cause the release of fibres even from new asbestos cement sheeting. Other possibilities are fires and unwanted demolition. It is hard to quantify the risk which again depends on intensity and duration, but measurements have been made in the vicinity of such buildings which are detectable but low.

Dr. Henderson:

5.193 Please see the preceding answer, and section C.1.1(e). Quantitation of the risk is based on backward extrapolation according to the linear no-threshold model because there are no observational data on the dose-response effects from low-level exposure to chrysotile, and the estimates are,

therefore, open to question and dispute, but the risks to health from very low-level environmental exposure appear to be minuscule or negligible.

Dr. Infante:

5.194 Yes, weathered and corroded asbestos cement products are capable of releasing chrysotile fibres into the environment, and most of the fibre is transported by rainwater though some will be released into the ambient air in low concentrations. One study indicates that chrysotile exposure in such circumstances will generally be less than 1,000 fibres longer than 5 microns per cubic meter of air. The fibres released were shown to have the same carcinogenic potency as "standard" chrysotile fibres (Spurny, 1989). Asbestos fibres also will be released into water from cement water pipes. I have not seen any estimates of risk from this type of asbestos exposure. Although the relative risk of disease is considerably less than that from occupational exposures, the population at risk is considerably larger.

Dr. Musk:

5.195 I understand that asbestos-cement products do release fibres as they weather. Release of fibres occurs from both old and new products. Asbestos fibres can also be released when asbestos-cement products are involved in fires. Quantitative estimates of the risks are theoretically possible as airborne concentrations can be measured and dose-response relationships are known.

1.(d) Can interventions on chrysotile-cement and other high-density chrysotile products release fibres, thus presenting a possible risk to the health of the individual making such interventions or to the public in general? Can you quantify this risk?

Dr. de Klerk:

5.196 It is during interventions such as drilling, sawing, sanding, moving in stacks, loading onto transport etc, that concentrations of fibres are greatest, both for the operators and bystanders. The concentrations associated with such operations have been extensively tabulated in the literature. Exposure response relationships can be used to estimate the risk for any combinations of intensity, duration and time after exposure, as shown in the Table below.

5.197 Lifetime risks (to age 85 years) of mesothelioma after exposure to chrysotile, assuming 0.1 f/ml for 10 years from age 20 with competing causes of death at 1992 Western Australian death rates.

Assumptions	Expected cases per million lifetimes
Health Effects Institute equation	724
Wittenoom crocidolite equation 1/12th potency	210
Wittenoom crocidolite equation , 1/80th potency	32
Background risk (Peto study of "unexposed" Los Angeles population)	112

Dr. Henderson:

5.198 My answer to the first question is YES. Operations such as drilling or sawing asbestos-cement products release fibres and produce elevated airborne fibre concentrations. (i) asbestos-cement sheets can release respirable fibres in the absence of manipulation, even when new (up to 0.001 f/ml; for references, see de Klerk and Armstrong [135]); (ii) a 1938 report in

New South Wales indicated that cutting asbestos-cement products with a power saw could generate 4-5 million particles/cubic foot (roughly equivalent to 12-15 f/ml); cutting with hand saws produced lower concentrations; (iii) as shown in the following Table 11, Sturm *et al.* [5, 7] reported measurable fibre concentrations from various operations on asbestos-containing materials, including asbestos-cement in the former East Germany, as measured by occupational inspectors.

TABLE 11: ASBESTOS FIBRE CONCENTRATIONS AT WORKPLACES, WITHOUT SUCTION DEVICES, DETERMINED BY KONIMETRY (FROM UNPUBLISHED REPORTS PREPARED BY OCCUPATIONAL INSPECTORATES)

Type of Work	Fibre Concentration (f/ml)
Scratching and crushing of asbestos-cement	0.03 to 0.3
Abrasive cutting of asbestos-cement without dust removal by suction	0.3 to 10.0 approx.
Drilling asbestos-cement without dust removal by suction	0.5 to 3.4
Machining of brake linings	0.1 to 13.0
Replacement of gaskets	0.02 to 0.5
Punching of gaskets (rubber asbestos)	0.02 to 1.9
Use of asbestos gloves	0.02 to 0.6
Replacement of clearing layers	0.06 to 0.5
Use of talcum for powdering gloves	0.6 to 20.0
Level limit value (over a whole working day)	1.0

5.199 In 1993, Kumagai *et al.* [4] in Japan reported on dust levels generated by repair work on asbestos-cement pipes, including use of a high-speed disc cutter both inside holes dug in the ground to gain access to the pipes and outside the holes. The concentration of asbestos fibres > 5 µm in length ranged from 48-170 f/ml inside the hole (average = 92 f/ml) and ranged from 1.7-15 f/ml outside the hole. The Abstract for this paper follows:

> "Asbestos cement pipes (ACPs) containing 15 to 20% chrysotile or crocidolite have been used for underground conduits. Even today 16.2% of all conduits in Japan are ACPs, though the production of ACPs was suspended in 1985. When such a conduit is accidentally damaged the workers belonging to the Waterworks Bureau of a local government cut off the damaged conduit using a high-speed disk cutter and replace it with a new conduit. This operation develops a cloud of dust and the workers involved run the risk of asbestos exposure. It was the aim of the present study to estimate asbestos exposure levels among these workers. First, in the experiment, we established the typical working conditions and requested an experienced worker to cut an ACP using a high-speed disc cutter in a hole dug in the ground as he routinely does. The experiment was repeated three times. During a bout of each experiment, dust was sampled at several points both inside and outside the hole. Second, a self-administered questionnaire survey was conducted to obtain information from the workers regarding their working conditions in cutting ACPs. The subjects of the survey were 1,048 men belonging to conduit repair sections of the Waterworks Bureau of 119 local governments. The results obtained can be summarized as follows. (1) Each bout of cutting ACPs required about five minutes. The concentration of asbestos fibers longer than 5 microns with 3:1 aspect ratio ranged from 48 to 170 fibers/ml (92 fibers/ml on an average) inside and 1.7 to 15 fibers/ml outside the hole. The concentration inside the hole exceeded the ceiling limit (10 fibers/ml) recommended for asbestos by the Japanese Association of Industrial Health. A concentration of 92 fibers/ml is equivalent to 0.96 fibers/ml as 8-h time-weighted average. (2) The number of subjects with experience of cutting ACPs was 849 (81.0%). The average length of service in conduit repair section was 14.2 yr. Based on the information obtained from each subject regarding the average working days per yr for each decade from 1946, the cumulative days to date expended in cutting ACPs was estimated to average 235 d, that is, 17 d per yr. Only 18.1% of the subjects used a protective respiratory device."

5.200 EHC 203 also gives the following data (p 40):

> "Weiner *et al.* (1994) reported concentrations in a South African workshop in which chrysotile asbestos-cement sheets were cut into components for insulation. The sheets were cut manually, sanded and subsequently assembled. Initial sampling showed personal sample mean concentration of 1.9 f/ml for assembling, 5.7 f/ml for sweeping, 8.6 f/ml for drilling and 27.5 f/ml for sanding. After improvements and clean-up of the work environment, the concentrations were 0.5-1.7 f/ml.
>
> Nicholson (1978) reported concentrations of 0.33-1.47 f/ml in a room during and after sawing and hammering of an asbestos-cement panel."

5.201 It is my perception that there is no dispute among experts on this issue.

5.202 In relation to the second part of this question, apart from stating that there is a risk because of the generation of airborne asbestos fibres from interventions on asbestos-cement and other high-density asbestos products, it is not possible to quantify the risk in a way that would meet with universal agreement or a broad consensus, because few data are available for the risks for this type of operation on chrysotile-cement products: the risk would be related to cumulative exposure, which would vary according to the types of operation carried out, and their frequency. In addition, risk estimates would be dependent on extrapolation from the linear dose-response model that has been called into question by Canada. Therefore, I would expect disagreement among authorities on the magnitude of the risk.

5.203 Table 12 derived from NICNAS 99 gives risk estimates for lung cancer at airborne chrysotile concentrations of 0.1-1.0 f/ml, according to the National Occupational Health and Safety Commission in Australia (NOHSC) and two US occupational health and safety bodies (OSHA and NIOSH).

TABLE 12: ESTIMATED RISK OF LUNG CANCER AT VARIOUS LEVELS OF EXPOSURE TO CHRYSOTILE

Exposure(yearly average fibre/ml)	**Excess risk (per 100,000 persons exposed)**		
	NOHSC	US OSHA	US NIOSH
1	173	2880	5760
0.5	86	1440	2880
0.1	17	288	576

Excess risk = Risk coefficient x lifetime exposure (yrs) x average exposure level (f/ml) background risk.*
*A cumulative background risk for lung cancer in the male population was used in these calculations (i.e. 7200/100,000 assuming mixed smoking habits).

5.204 However, NICNAS 99 goes on to discuss uncertainties concerning these risk estimates:

> "There are several other reasons why there is considerable uncertainty regarding these risk estimates, which include:
>
> 1. Past occupational exposures have generally involved exposure to a mixture of asbestos fibres. As it appears likely that different types of asbestos have different degrees of hazard, it is difficult to determine the risk attributable to chrysotile per se. In addition, commercial chrysotile often has low levels of tremolite contamination.
>
> 2. Fibre size, such as difference in fibre size between different chrysotile industries, probably influences the degree of hazard and/or potency.
>
> 3. There is a long latency between exposure to asbestos and development of lung cancer. Hence, it is not possible to state definitively what fibre type and level of exposure caused the disease. Consequently, risk estimates are related more to duration of employment rather than intensity of exposure.

4. A linear, non-threshold model may not be an appropriate model as there is some evidence suggesting that lung cancer due to chrysotile exposure may have a threshold for effect.

5. Past exposure estimates (both quantitative and qualitative) are subject to considerable error. For example, conversion of historical results in mpcf units to fibres/mL has inherent uncertainties.

6. There is a high background level of lung cancer in the general population due to smoking. Cases of lung cancer attributable to asbestos cannot be distinguished from those due to smoking. Attribution can only be assessed in terms of excess of lung cancers above a control population, hence the choice of control population is critical.

7. The identification of the disease is dependent on medical diagnosis, however autopsies are not always conducted.

The impact of some of these uncertainties can be accounted for to some extent. For example, it is considered that (1) and (2) are largely accounted for by basing risk estimates on epidemiological studies where exposure was only to chrysotile in the most relevant industry. For the remainder of the above uncertainties it is unclear what influence they have on the risk estimates and how they should be accounted for. For example, recently there has been some debate in the literature as to whether a threshold or non-threshold model should be used when predicting risk due to chrysotile exposure. Meldrum (1996) states that based on balance of toxicological evidence, the linear no-threshold model for chrysotile-induced lung cancer may not be appropriate. ... Epidemiological data alone are not able to clearly distinguish between the possibility of a threshold or a non-threshold model due to the relatively high background rate of lung cancer in the human population. There is at present no consensus with respect to a threshold level of exposure for chrysotile below which there is no risk of disease" [pp 70-71].

5.205 Table 13 gives an estimate of lifetime mesothelioma risk from exposure to low levels of chrysotile (1.0 f/ml and 0.1 f/ml), based on dose-response data for the Wittenoom cohort, and assuming lower potencies for chrysotile than crocidolite (i.e. 1/12th, 1/30th and 1/80th).[20]

TABLE 13: ESTIMATES OF LIKELY MESOTHELIOMAS RELATED TO CHRYSOTILE INHALATION AT AIRBORNE CONCENTRATIONS OF 1.0 AND 0.1 F/ML, ASSUMING A CARCINOGENIC POTENCY 1/12TH, 1/30TH OR 1/80TH THAT OF CROCIDOLITE

	Numbers to age 85 Mesotheliomas/million persons		
Airborne fibre concentration; Potency	**Duration of exposure* (years)**		
	1 yr	**10 yrs**	**40 yrs**
1.0 f/ml -1/12th	282	2101	3530
1.0 f/ml - 1/30th	113	840	1412
0.1 f/ml - 1/12th	28	210	353
0.1 f/ml - 1/30th	11	84	141
0.1 f/ml - 1/80th	4	32	53

*Starting at age 20 yrs.

[20]Estimates calculated at my request by Dr. N.H de Klerk.

Dr. Infante:

5.206 Interventions on chrysotile cement products can result in extremely high atmospheric fibre concentrations (Rodelsperger *et al.,* 1980) and studies of roofers have demonstrated asbestosis from such exposures (Stauder *et al.*, 1982). A study of workers involved in inside finishing work with concrete asbestos containing 30 per cent chrysotile asbestos has also shown that airflow obstruction among workers can be caused by such exposure (Harless *et al.* 1978). Open-air cutting such as that involved in roofing and inside finishing operations also will result in exposure to other workers not directly involved in the manipulation of the asbestos, e.g., standby exposure. Such manipulation of asbestos cement will also expose the general population.

5.207 A study of 404 roofers with long term exposure to cement dust indicated that 14 per cent had significantly increased small irregular opacities with profusion in 13 per cent (Stauder *et al.*, 1982). The prevalence of these abnormalities was significantly greater than that observed in the control group. The study by Harless *et al.* (1978) indicated that approximately 50 per cent of workers exposed for about six months to dust from asbestos cement developed airflow obstruction. The risk of developing lung pathology per unit of asbestos fibre exposure cannot be determined from these studies because of lack of exposure data. The studies do indicate, however, that uncontrolled manipulation of chrysotile cement products can result in a high rate of lung pathology. Lung function can be adversely affected as a result of exposure over a very short period of time.

5.208 A large number of reports indicate mesothelioma related to car mechanics involved in brake repair. General population exposures from such work would be minimal except for those situations where individuals would engage in their own brake repair work.

Dr. Musk:

5.209 Interventions on asbestos-cement products can release fibres therefore a risk of disease exists as in 1(c).

1.(e) Can occasional interventions on high-density chrysotile products, either in occupational circumstances (such as electricians, plumbers, repairers, insulation workers, etc.) or by private individuals ("handyman" type) release fibres, thus presenting a possible risk to the individual making such interventions or to the public in general? Can you quantify this risk?

Dr. de Klerk:

5.210 Yes of course, see (c) and (d).

Dr. Henderson:

5.211 To answer the second question first, I am unable to quantify potential risk, because there are no systematic observational data available for this type of work, to the best of my knowledge (but please see Tables 12 and 13 above in my answer to Question 1(d)

5.212 The first part of the question has been covered in the preceding answer, with the observation that occasional interventions of this type would predictably produce low cumulative exposures, with a lower risk, for the reasons discussed earlier. Please also refer to AMR 99, for data on mesotheliomas among electricians, carpenters, plumbers, insulation workers and so forth (it is acknowledged that most if not all these mesotheliomas are a consequence of exposure to asbestos-containing materials that included a mixture of asbestos types, including chrysotile and one or more of the amphiboles); in drawing attention to AMR 99, my purpose is simply to use mesothelioma rates as a reflection of past exposures and hence evidence that airborne fibre concentrations were produced by these types of

operation, without regard to the fibre types. My own cases of mesothelioma also include a number of individuals whose only exposure to asbestos took the form of maintenance work and renovations carried out on the patient's home, where there were asbestos-cement building materials. Again, in drawing attention to this type of background, it is not my intention to address fibre type, but simply to indicate that mesothelioma as an outcome of this type of exposure indicates that elevated concentrations of respirable airborne fibres were produced.

5.213 EHC 203 gives the following account (pp 122-123):

> "Although the odds ratio for lung cancer associated with exposure to "asbestos" has been estimated in many case-control studies, the studies have not been in general able to distinguish between chrysotile and amphibole exposure, and are therefore less informative for the present evaluation ... In a multisite case-control study from Montreal, Canada, however, exposures to chrysotile and to amphiboles were separated, although exposure to amphiboles was not controlled for in the analysis for exposure to chrysotile (Siemiatycki, 1991). In this study, the occupational history of male cases (age 35-70) of cancer at 20 sites and of 533 population controls was evaluated by a team of industrial hygienists and chemists to assess exposure to 293 agents. Overall, the lifetime prevalence of exposure to chrysotile was 17% and that of exposure to amphiboles 6%. The main occupations involving exposure to chrysotile that were considered were motor vehicle mechanics, welders and flame cutters, and stationary engineers. When lung cancer cases (N = 857) were compared with cases of all other types of cancer, the odds ratio (OR) of any exposure to chrysotile was 1.2 (90% CI = 1.0-1.5; 175 exposed cases), and that of 10 or more years of exposure with at least 5 years of latency ('substantial exposure') was 1.9 (90% CI = 1.1-3.2; 30 exposed cases). Corresponding ORs of exposure to amphiboles were 1.0 and 0.9. The OR of exposure to chrysotile was higher for oat cell carcinoma than for other types of lung cancer. Twelve cases of mesothelioma were included in this study. The OR of any exposure to chrysotile was 4.4 (90% CI = 1.6-11.9; 5 exposed cases) and that of substantial exposure was 14.6 (90% CI = 3.5-60.5; 2 cases). Corresponding ORs of exposure to amphiboles were 7.2 (90% CI = 2.6-19.9; 4 cases) and 51.6 (90% CI = 12.3-99.9; 2 cases). "

5.214 Please see also Tables 5, 9, 10, 11, 12, 13, in EHC 203.

5.215 It is my perception that there is no dispute among experts that such interventions release fibres; disagreement is likely over the magnitude of the risk.

Dr. Infante:

5.216 The worker making the intervention would be the most highly exposed and presented with the greatest risk of asbestos related diseases. The extent of exposure to the worker as well as to those in the surrounding area would depend on the nature of the intervention, e.g., the circumstances under which the chrysotile asbestos product is manipulated in terms of work practices, the controls, or lack of controls in place and the type of personal protective equipment provided to the worker. While data on fibre exposure levels in these situations are sparse, data on mesothelioma indicates association with workers who have jobs that result in occasional interventions to asbestos products. Because these exposures are not routine and the hazard often goes unrecognized, these operations are unlikely to be well controlled, i.e., they are not anticipated so proper training and education about these types of exposures is often lacking.

5.217 It is difficult to quantify this risk because atmospheric measurements are usually not made during these interventions. However, the identification of cases of mesothelioma associated with these interventions in the literature indicate that they are perhaps the most detrimental to human health. Mesothelioma has been identified from these exposure situations because it is a marker cancer related to asbestos exposure. What goes unidentified and unmeasured from these situations is the much larger burden of disease and death from pneumoconiosis and lung cancer. The attributable burden from these latter diseases will be much greater than that from mesothelioma, but they are not usually recognized because lung cancer has a high background rate in the general population and

asbestosis may be diagnosed as another type of pneumoconiosis unrelated to asbestos exposure. Mesothelioma has also been documented among the wives of construction workers, indicating that the family member portion of the public in general is also at risk. These latter cases of mesothelioma are most likely the result of carry-home exposure from contaminated clothing.

5.218 If one considers that the handyman types of exposures are considered as exposures to the general public, then this segment of the general population would also be at an elevated risk of developing asbestos related diseases. Exposures to family members that might result from interventions by home owners would depend on the nature and location of the removal or manipulation of the asbestos. The general public is also exposed through manipulation of asbestos in residential buildings that is not carried out with appropriate controls in place and by carry home exposures from contaminated work clothing.

Dr. Musk:

5.219 Occasional interventions on asbestos-cement products by anyone can release airborne fibres, therefore there is some risk as in Question 1(c).

1.(f) Are chrysotile fibres from chrysotile-cement dust released during interventions (cutting, sawing, etc.) on chrysotile-cement products as dangerous as pure chrysotile fibres? Is the physical and chemical composition of asbestos-cement dust different from pure asbestos dust?

Dr. de Klerk:

5.220 Risk from fibres depends on size, shape and durability (and their quantity). Asbestos cement contains about 10-20 per cent asbestos, so that the dust concentration is going to be less than if the sheets were pure asbestos. However, cement does not form fibres, so that any airborne fibre measurements made would only reflect the asbestos concentration in the air.

Dr. Henderson:

5.221 To answer the second part first, the physico-chemical composition of asbestos-cement dust does differ from pure asbestos dust, because the asbestos in asbestos-cement products is diluted by the cement (asbestos = 10-15 per cent by weight); this being so, one expects the asbestos fibres to be diluted by cement dust, in comparison to equivalent operations on pure asbestos materials.

5.222 To return to the first part of this question: the claim may be made that chrysotile fibres released from asbestos-cement products by high-speed cutting are altered physically or chemically, with a predominance of short-length fibres not implicated in carcinogenesis. For example, in Canada's first oral submission, the following comments are made:

> "The European Community has also advanced the thesis that the ban is necessary because France has no control over trade persons or the 'handyman' who will cut into chrysotile-cement and, in so doing, free some of the chrysotile that was locked into it. Canada is puzzled by France's assertion that la République Française is unable to regulate its handymen. In any event, there are three technical reasons why France's concern is misplaced.
>
> First, this thesis is based on the misconception that cutting high-density locked-in non-friable asbestos-containing materials releases substantial amounts of chrysotile. In fact, even if improper tools such as high-speed saws are used to cut chrysotile-cement, the dust released from such an operation contains only a very small amount of pure, respirable-size chrysotile fibres, if any at all.
>
> Second, science tells us that most of the chrysotile fibres released during high-speed cutting have been chemically altered: the resulting entity is chemically and structurally different, and has a biological

> potential to induce harmful effects, which is different, and less than amphiboles. Similarly, the dust that results from abrading chrysotile-containing resin or plastic reinforced products contains very small amounts of chrysotile fibres. The same is also true of the dust that comes from wear and abrasion of friction materials: analysis of brake shoes shows that almost all of the chrysotile fraction of the finished product is found to be transformed into a totally different, biologically-inactive material called forsterite ...."

5.223 The first paragraph of the Canadian statement is dealt with in later discussion in this report (my answers to Question 5). For the second and third paragraphs of this statement, one can state that in other situations, only a small fraction of airborne asbestos fibres are of respirable size: as one example, about 0.67 per cent of airborne asbestos fibres within indoor air of buildings were longer than 5 µm in length. However, in the Japanese study reported by Kumagai *et al.* [4] on cutting asbestos-cement pipes with a high-speed disc cutter, where airborne fibre concentrations within the hole used to gain access to the pipes averaged 92 fibres/ml (range 48-170 fibres/ml), the study dealt with fibres longer than 5 µm (i.e. dimensions in the range for which carcinogenicity has been reported). Please see also Table 11 in EHC 203 where Rödelsperger *et al.* recorded airborne fibre concentrations of 4-5 f/ml and 5-10 f/ml for fibres longer than 5 µm, from blowing off and grinding brake blocks, including truck brakes. (Please see also Table 11 and my answer to Question 2.)

5.224 Clearly, there is disagreement between the parties to the dispute and their respective experts over the issue of whether chrysotile fibres released from high-density products are dangerous. For the reasons outlined above and in later discussion, it is my perception that at least a small proportion of the fibres has dimensions that are associated with carcinogenicity.

Dr. Infante:

5.225 As long as the interventions result in the release of chrysotile fibres, the exposures should be considered as dangerous as pure chrysotile fibres because respirable-sized asbestos fibres will be released. The study by Spurny (1989) indicates that the fibres released from weathered and corroded chrysotile asbestos cement products have the same carcinogenic potency as "standard" chrysotile fibres. Although fibres released by weathering may be somewhat different from fibres released from cutting or drilling asbestos cement products, the former fibres show a potency similar to that of pure chrysotile fibres. Moreover, because of the potential for cleavage during interventions on asbestos cement products, the dust resulting from cutting, drilling, etc. on asbestos cement may actually contain a greater portion of the asbestos fibres being thinner and more respirable than those that were initially mixed into the cement during the manufacturing process. Therefore, the fibres released from cement during interventions should be considered at least as dangerous as "pure chrysotile fibres." I can find no data to support an opinion that fibres released from interventions on chrysotile asbestos cement products would be less carcinogenic, or less dangerous. Further, asbestos related pathology has resulted from such situations.

5.226 The asbestos cement dust would be somewhat different in physical and chemical composition from pure chrysotile asbestos because the cement dust would contain respirable asbestos fibres, crystalline silica plus other substances added to the cement.

Dr. Musk:

5.227 It is my opinion that in general airborne fibres released from asbestos-cement products pose a risk. This may differ from other sources of chrysotile depending on the characteristics of the fibres. The area of fibre characteristics and their relationship to different sources is not within my area of expertise.

1.(g) What is the risk to human health associated with demolition and removal of high-density chrysotile products, such as chrysotile-cement products? Can you quantify this risk?

Dr. de Klerk:

5.228 See my answers to Questions 1(c) and (d).

Dr. Henderson:

5.229 I am not aware of any studies that have specifically focussed on either of these situations: therefore, no firm data are available, but one would expect the biohazards to be related to cumulative doses of respirable fibres (i.e. airborne fibre concentrations and the frequency of exposure from these types of work). This being so, one would expect the risks to be equivalent to other operations of like frequency that generated similar airborne fibre levels (Tables 12 and 13).

Dr. Infante:

5.230 Exposure to high density chrysotile products through demolition carries with it the potential risk of lung cancer, asbestosis and mesothelioma. Testimony presented at the OSHA hearings related to its Final Asbestos Standard that was promulgated in 1994 indicated that removal of intact chrysotile asbestos "transite" panels that were held in place by screws can result in airborne fibre concentrations that exceeded 1 f/cc. In this situation, the exposed surfaces were wet prior to removal and the operation was done within a negative pressure enclosure. Many transite panels used in interior wall construction consist of rough inner surfaces from which asbestos fibre is readily released into the air. Other testimony (OSHA, 1994) presented evidence that transite panels can be removed in a manner that results in exposure well below 0.1 f/cc when appropriate work practices are followed. Because of concern for the potential release of asbestos fibres into the air from such demolition, the OSHA standard requires that a "competent person" supervise such activities, e.g., make an assessment and determine that the type of controls being used are appropriate for the removal situation and that the required work practices are being followed. Therefore, the extent of the risk during demolition of chrysotile cement products depends upon the compliance with mandated requirements. (See my answer to Question 5(c) regarding compliance with procedures to reduce risk of disease from asbestos exposure.)

Dr. Musk:

5.231 In so much as demolition activities may result in airborne fibres there is a risk (as above).

1.(h) What is the risk to human health associated with high-density chrysotile wastes, such as chrysotile-cement waste? Can you quantify this risk?

Dr. de Klerk:

5.232 This depends on how the waste is treated and stored, depending of course on the chance of any fibres becoming airborne and hence respirable. Otherwise, see my answers to Questions 1(c) and (d).

Dr. Henderson:

5.233 See my response to Question 1(g).

Dr. Infante:

5.234 I have not researched this issue, but I am inclined to believe that there would not be much potential for fibre exposure from the handling of such waste unless a person at a waste site was hauling asbestos cement and not aware of the product he/she was moving.

Dr. Musk:

5.235 The risk posed by waste products will also be dependent on the chances of fibres becoming airborne as above.

1.(i) Can high-density chrysotile products wastes, such as chrysotile-cement wastes, be dealt with so as to eliminate risks to human health?

Dr. de Klerk:

5.236 They can, by following approved methods for disposal which ensure that fibres are sealed from airborne release. There is of course the chance that subsequent work (for example, waste removal) may disturb the waste and release fibres.

Dr. Henderson:

5.237 In theory, YES — once the asbestos-cement or other high-density product has been removed from its in-place location (though few data are available on exposure levels produced by the actual removal). For example, in Australia, imported chrysotile is delivered to production facilities in sealed plastic bags, so that the same procedure for bagging or encapsulation of high-density wastes should also be applicable, and should prevent release of asbestos fibres once the encapsulation or bagging exercise is complete, unless the bags are ruptured for one reason or another.

5.238 According to NICNAS 99 (p 74), in Australia:

> "Waste chrysotile, the polyethylene bags in which it is supplied, and chrysotile containing materials from the manufacturing process, are disposed to landfill by licensed disposal contractors. As chrysotile fibres are unlikely to be mobile in the soil or water table, landfill is not inappropriate from a public health perspective."

Dr. Infante:

5.239 I have not researched this issue.

Dr. Musk:

5.240 These risks may be eliminated if the fibres could be successfully sealed so that they cannot become airborne.

Question 2:

What is the risk to human health associated with other current applications of chrysotile asbestos (in particular, friction materials and textiles)? In occupational circumstances? In non-occupational circumstances?

Dr. de Klerk:

5.241 While the industries themselves may be well regulated, controlled and compliant with standards, the major problem again could occur in "downstream" users: boilermakers, plumbers, brake mechanics etc. Fibres released from friction products have a higher proportion of shorter fibres than those from textiles, which release the highest proportion of longer fibres.

Dr. Henderson:

(i) Friction Products (e.g. brake linings)

5.242 Automotive mechanics and garage workers constitute a large population of workers potentially exposed to chrysotile derived from brake linings. For example, brake blocks and linings used in Australia have contained only Canadian chrysotile for many years, and the materials are either imported as pre-formed brake blocks and linings, or chrysotile is imported into Australia for subsequent manufacture of these products. It has been estimated that this group of mechanics amounts to at least 900,000 workers in the US, and the figure may be even higher if one adds in all those who have ever worked in the automotive repair industry but then moved into other employments, and those who have retired.

5.243 For Australia, the number of persons employed as mechanics in 1991 amounted to 85,155 (84,293 males); for 1996, the corresponding figures are 83,647 (82,827 males), out of a total population of 16,852,256 in 1991 (8,363,677 males); for 1996, the total population was 17,892,423 (8,849,224 males). These figures for Australia include all mechanics, including automotive, brake and engine mechanics, together with supervisors and apprentices; the figures for 1996 also include mechanics' assistants (not included for the 1991 figures).[21] Taking into account the fact that the Australian population is less than $1/10^{th}$ that of the United States population, these statistics appear to be roughly comparable.

5.244 The literature contains anecdotal reports of malignant mesothelioma among automotive and brake mechanics. However, the question that arises is whether these anecdotal reports are explicable as the chance occurrence of spontaneous or background mesotheliomas among a large population of mechanics, or whether this group of workers has sustained other significant exposures to asbestos, including one or more amphiboles. In other words, the question is whether there is a general increase in the incidence of mesothelioma among automotive and brake mechanics with no other exposures to asbestos.

5.245 Brake repair workers are potentially exposed to asbestos during a number of procedures, which include removal of dust from bakes by air hoses, and a variety of other manipulations that include bevelling, grinding and drilling. Clearance of dust from brakes by use of an air hose can create a cloud of visible dust, and airborne fibre concentrations of 2.0 to 29.4 f/ml have been recorded in the immediate vicinity [225, 226]. Please see also Table 11 in EHC 203 (pp 42-43).

5.246 In North America, chrysotile has been used almost exclusively in brake linings since the 1940s; chrysotile is also the type of asbestos used in brake linings in Europe (and also Australia). As I mentioned previously, commercial chrysotile (e.g. Canadian chrysotile) contains on average small quantities of contaminant amphiboles in the form of tremolite (usually $\leq 1\%$).

5.247 However, the significance of this type of potential exposure among brake repair workers is complicated by a number of factors:

[21]Statistics supplied by the Australian Bureau of Statistics on 12 October 1999.

- During moderate braking of automobiles, temperatures as high as ≥ 500°C can be reached within the brakes, and at this temperature a proportion of the chrysotile undergoes dehydroxylation and recrystallization to form the mineral forsterite, which is not implicated in mesothelioma induction.

> "Heating of chrysotile at 700°C for an hour converts it to an amorphous, anhydrous magnesium silicate material ... Intensive dry grinding also destroys the structure of chrysotile. Analysis of wear debris from brake linings made with asbestos has shown that virtually all of the chrysotile fibre is converted to amorphous material, in association with the mineral forsterite (a recrystallization product). The conversion is explained by localized temperatures above 1000°C at the point of contact between the brake lining and the drum" ... . [EHC 203, p 14].

- Most chrysotile fibres released from brakes comprise short-length fibres < 0.4 μm in length (> 80 per cent of all chrysotile fibres from brakes). However, some fibres > 5 μm in length and even > 10 μm in length appear to survive (e.g. please see Table 11 in EHC 203). The short-length fibres appear to have only questionable or limited carcinogenicity, and this property is thought to reside primarily in fibres > 5 μm in length. In addition, limited fibre burden studies on brake repair workers have shown a low pulmonary asbestos content.

> "The fibres found in the brake wear debris are predominantly (99%) less than 0.4 μm in length … Rödelsperger *et al.*, (1986) found less than 1% of fibres longer than 5 μm." [EHC 203, p 14]

- One also needs to remember that assessment of mesothelioma risk among brake repair workers can be confounded by other occupational exposures to asbestos [227].

5.248 In a review of changing risk groups for malignant mesothelioma, Huncharek [228] gives the follow account for brake mechanics:

> "A major problem with epidemiologic studies of this workforce is the difficulty in tracing a large, non-unionized group of workers. Estimation of disease risk has been impeded by lack of quantitative data on exposure levels among individuals with long-term exposure. ...
>
> In 1976, investigators at the Mount Sinai School of Medicine studied asbestos exposure among brake repair workers in New York city. Both clinical examinations and fibre counts produced by various operations in brake maintenance workers were analyzed. Samples taken at a distance of 3-5 feet from brake drums during periods of blowing dust showed fibre concentrations of 6.6 to 29.4 fibres/ml, with a mean of 15.9 fibres/ml. In addition, ten samples of brake drum dust were analyzed by phase contrast, optical microscopic examination and transmission electron microscopic examination to determine the percentage of short fibres (i.e., 25-500 angstroms x 760 to 3750 angstroms[22]). Eighty-three percent of all chrysotile fibres were in this category, and almost 20% of the total mass of 10 samples was chrysotile (determined by electron diffraction). 'Throughout the examination by electron microscopy, attention was given to the morphology of the fibres. A majority of fibres showed little alteration in the typical chrysotile fibre'.
>
> In an additional report from Mount Sinai, Rohl *et al.* analyzed residual dust recovered from brake linings and made direct measurements of the free asbestos fiber content of 'workroom air' in areas in which brake lining maintenance and brake shoe installation occurred. Airborne asbestos dust concentrations were similar to those cited by Lorimer et al. (i.e., mean airborne fiber concentrations during compressed air blowing of brake drums ranged from 2.6 fibers/ml at a distance of 10-20 feet to 16.0 fibers/ml at 3-5 feet). Samples of brake drum dust showed that the proportion of chrysotile in this material averaged 3% to 6% (both as free fibre and as particulates in pulverized binder).

[22] 10,000 Ångstroms = 1.0 μm.

> Regarding the health effects resulting from the exposures described, Langer and McCaughey published ... a case of mesothelioma in a brake repair worker ... a 55-year-old man who had worked in the used car, tire and car repair business since the age of 19 years. He reported routinely servicing automobiles, including the replacement of brake linings. No other source of asbestos exposure was found.
>
> Analysis of lung tissue showed the presence of chrysotile fibres (no amphibole was found) confirmed by electron diffraction techniques. Ten percent of the fibers found were longer than 10 microns.[23] The authors point out that 'Controversy over the potential of chrysotile to cause mesothelioma has continued despite evidence from asbestos textile fabricators, thought to have used only chrysotile, from workers making brake pads, from chrysotile miners and millers, and from animal studies'. They also state 'The risk of malignant asbestos disease among these workers seems to be low but mortality data have yet to be thoroughly evaluated.'
>
> The most recent report of mesothelioma in a brake mechanic reviews a pleural mesothelioma occurring in a 47-year-old male automobile mechanic whose only known exposure to asbestos was from clutch and brake repair work during an 11-year period. ...
>
> Another case of mesothelioma in a brake repair worker was recently published. In this report, a 56-year-old male elevator mechanic ... reported working as an elevator mechanic for 30 years. He reported exposure primarily from elevator brake linings that he routinely cut, fitted, and removed during elevator installation and maintenance.
>
> Several recent studies from Scandinavia on this topic also deserve mention. Hansen, from the Institute of Community Medicine in Denmark, completed a historical cohort study examining the mortality of car mechanics from ischaemic heart disease and malignant neoplasms. The study cohort was identified using records of a nation-wide census carried out in Denmark in November 1970. Comparison was made with another cohort of skilled male workers who were not exposed to asbestos or 'petrochemical substances'. Of 583 observed deaths, one case of pleural mesothelioma was found.
>
> Likewise, Jarvholm and Brisman, in a 1998 report, used the Swedish death register and the census of 1960 to study the occurrence of asbestos-associated tumors in car mechanics. One hundred and eighty-seven deaths attributable to cancer were observed, whereas 154 were expected. Thirty-nine were caused by lung cancer, whereas only 23 were expected. Again, one death from pleural mesothelioma was found. ...
>
> It has been estimated that 20,000 deaths from asbestos-related cancer will occur during the next 40 years among automotive maintenance workers in the United States. With the many difficulties faced by epidemiologists studying this workforce, it is unclear how accurate this estimate will prove to be. Clearly, what is needed is better information on duration and intensity of exposure to respirable asbestos fibers in this occupational group. Additional study is needed to accurately determine the incidence of mesothelioma among members of this workforce." [pp 2704-2705].

5.249 The situation is further complicated by other reports on garage mechanics and workers involved in friction products manufacture [229, 230]. These studies have been reviewed briefly by Wong [231]: three found no increase in the RR for mesothelioma among garage mechanics (RR = 0.9, 0.65 and 1.0 respectively).

5.250 An analysis of > 13,000 workers at a UK friction products factory showed no detectable excess mortality due to lung cancer or other cancers; 13 mesotheliomas were found but 11 had known exposure to crocidolite [229, 232].

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[23]This relatively high proportion (10 per cent) in comparison to the smaller fraction of airborne fibres of the same size is presumably explicable by preferential clearance of short fibres from lung tissue, with a proportional increase of long fibres over time.

5.251 McDonald *et al.* [230] identified excess mortality from lung cancer among friction products workers, but there were no mesotheliomas:

> "A study by McDonald *et al*. (1984) investigated mortality due to lung cancer, mesothelioma and asbestosis in three US factories manufacturing friction products and packings. The cohort comprised 3641 men employed between 1938-1958. During the 1930s exposures for most processes were 1-5 mpcf (millions of particles per cubic foot) and > 10 mpcf during dry mould mixing. By the 1960s most exposures were < 0.5 mpcf. A significant excess of deaths (reference was to mortality rates for Connecticut) due to respiratory cancer was observed however this was not related to duration of employment. No cases of mesothelioma were reported. There was limited evidence of an increase in risk of lung cancer with increasing exposure. However the SMR for lung cancer was noted in workers with less than one year of service.
>
> A study by Finkelstein, (1989) investigated mortality rates among 1657 employees at two Ontario factories manufacturing chrysotile friction materials. The study population consisted of workers employed for at least 12 months after 1 January 1950. The study showed a significant increase in mortality from laryngeal cancer and lung cancer. No increase in mortality was noted from gastrointestinal cancer or from non-malignant respiratory disease. One or two deaths may have been due to pleural mesothelioma. Case-control analysis demonstrated a lack of association between the risk of death from laryngeal or lung cancer and the duration of employment or employment in departments where chrysotile had been used. The author also noted that cigarette smoking is a risk factor for laryngeal cancer and lung cancer, and therefore, increased risk may be in part attributable to differences in smoking habits." [NICNAS 99, p 65].

5.252 Similarly, Woitowitz and Rödelsperger [227, 233] found that:

> "There is no evidence that car mechanics are exposed to an increased risk of mesothelioma even if they do brake repairs, but asbestos exposure in other employment is an important confounding factor, so that if there is a mesothelioma risk for car mechanics but it was small, it would not be detectable."

5.253 Nonetheless, the 1999 Report for the Australian Mesothelioma Register[24] (AMR 99) records 58 mesotheliomas among brake mechanics with no other exposures to asbestos, during the almost 13-year period between 01 January 1986 and 31 October 1999 (total cases with a stated history of asbestos exposure = 2585). Mechanics who frequently or consistently work on brake linings and brake blocks represent only a sub-fraction of the total workforce of mechanics in Australia. If one takes the 1996 census figure of 82,827 for male mechanic[25], this amounts to 58 mesotheliomas in 1,062,946 person-years (≡ 54.6 mesotheliomas per million person-years). If one rounds off the workforce to 100,000 male mechanics, the figure becomes 45 mesotheliomas per million person-years. If one then doubles the workforce population to take into account retirees and other workers who moved on to other occupations (although a figure of 200,000 is almost certainly an overestimate because it would include all mechanics, whereas brake mechanics constitute a smaller sub-class), the mesothelioma rate becomes 22.6 per million person-years — well under the rate of 337 mesotheliomas per million person-years for the Quebec chrysotile miners and millers but still substantially above the upper limit of the estimated background rate of 1-2 mesotheliomas per million person-years (about 10-fold). One might suspect that mesotheliomas in brake mechanics will cluster in those involved in the grinding, bevelling and other operations on new brake blocks and brake linings (i.e. brake materials unaltered by heat).

5.254 Using an earlier set of data for Australia, NICNAS 99 came to a similar conclusion:

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[24]The Register is a compilation of all and unselected mesotheliomas throughout Australia.

[25]This over-estimates the number of brake mechanics, because the figure includes all automotive mechanics, engine mechanics, apprentices, and supervisors: Australian Bureau of Statistics, 12 October 1999.

> "Out of 2119 mesothelioma cases registered (with a response to history) for the period 1986-1995, 46 cases were listed for the category 'brake lining - manufacture/repair', 40 of which were recorded in car mechanics, of which 37 were exposed to asbestos in this occupation only ... Overall the numbers indicate a slight increase of around 1-2 cases per year, which is roughly proportional to the growth rate of all mesothelioma cases in Australia" ... [p 66].

5.255 It is apparent that these considerations apply to occupational circumstances.

5.256 Evidence indicates that the general population is exposed to only very low levels of asbestos derived from the braking of passing automobiles, and that most of these fibres represent short-length fibres and heat-altered chrysotile. NICNAS 99 has this to say on the subject:

> "It is claimed that the amount of asbestos found in the dust arising from braking is rarely more than 1% of the wear product (Asbestos Information Committee, 1975). It is not known what quantity of chrysotile is imported in brake linings and other friction materials, but ABS [Australian Bureau of Statistics] data indicates in excess of 750,000 articles (brake linings, pads and clutch facings) being imported in 1997 containing asbestos and therefore possibly containing chrysotile. Assuming each unit weighs 200 g and contains 50% chrysotile, this equates to around 150 tonnes of chrysotile per annum. Assuming a further 1000 tonnes of chrysotile present in friction products manufactured in Australia, it is estimated that (assuming a worst case scenario of 1% release per annum, i.e. all products are completely worn in one year), around 11.5 tonnes of chrysotile will be released per annum countrywide or 32 kg per day spread all around the country. It is acknowledged that this figure may be an overestimate, as studies have shown that some of the chrysotile is degraded to magnesium silicates and forsterite ... In addition, some of the debris will be retained in the brake system and removed and disposed of under controlled conditions." [p 78].

(ii) Exposure from chrysotile textile materials

5.257 Table 14 represents a reproduction of Table 7 in EHC 203 for exposure estimates in the South Carolina chrysotile textile plant (1930-1975) before and after controls on exposure levels. As can be seen from this Table, the application of controls on exposure levels produced a significant reduction of exposure, and currently available control technology allows even lower levels to be attained (EHC 203).

5.258 EHC 203 refers to a study in Japan which reported a geometric mean concentration of 0.1-0.2 f/ml in the period 1984-1986, for asbestos spinning. From published studies, it seems clear that asbestos textile workers are at greater risk for asbestosis (historically) and lung cancer than mesothelioma. EHC 203 also gives the following comments:

TABLE 14: EXPOSURE ESTIMATES IN A CHRYSOTILE TEXTILE PLANT (1930-1975)
(ESTIMATED MEAN EXPOSURE TO FIBRES LONGER THAN 5 μM IN F/ML)

Operation	Without controls	With controls
Fibre preparation	26.2-78.0	5.8-17.2
Carding	10.8-22.1	4.3-9.0
Spinning	4.8-8.2	4.8-6.7
Twisting	24.6-376.0	5.4-7.9
Winding	4.1-20.9	4.1-8.4
Weaving	5.3-30.6	1.4-8.2

From Dement *et al.* (1983)

> "Studies that correlate disease prevalence or symptoms with cumulative exposure can under-estimate disease risk due to progression of disease after employment ceases. Although workers were exposed to both chrysotile and crocidolite (the latter being approximate 5% of all asbestos used), results for 379 men employed at least 10 years in the Rochdale asbestos textile plant are informative ... Exposure estimated from work histories range from an average of 2.9 to 14.5 f/ml. Overall, small opacities (> 1/0) were reported in 88/379 (23%) of chest radiographs, with evidence of a gradient seriously confounded by date of first employment and transfer of subjects with suspected asbestosis to less dusty conditions. On the basis of data on incidence, the authors drew conclusions on exposure-response between cumulative exposure and prevalence or incidence of crepitations, possible asbestosis and certified asbestosis - all three depending on clinical opinion and judgement. The authors state that possible asbestosis occurs in no more than 1% of men after 40 years of exposure to concentrations between 0.3 and 1.1 f/ml" [EHC 203, p 105].

5.259 On p. 114, EHC 203 goes on to discuss other consequences of exposures sustained during textile manufacture:

> "The health of employees has been studied in any detail in only three asbestos textile plants. These comprise a factory at Rochdale, England, originally studied by Doll (1955) and more recently by Peto *et al.* (1985), another located in Mannheim, Pennsylvania, USA, studied by McDonald et al. (1983b) and a plant in Charleston, South Carolina, USA. Only the study in South Carolina is considered primarily relevant for assessment of the health effects of chrysotile. Although the SMRs for lung cancer in these plants were broadly equivalent, the rates of mesothelioma varied considerably, which may reflect the greater proportions of amphiboles in the Mannheim and Rochdale cohorts.
>
> The textile workers in South Carolina plant have been studied in two separate but overlapping cohorts ... . The only amphibole used in this plant was approximately one tonne of imported crocidolite from the early 1950s until 1972, plus a very small quantity of amosite for experimental purposes briefly in the late 1950s. The crocidolite yarn was processed at a single location only, so Charleston can be considered an almost pure chrysotile operation. Exposure levels for workers at this plant were estimated by Dement *et al.* (1983a) using nearly 6000 exposure measurements covering the period 1930-1975 and taking into account changes in plant processes and engineering controls (Table 7). The conversion of past exposures measured in mpcm (mpcf) to f/ml was based on both paired sample data (100 pairs) and concurrent samples (986 samples) by these two methods collected in plant operations during 1968-1971.
>
> The most recent update of the Charleston study by Dement *et al.* (1994) demonstrated an overall lung cancer SMR of 1.97 (126 observed) and an overall SMR for non-malignant respiratory diseases ... of 3.11 (69 observed). The data for white males, for which data were more complete, demonstrated an overall lung cancer SMR of 2.34 for those achieving at least 15 years of latency. The risk of lung cancer was found to increase rapidly in relation to cumulative exposure. Data for the entire cohort demonstrated an increase in the lung cancer risk of 2-3% for each fibre/ml-year of cumulative chrysotile exposure. Two mesotheliomas were observed among this cohort and an additional mesothelioma was identified among plant workers, occurred after the study follow-up period. Analyses of an overlapping cohort from the same factory ... provided similar results.
>
> ... the regression line slopes for relative risks of lung cancer in relation to accumulated exposure in the Charleston plant are all some 30 times steeper than those observed in chrysotile mining and cement product manufacture."

5.260 From the foregoing discussion, it is plain that these risks apply to occupational circumstances, and not to non-occupational situations. It is my perception that there is debate among experts over the carcinogenicity of chrysotile released from or associated with friction products and textiles respectively.

Dr. Infante:

5.261 Exposure to chrysotile asbestos through the manufacturing and downstream manipulation of friction products and textiles carries with it the risks associated with exposure to asbestos, most notably, lung cancer, asbestosis and mesothelioma. This is mostly an occupational issue except for consumers, who do their own brake replacement which would put them at risk of developing these diseases.

5.262 Epidemiological studies of workers involved in the manufacturing of friction products demonstrate an elevated risk of lung cancer (McDonald *et al.* 1994). Other investigators have not observed an excess of lung cancer in the manufacturing of chrysotile and cricidolite containing friction products, but have identified cases of mesothelioma related to both types of asbestos used to produce these products (Berry and Newhouse, 1983). Cases of mesothelioma also have been reported among car mechanics who serviced brakes containing chrysotile fibres only and were exposed to levels estimated to be below 1 f/cc-year cumulative exposure (Woitowitz and Rodelsperger, 1991). Epidemiological study results indicate a high risk of disease related to chrysotile textiles. See my responses to Questions 4(a)-4(c).

Dr. Musk:

5.263 It is my opinion that there is a risk of disease from the release of chrysotile fibres from friction materials (as in brakes and clutches) or textiles (as in asbestos blankets and suits). In general the risk will be dependent on the degree of exposure (as above) and is therefore likely to be greater in people with occupational rather than non-occupational exposure. Fibres released from friction materials may be shorter than from other sources. These fibres may clear more rapidly from the lungs and possibly be related to lower risks but I am not aware of any direct data on this.

Question 3:

The parties disagree as to the relative pathogenicity of amphibole and chrysotile asbestos. Canada argues that, due to chemical and physical differences, a crucial distinction is to be made between amphibole and chrysotile asbestos: the latter is less pathogenic than the former. The European Communities, on the other hand, argues that chrysotile is as dangerous as amphiboles. In answering the four sub-questions below, please specify to what extent your opinion is based on epidemiological data, in vivo or in vitro evidence.

3.(a) For the purpose of assessing the risk to human health arising from exposure to asbestos fibres, should a distinction be made between chrysotile and amphibole asbestos?

Dr. de Klerk:

5.264 In terms of risks to human health, epidemiological evidence is clear that, for a given quantity (intensity and duration) of exposure, chrysotile imparts less risk than amphibole fibres.

Dr. Henderson:

5.265 YES — a clear distinction should be made between chrysotile and the amphibole forms of asbestos. On a fibre-for-fibre basis, amphiboles such as crocidolite and amosite are substantially more carcinogenic for the mesothelium than chrysotile. This potency differential is to some extent confounded by the far greater usage of chrysotile both now and historically (> 95 per cent of world asbestos production). In addition, it is worth reiterating that Canadian chrysotile on average contains trace quantities of fibrous tremolite (an amphibole).

5.266 It is my perception that there is broad agreement among experts that the amphiboles are more potent carcinogens for the mesothelium than chrysotile.

Dr. Infante:

5.267 For purposes of assessing disease risk from exposure to asbestos fibres, I see no basis for making a distinction between chrysotile and amphibole asbestos. Several high quality epidemiological studies of workers exposed to chrysotile asbestos demonstrate an elevated risk of death from lung cancer, asbestosis and mesothelioma. The risk of death from lung cancer and asbestosis related to chrysotile exposure appears to be similar to that from exposure to other forms of asbestos. Although epidemiological study suggests that the risk of death from mesothelioma from chrysotile exposure may be less than the mesothelioma risk from amphibole asbestos, it is somewhat difficult to make this comparison. Many of the studies of workers exposed to amphibole asbestos go back further in time and less information is available on the quantitative aspects of exposure. Thus, the role of error in exposure estimation on the perceived difference is difficult to determine. On the other hand, some experimental inhalation studies demonstrate that chrysotile asbestos may be more potent than other forms of asbestos in the induction of mesothelioma (and lung cancer) in relation to the amount of dust deposited in the lungs (Wagner *et al.,* 1974). In any event, the attributable risk of respiratory diseases from exposure to asbestos is going to be heavily weighted by lung cancer and asbestosis. So, even if exposure to chrysotile asbestos would result in a slightly lower relative risk of death from mesothelioma, the overall risk of the asbestos related diseases combined, i.e., lung cancer, asbestosis, mesothelioma, decrements in pulmonary function, will not be perceptively different for chrysotile as compared to the amphiboles. Thus, a distinction should not be made between chrysotile asbestos and amphibole asbestos. In my opinion, exposure to all forms of asbestos results in a significant disease burden to society.

5.268 I believe that there is a need to distinguish chrysotile asbestos from amphiboles based on the epidemiological data at least.

3.(b) What are the key properties which cause pathogenicity of, respectively, amphiboles and chrysotile fibres for (i) asbestosis, (ii) lung cancer, (iii) mesothelioma, and (iv) other asbestos-related pathologies?

Dr. de Klerk:

5.269 The properties are the same: size, shape and durability in the lung, that is fibres have to be of certain size and shape to be deposited in the lungs and have to stay there long enough to produce a response. Since most of the body's responses to fibres appear to be stochastic in nature, the additional features are of course the intensity and duration of exposure as outlined above. All the types of asbestos differ according to these properties, the main difference with chrysotile is that it is less durable in lung tissue than amphibole fibres: it is more soluble and the fibres tend to break more readily into smaller fibrils, it also tends to be more curly rather than dead straight in shape.

Dr. Henderson:

5.270 As discussed already, the pathogenicity of asbestos appears to reside in the physical properties and biopersistence of the fibres, summarized as the 3 Ds — namely dose, fibre dimensions and durability (bio-persistence). All commercial asbestos has the capacity to induce asbestosis, lung cancer, mesothelioma and other pleural abnormalities (e.g., parietal pleural fibrous plaques, benign asbestos pleuritis with effusion, and diffuse pleural fibrosis). Chrysotile and the amphiboles have different potencies in generating these disorders: for example, the amphibole varieties of asbestos appear to be substantially more pathogenic than chrysotile for the induction of asbestosis and mesothelioma, whereas the differential is not sustained for the induction of lung cancer, for which

chrysotile is associated with one of the lowest lung cancer rates (in Quebec chrysotile miners and millers) and the highest rate of lung cancer (South Carolina asbestos textile workers, who used Canadian chrysotile).

5.271 Asbestosis: There is good evidence that asbestosis is a dose-dependent disorder with a threshold effect. There is widespread agreement that asbestosis in general is a consequence of high intensity exposure (or lower intensity but more prolonged exposure) than mesothelioma not associated with asbestosis, so that the concentration of asbestos bodies and uncoated asbestos fibres within the lung tissue of asbestotics is considerably higher than the concentrations encountered in mesothelioma patients without asbestosis and in individuals with parietal pleural plaques. In addition, some studies have shown that the severity of asbestosis and its liability to progression are related to the asbestos body and fibre concentration in lung tissue. In the past, asbestosis as a consequence of high-dose exposure was a progressive disorder leading to progressive respiratory insufficiency and death, whereas many cases of asbestosis encountered during the 1980s and 1990s represent milder and static forms of the disease.

5.272 Churg [234] points out that:

> " ... a considerably greater burden of chrysotile (with its accompanying tremolite) than of amosite or crocidolite is required to produce any particular diseases. ... For example, the mean burden of chrysotile plus tremolite in the lungs of [Quebec chrysotile] miners and millers with asbestosis is 17 times the amosite burden in the lungs of shipyard workers with asbestosis." [p 294].

5.273 To some extent, this differential in potency may reflect fibre dimensions and the generation of oxidants, but a more likely explanation is the faster clearance of chrysotile from lung tissue than any of the amphiboles. However, Churg's comments seem to apply to Quebec chrysotile miners and millers in particular; in contrast, the study reported by Green *et al*. [191], which reported histological asbestosis at relatively low cumulative exposures was carried out on South Carolina asbestos textile workers who also worked with Canadian chrysotile (please see following discussion).

5.274 There is also evidence that long fibres are implicated in the development of asbestosis, but this may reflect in part the anatomical distribution of long versus short fibres in lung tissue. For example, some studies have shown that short fibres in the vicinity of 1 µm in length have a biological potency similar to that of the longer fibres for initiation of the inflammatory changes implicated in the development of asbestosis, but they do not penetrate the walls of bronchi or bronchioles to the same extent as the longer fibres, to reach the alveolar interstitium. Another study related the development of asbestosis to the total surface area of deposited fibres, rather than to particular lengths of fibres.

5.275 The effect of dose: There is good evidence that the inhaled dose of asbestos affects: (i) the development of the disease itself; (ii) the latency period between exposure and the onset of the disease; and (iii) the severity and progression of disease.

5.276 Fibre burden studies on human lung tissues show that patients with asbestosis in general have higher tissue burdens than patients with asbestos-related diseases other than asbestosis. Accordingly, Mossman and Churg [202] state that:

> " ... asbestosis is clearly a fiber-dose driven disease but, nonetheless, only a fraction of any cohort exposed to a fibrogenic dose of asbestos develops asbestosis. It has been proposed that person-to-person variations in either fiber deposition or fiber clearance may account for this phenomenon." [p 1671].

5.277 The Ontario Royal Commission [235] noted that asbestos exposures < 25 fibre-years would be unlikely to produce clinical asbestosis (about ≤ 1 per cent of individuals exposed at this level may

develop clinical or radiological asbestosis), whereas Browne [236] considered that the minimum dose required to produce clinical asbestosis was in the range of 25-100 fibre-years.

> "Chest X-ray changes among textile and friction product workers in China were reported by Huang (1990). A total of 824 workers employed for at least 3 years in a chrysotile products factory from the start-up of the factory in 1958 until 1980, with follow-through to September 1982, were studied. Chest X-ray changes compatible with asbestosis were assessed using the Chinese standard system for interpretation of X-rays. Cases were defined as Grade I asbestosis (approximately equivalent to ILO ≥ 1/1). Overall, 277 workers were diagnosed with asbestosis during the follow-up period, corresponding to a period prevalence of 31%. Exposure-response analysis, based on gravimetric data converted to fibre counts, predicted a 1% prevalence of Grade I asbestosis at a cumulative exposure of 22 f/ml-years." [EHC 203, p 106]

5.278 In an autopsy study of South Carolina asbestos textile workers who used Canadian chrysotile — the same group studied by Dement *et al*. [171, 172, 237-241] and McDonald et al. [161, 242] — Green et al. [191] showed that histological asbestosis was usually present at ≥ 20 fibre-years of exposure, and a few cases were observed at 10-20 fibre-years. Thimpont and de Vuyst [243] reported that around 50 per cent of specimens of lung tissue removed because of lung cancer showed low-grade airway and interstitial fibrosis with asbestos bodies, when the asbestos body concentration was ≥ 5000 per gram dry lung tissue.

5.279 These different threshold doses are not inconsistent with each other, because they deal with identification of asbestosis by different modalities (i.e. clinical/radiological asbestosis versus histological asbestosis). In this respect, histological examination is generally considered to represent the most sensitive and specific technique for the diagnosis of asbestosis, followed in descending order by high-resolution CT scanning, conventional CT scans and chest X-rays (which will fail to detect asbestosis in about 20 per cent of cases, especially low-grade asbestosis). In other words, early (grade I) asbestosis may be undetectable by clinical investigations.

5.280 Latency interval: there is also evidence that the latency period between first exposure to asbestos and the subsequent diagnosis of asbestosis is roughly inversely proportional to the exposure level, so that short latencies are encountered with high exposures (e.g. the Wittenoom cohort).

5.281 Mossman and Churg [202] also state that:

> "Fibre burden studies also indicate that there is a correlation between pathologic severity of asbestosis and increasing burden of asbestos bodies (which are largely markers of amphibole exposure) or uncoated amosite and crocidolite fibres" ... . [p 1670].

5.282 There are two additional points that are worth emphasis:

- There appears to be considerable variation among individuals in their propensity to develop asbestosis (or variation in the latency intervals for equivalent exposures). For example, I have seen cases where there was a high content of amphibole asbestos in lung tissue (up to 100 million fibres per gram dry lung tissue or more), in the absence of histological asbestosis — at the time when the fibre burden analysis was carried out — whereas other cases had clinical asbestosis with much lower tissue fibre burdens. Of course, one caveat about this situation concerns latency, whereas another relates to the time when the fibre burden analysis was carried out, which is different from the time when the disease was developing.

- In addition to high fibre burdens, the severity and progression of asbestosis can be

influenced by other factors, such as cigarette smoke (though tobacco smoke by itself cannot cause asbestosis, of course).

5.283 Mesothelioma: Please see discussion in Section C.1.(f) to(h).

5.284 Lung cancer: Please see discussion in Section C.1.(i).

5.285 Other asbestos-related pathology: The effect of dose is less clear for the induction of parietal pleural fibrous plaques than for other asbestos-related disorders. There is evidence that the frequency and extent of plaques are dose-related, so that plaques tend to be more extensive with higher exposures. However, plaques can also follow trivial exposures to asbestos and asbestos-like minerals, so that the frequency of asbestos-related pleural plaques appears to correlate more closely with duration since exposure than the level of exposure. Plaques are known to be endemic in Finland, apparently as a consequence of very low-level exposure to asbestos-like fibres in the general environment; on the other hand, in societies where plaques are not endemic — e.g. North America, Western Europe and Australia — about 80-90 per cent of radiologically well-defined plaques are a consequence of occupational exposure to asbestos. In such societies, pleural plaques also represent a useful tissue marker for prior asbestos exposure. At the same time, it is also worth emphasising that parietal pleural plaques by themselves do not predispose to any other asbestos-related disorder, the liability being related to inhaled dose and fibre types.

Dr. Infante:

5.286 The key properties of the pathogenicity of amphiboles and chrysotile fibres, although not known for certain, are thought to be related to the physical characteristics of the fibres, namely the diameter, length, aspect ratio of length to diameter, surface area and perhaps surface charge of the fibres. Toxicological data suggest that long thin asbestos fibres may be relatively more potent than other asbestos fibres in their ability to induce asbestos related diseases. There is also experimental evidence, however, that shorter fibres can produce asbestos related diseases, though not in as great a magnitude. Any manipulation of these fibres that results in their diameter becoming thinner may provide a relatively greater contribution to the associated pathology and a greater toxic response than if the fibres were not manipulated in any way. The issue of solubility has been raised in terms of asbestos fibres and their capability to cause disease. The role of solubility with asbestos fibres and disease potential, however, is not so clear because chrysotile asbestos seems to have the same overall potency as other forms of asbestos, yet chrysotile fibres appear to be relatively more soluble than amphibole fibres.

Dr. Musk:

5.287 It is my opinion that the key characteristics determining the pathogenicity of asbestos for asbestosis, lung cancer, mesothelioma and other diseases are determined by the physical and chemical characteristics of the asbestos. The physical characteristics include length, diameter and "straightness" of the fibres. The chemical properties determine the durability of the fibres.

3.(c) What is the respective capacity of amphiboles and chrysotile to induce (i) asbestosis, (ii) lung cancer, (iii) mesothelioma, and (iv)other asbestos-related pathologies?

Dr. de Klerk:

5.288 Comparisons between chrysotile and the amphiboles in their capacity to produce mesothelioma and lung cancer have been extensive, for the other diseases, much less so. There is some *in vitro* and *in vivo* evidence that amphiboles, particularly crocidolite, are more fibrogenic than chrysotile, but there is no clear epidemiological evidence on this. Pleural plaques appear to be more

common among anthophyllite workers than others while crocidolite workers have more diffuse pleural thickening, and benign asbestos pleurisy also seems to be more common after crocidolite exposure. Historically, asbestosis occurred commonly after heavy exposure to all types of asbestos. For mesothelioma, it is thought that for a given cumulative exposure, chrysotile is between one tenth and one hundredth as potent as crocidolite. There is some controversy over the relative capacity of amosite and crocidolite, but amosite seems to carry about one tenth of the risk of crocidolite. For lung cancer, amosite and crocidolite seem to have similar capacities, with chrysotile weighing in around one tenth to one fiftieth of this.

Dr. Henderson:

5.289 See my response to Question 3(b).

Dr. Infante:

5.290 The quantitative risk of dying from lung cancer as a result of exposure to chrysotile asbestos is at least as great as that from exposure to other forms of asbestos. Quantitative risk assessments based on several epidemiological studies indicate a very high risk of lung cancer (potency) among workers exposed to chrysotile asbestos. The cohort study by Dement et al., first published in 1983 and updated in 1994 contains one of the best estimates of worker exposure to chrysotile accompanied by the estimates of relative risk (RR) for lung cancer and asbestosis. In this study, the investigators determined conversion ratios from the available industrial hygiene data by evaluating sampling results from surveys that used the impinger method to measure dust in million particles per cubic foot (MPPCF), and membrane filter samples that allowed for the counting of fibre concentrations. For early exposure periods, the investigators converted one MPPCF to the equivalent of 3 f/cc > 5 um in length for all areas except for preparation where a conversion factor of 8 fibres for every MPPCF was used. In my opinion, this study is the strongest in its methodology for estimating asbestos exposure among cohort members. Quantitative risk assessment based on data for the entire cohort estimates an increase in the RR of lung cancer ranging from 2-3 per cent for each fibre/cc-year of cumulative chrysotile exposure. To my knowledge, this is the highest estimated risk of lung cancer among asbestos exposed workers that has been corroborated by other investigators, i.e., the same population was also studied by McDonald et al., (1983) and the results are remarkably similar. Studies of lung cancer risk among chrysotile asbestos textile workers from two additional occupational cohorts by McDonald et al., (1982) and Peto et al., (1985) also provide similar results. Using data from the McDonald et al., (1983) study and a conversion factor of 6 fibres per MPPCF, Peto et al., (1985) estimated an increase in the RR of lung cancer among chrysotile textile workers to be 1.25 per cent per fibre/cc-year of exposure. From their own study of Rochdale textile workers, Peto et al., (1985) estimated the excess lung cancer risk to range from 0.5-1.5 per cent per f/cc-year of cumulative exposure depending upon whether the estimate was based on the entire cohort or on those employed in 1951 or later, respectively. These estimates are of surprisingly similar magnitude given that they are from epidemiological studies that incorporated retrospective exposure estimation that had to rely upon the conversion of measurements from particles to fibres per cc. Thus, three separate populations of chrysotile asbestos textile workers demonstrate remarkably similar elevated risks of lung cancer and therefore add to the confidence of the estimates of excess lung cancer risk per unit of fibre exposure that these studies demonstrate.

5.291 Studies of workers exposed to chrysotile in several industries demonstrate a significantly elevated risk of lung cancer. Studies of workers exposed to a combination of chrysotile and cricidolite, or to chrysotile only in cement production (Hughes et al., 1987) indicate a virtually identical excess risk of mortality from lung cancer. In a study of workers exposed to crocidolite in mining, de Klerk et al., (1989) estimate an elevated relative risk of lung cancer of 1 per cent per f/cc-year of exposure. Essentially, the excess relative risk for lung cancer indicated in all of these studies is close to about 1 per cent per fibre per cc-year of exposure (Stayner et al., 1997). The risk of lung

cancer from chrysotile asbestos exposure is at least as great as the risk of lung cancer associated with amphibole asbestos exposure.

5.292 Analyses based on the study by McDonald et al. (1993) indicates a much lower dose response for lung cancer in relation to chrysotile asbestos in mining and milling as compared to the risk estimates from other studies, particularly chrysotile textile workers. I suspect, however, that the fibre exposure from this study may be overestimated, particularly among the portion of the cohort that is comprised of miners and that a fair amount of misclassification took place in the amount of fibre exposure estimated for individual cohort members.

5.293 Gibbs and Lachance (1972) who published the initial exposure estimates for this population of workers stated that their cumulative dust concentrations for the cohort members may have been far from their actual experience. Subsequent dose response analysis of this cohort applied only a single conversion factor to estimate fibre exposures from the dust count data for the entire cohort. In the study of Siberian chrysotile miners and millers (Tossavainen et al., 1999), those involved in mining experienced average exposures of 0.08 f/cc, while those involved in two separate mills experienced average exposures of 3.62 f/cc (ranges of average exposures for different milling operations 0.37-6.21 f/cc) and 0.65 f/cc (range of average exposures 0.20-1.26 f/cc). The gravimetric sampling results indicate a 5-fold difference in average exposure for miners versus millers, while the sampling results for fibre exposures (the exposure of concern) indicate a 45-fold difference in average exposure concentrations between miners and millers. Taking into consideration the variation within mining and milling jobs, the difference between exposures to workers involved in these jobs would be even greater. The large difference in the fibre exposures between miners and millers that was observed in the Tossavainen et al. (1999) study adds further support to my concern that applying a single conversion factor from dust samples in estimating chrysotile fibre exposures for miners and millers is the most likely explanation for the slope of the dose response for lung cancer in the McDonald et al. study being so different from the slope for lung cancer based on the studies of chrysotile textile workers. Stayner et al. (1996) provide a summary of data indicating that the lung cancer risk from exposure to chrysotile in either experimental animals or in humans is similar to the risk from exposure to amphibole asbestos in these species.

5.294 With regard to asbestosis, Stayner et al. (1997) published a dose response analysis based upon the updated study of chrysotile textile workers by Dement et al. (1994). Their analysis indicates an excess risk of 2 deaths from asbestosis per 1000 employees exposed to 0.1 f/cc for an occupational lifetime exposure of 45 years, or 0.2 per cent from a cumulative exposure of 4.5f/cc-years. Two additional studies estimate similar risks of death from asbestosis in relation to cumulative chrysotile exposure. The study by Berry et al. (1979) estimates a risk of 1 per cent for those categorized as "probably having asbestosis" among chrysotile textile workers who were exposed to an estimated range of 0.3 f/cc to 1.1 f/cc for 40 years, or a cumulative exposure of 12-44 f/cc-years. For those categorized as "certified asbestosis" a 1 per cent excess risk of death was associated with 63 f/cc-years of exposure. Huang (1990) estimates a risk of asbestosis of 1 per cent associated with 22 f/cc-years of exposure during the manufacturing of chrysotile textile and friction products. Data from Dement et al. (1994) allow for an estimate of 2 per cent asbestosis associated with 22.5 f/cc-years of exposure. Studies of workers exposed to a mixture of chrysotile and crocidolite asbestos in the manufacture of cement products have demonstrated an elevated the risk of "certified asbestosis" of 1 per cent associated with 10 f/cc-years of exposure (Finkelstein 1982). Finkelstein was of the opinion that he identified a 1 per cent excess risk of asbestosis related to a lower cumulative dose of asbestos exposures than Berry et al. (1979) because of the longer period of follow-up of the cohort which gave more time for the asbestosis to clinically manifest itself.

5.295 I am not aware of evidence that similar cumulative exposures to amphibole forms of asbestos will result in a greater risk of asbestosis. Thus, it is difficult to make any distinction in potency between the amphiboles and chrysotile asbestos in relation to asbestosis.

5.296 Chrysotile exposures related to numerous jobs and occupations has been associated with mesothelioma through epidemiological studies and case reports. In some situations, standby exposure only was associated with mesothelioma. Based on epidemiological studies, the potency of chrysotile to induce mesothelioma may be less than that from other forms of asbestos. However, the rarity of mesothelioma in the general population and the difficulty in determining asbestos exposure levels experienced by cohort members decades before measurements were taken, coupled with conversion of dust counts in particles to fibres per cc, make it difficult to determine differences in potency estimates with regard to the various forms of asbestos and mesothelioma. Based on toxicological study results, in terms of the quantity of dust deposited and retained in the lungs, chrysotile may be more potent than other forms of asbestos in the induction mesothelioma and fibrosis (Wagner et al., 1974). The population attributable risk of contracting mesothelioma from chrysotile, however, will be greater than from other forms of asbestos because of the much greater potential for exposure to chrysotile.

5.297 I have not seen any quantitative data related to decrements in lung function for either chrysotile and amphibole asbestos. On the basis of mortality from asbestosis, I assume there is little difference in lung function related to the various forms of asbestos.

5.298 In summary to this question, in evaluating the epidemiological evidence, I see no basis for concluding that the overall disease potential from exposure to the amphiboles is any different than that from exposure to chrysotile asbestos with the possible exception that amphiboles may be more potent in causing mesothelioma and chrysotile may be more potent in causing lung cancer. Studies in experimental animals demonstrate the ability of chrysotile asbestos as well as the amphiboles to induce fibrosis, lung cancer and mesothelioma. From a public health standpoint, in terms of quantification of disease, it would be extremely difficult to make any distinction between exposure to the amphiboles and chrysotile asbestos fibres.

Dr. Musk:

5.299 Broadly it is my understanding that the relative pathogenicity of the different fibres for the various diseases is different (see Table)

	CROCIDOLITE	**AMOSITE**	**ANTHOPHYLLITE**	**CHRYSOTILE**
Asbestosis	1	1	1	1
Lung cancer	10	10	10	<1
Mesothelioma	100	10	5	1
Benign asbestos pleural effusion/ diffuse pleural thickening	100	10	10	1
Pleural plaques	1	1	10	1

<u>Question 4</u>:

The parties in this dispute disagree as to the risk to human health associated with chrysotile asbestos fibres at low levels of exposure, i.e. either prolonged exposure to low concentrations of fibres or occasional peaks of exposure. The European Communities considers that, because of a lack of data at low levels of exposure, it is appropriate to endorse the linear relationship model to assess risks associated with such low levels of exposure. On the other hand, Canada is of the view that, at such low levels of exposure, empirical evidence suggests that there is a practical threshold below which chrysotile asbestos fibres present no measurable effects on health.

4.(a) Are epidemiological data available for low levels of exposure to chrysotile fibres and what do they show?

Dr. de Klerk:

5.300 There have been several epidemiological studies that have shown no increased risk for low levels of exposure to chrysotile, particularly in friction products industries.

Dr. Henderson:

5.301 So far as I am aware, there are no exposure-response data for such levels of exposure.

5.302 For example, EHC 203 states the following:

> "Few data on concentrations of fibres associated with the installation and use of chrysotile-containing products are available, although this is easily the most likely place for workers to be exposed" [EHC 203, p 3.].
>
> "Overall, the available toxicological data provide clear evidence that chrysotile fibres can cause fibrogenic and carcinogenic hazards to humans. The data, however, are not adequate for providing quantitative estimates of the risk to humans. This is because there are inadequate exposure-response data from inhalation studies, and there are uncertainties concerning the sensitivities of the animal studies for predicting human risk" [EHC 203, p.7].
>
> "There is evidence that fibrous tremolite causes mesothelioma in humans. Since commercial chrysotile may contain fibrous tremolite, it has been hypothesized that the latter may contribute to the induction of mesotheliomas in some populations exposed primarily to chrysotile. The extent to which the observed excesses of mesothelioma might be attributed to the fibrous tremolite content has not been resolved" [EHC 203, p 8-9].
>
> "Epidemiological studies that contribute to our understanding of the health effects of chrysotile conducted to date and reviewed in this monograph have been on populations mainly in the mining or manufacturing sectors and not in construction or other user industries. This should be borne in mind when considering potential risks associated with exposure to chrysotile" [EHC 203 , p 137].

Dr. Infante:

5.303 One means of determining the risk from low exposure levels for carcinogens is to estimate the risk from studies where exposure information is of reasonably good quality and the estimates of risk were made using sound epidemiological principles and methodology. Once these studies have been identified, an appropriate way to determine quantitative risk from low exposure levels is to use all of the available data in a particular study and to estimate dose response. As mentioned in my response to Question 3(c) above, several studies of workers exposed to chrysotile asbestos can be used to estimate risk from low levels of exposure. The studies mentioned above, which represent three separate populations of chrysotile textile workers demonstrate an excess relative risk of lung cancer ranging from 0.5-3 per cent for each fibre/cc-year of exposure. Risk assessment based on the study of South Carolina chrysotile textile workers (Stayner et al., 1997) indicates that individuals exposed to 0.1 f/cc-year for an occupational lifetime of 45 years, e.g., 4.5 f/cc-years cumulative exposure to chrysotile, have an elevated risk of 5 extra deaths from lung cancer and 2 extra deaths from asbestosis per 1000 workers. Dose response for mesothelioma could not be estimated because there were too few deaths from this cause in the study.

5.304 Epidemiological study results and case reports indicate that a large number of jobs which entail occasional peak exposures to chrysotile asbestos have resulted in workers being diagnosed with

mesothelioma. Furthermore, mesothelioma has been diagnosed among household contacts of asbestos cement workers (Magnani et al., 1992; Ascoli et al., 1996), among individuals living near chrysotile mining and milling operations (Began et al., 1992), or living in houses constructed with asbestos cement (Ascoli et al., 1996), or who were exposed to low cumulative amounts of chrysotile asbestos from brake lining work (Woitowitz and Rodelsperger, 1991), or from standby exposure as bakers (Ascoli et al., 1996). This information contributes to the evidence that very low exposure to all forms of asbestos can induce cancer. These observations of mesothelioma should be considered as sentinel events for the pathologies other than mesothelioma that are more difficult to identify among large populations that experience relatively more remote exposure to chrysotile asbestos. In my opinion, these studies constitute high level risk from low levels of exposure to chrysotile asbestos.

Dr. Musk:

5.305 It my understanding there are epidemiological studies which do not show a statistically increased risk of disease from low levels of exposure to chrysotile. However, the absence of demonstrating an increased risk does not mean that there is not some risk as it is not possible to prove a negative and a threshold has not been demonstrated for any carcinogen (nor in my opinion is it biologically likely that one exists).

4.(b) Is there a threshold below which exposure to chrysotile fibres does not induce (i) asbestosis, (ii) lung cancer, (iii) mesothelioma, and (iv) other asbestos-related pathologies, such as pleural plaques? If there is such a threshold, is it a practical one or is it scientifically established?

Dr. de Klerk:

5.306 It is extraordinarily difficult to demonstrate lack of an effect, or a threshold effect, in epidemiological studies because of the ubiquitous problems of bias, confounding and chance. In particular, the smaller effect that needs to be demonstrated, the larger the study needs to be, both in population size and follow-up time and such studies can rarely be done, even with animals.

Dr. Henderson:

(i) Asbestosis

5.307 Please see my answer to Question 3(b).

(ii) Lung Cancer

5.308 Please see discussion in Section C.1.(i). Please see also the statement from EHC 203 below on the question of a threshold for carcinogenesis by asbestos. Some authorities favour a linear no-threshold model, whereas others argue that a threshold probably exists; nonetheless, there is no general agreement on a numerical threshold for asbestos-induced lung cancer. Dement et al. [171] observed odds ratios of > 2.5 at 2.7-6.8 fibre-years of exposure among South Carolina asbestos textile workers.

(iii) Mesothelioma

5.309 As indicated in previous discussion in this report, a linear dose-response model has been identified for mesothelioma induction by the amphiboles, and the dose-response relationship is maintained at low occupational levels of exposure that overlap with environmental exposures: e.g. definite dose-response relationship reported by Rödelsperger et al. [25, 137] at asbestos fibre concentrations in lung tissue of 100,000-200,000 fibres per gram dry lung tissue, with an indication that this relationship is maintained at lower levels of 50,000-100,000 fibres per gram dry lung (the

level of 100,000-200,000 fibres corresponds to a cumulative dose of 1-2 fibre-years). Iwatsubo et al. [136] identified an increase in the relative risk at 0.5-0.99 fibre-year. No threshold has been identified for amphibole-related mesothelioma. For chrysotile exposures, a dose-response relationship has also been identified at high exposures, but to the best of my knowledge, there are no dose-response data for low-level exposures to chrysotile.

5.310 On this point, EHC 203 states that "No threshold has been identified for carcinogenic risks" [for chrysotile; p 144]. At the same time, no increase in risk for mesothelioma has been identified at very low-levels of exposure, of the type associated with well-maintained asbestos in place, in public buildings. However, it is impossible to ascertain whether or not there is an increase in risk at this order of exposure, because no control or reference group can be assembled where there is no asbestos content in lung tissue. If a threshold exists, it must lie somewhere in this area, between no exposure, low-level environmental exposure, and low-level occupational exposure.

5.311 De Klerk [115] has also commented on the difficulty or impossibility of distinguishing between background versus environmental mesotheliomas:

> "There have been increases in the incidence rates of malignant mesothelioma in women, in those without identified exposure to asbestos and, possibly, those younger than 35 years of age in Australia and Western Australia. Although part of the first two increases, at least, may be attributable to specific exposure to asbestos, mathematical modelling of the Western Australia data suggests that there has been about a twofold increase in incidence rates from the 1970s to the 1980s that may be due to increased general environmental exposure to asbestos. ... The excess of 1 per million person years over this presumed 'background' rate is also, coincidentally, the amount that was estimated as possibly caused by exposure of school children to 1 fiber per liter ... , a level that might result from use of asbestos-based insulation or other general contamination of the environment with asbestos.
>
> A final consideration in the use of national trend data for estimating environmental effects is the comparison of the likely extrapolated risk from occupational data with the background risk estimated here or from Peto's Los Angeles data. From the Peto paper ... , the incidence of mesothelioma is related to age in the following way:
>
> $\text{Incidence} = 1.7 \cdot 10^{-12} \cdot (\text{age})^{3.5}$
>
> which translates to a lifetime risk to age 80 of just over 100 per million people, which is much greater than any of the estimated environmental risks described earlier. An equivalent risk from the adjusted Western Australian data is about 160 per million lifetimes. The question remains as to how these background risks and environmental risks interact. Is the postulated environmental incidence already included in the background incidence, or should the risks be added or even multiplied together? This question is almost certainly unanswerable using epidemiological methods. ...
>
> It is doubtful whether epidemiological methods ... could ever be definitive in deciding whether there is an appreciable hazard from general environmental exposure to asbestos ... or, more importantly, whether the hazard is large enough to justify specific remedial action ..." [pp 29-31].

5.312 Clearly, this issue is one major focus of dispute between experts; from the preceding discussions, it is my perception that — with the exception of asbestosis — no threshold has been delineated, and that even those who claim that a practical threshold must exist cannot delineate such a threshold in precise numerical terms (in this respect, I do not know what the expression "practical threshold" really means).

Dr. Infante:

5.313 Thresholds have not been demonstrated for any substance known to cause cancer and there is no theoretical basis to assume a threshold for the diseases related to chrysotile, or other forms of

asbestos, particularly when the mechanisms involved in the pathology are not fully understood. Furthermore, it is not possible to determine thresholds from epidemiological studies because of lack of statistical power to distinguish that the risk is virtually zero. [Note: At times, some investigators state that a single point estimate from the lowest dose evaluated in an epidemiological study that does not demonstrate a significant elevation in cancer risk constitutes a threshold level for the carcinogen. Such a conclusion is scientifically invalid. When estimating dose-response, one has more confidence in the risk related to a particular dose level by using all of the data available in the study. Using only a single point estimate results in more instability in the estimate of risk for that data point in contrast to using all of the available data in the study.]

5.314 Dose response analyses and modeling specifically for chrysotile asbestos exposure and lung cancer and asbestosis have been conducted recently by Stayner et al. (1997) using data from the Dement et al. (1994) study. Alternative exposure-response models were evaluated as part of the study. A model designed to evaluate evidence of a threshold also was fitted for asbestos exposure in relation to lung cancer and asbestosis. There was no significant evidence for a threshold in models pertaining to either lung cancer or asbestosis.

5.315 With regard to mesothelioma, and other asbestos-related diseases, I am not aware of any evidence of a threshold pertaining to either chrysotile, or other forms of asbestos. Furthermore, from a practical standpoint, even if there were a threshold for the chrysotile related diseases, the exposures that workers will routinely encounter in the future through continued use of chrysotile in commerce, will expose them to concentrations of asbestos that have already been related to pathology in humans. In other words, continued use of asbestos will continue to expose individuals to levels and exposure circumstances that have already been related to disease. The threshold question, therefore, seems moot.

Dr. Musk:

5.316 It is my understanding that a threshold for disease has not been scientifically established.

4.(c) Is the linear relationship model an appropriate method for assessing the risk to human health posed by exposure to chrysotile asbestos at low levels of exposure?

Dr. de Klerk:

5.317 The linear relationship model is generally used as a so-called "conservative" estimate, that is, if it is incorrect, it is more likely to err on the side of safety. In some ways, how one extrapolates risk assessment outside the range of available data is more of a societal decision than a scientific one. Biological plausibility could probably be given to any model.

Dr. Henderson:

5.318 In the absence of alternatives because of unavailability of data on exposure-response relationships at low levels of exposure to chrysotile, the linear relationship model is widely employed. Under these circumstances, this may be an appropriate method for risk assessment at low levels of exposure. Whether or not it is a valid method is unknown.

5.319 NICNAS 99 (p. 72) observes that:

> "There are many problems associated with low-dose risk extrapolation, such as the assumption of a linear relationship. However, as insufficient data exist to indicate a threshold exposure for effect, the linear extrapolation methodology provides a conservative worst-case scenario estimate of risk. Other

> confounding factors in estimating risks from epidemiological data are possible contamination by other fibre types and inaccurate estimates of historical exposures."

5.320 Clearly, this too is one major focus of dispute between experts.

Dr. Infante:

5.321 A linear relationship model is appropriate for determining dose response for chrysotile exposure and lung cancer, and perhaps asbestosis and mesothelioma as well, but the most reasonable model for the latter two diseases are less clear than for lung cancer. With regard to this issue, Stayner et al. (1997) evaluated exposure-response relationships for chrysotile asbestos, and lung cancer and asbestosis by applying several alternate models. The exposure-response relation for asbestos and lung cancer gave the best fit when using a linear model. This observation is consistent with the conclusions of other investigators, who have evaluated dose response for chrysotile asbestos textile workers, or other asbestos workers and mortality from lung cancer (McDonald et al., 1983; Peto et al., 1985; Enterline, Hartley & Henderson, 1987). Furthermore, there appears to be a linear relationship between asbestos exposure and lung cancer over a wide range of exposures where such data are available. Therefore, it seems reasonable to accept a linear relationship for lung cancer when extrapolating risks to exposures below the ranges that have been evaluated in epidemiological studies. Moreover, I am not aware of any literature that convincingly proves that the dose response for asbestos and lung cancer is non-linear. Thus, in my opinion, the linear model is the most appropriate model for estimating dose-response for chrysotile exposure and lung cancer.

5.322 A linear relationship might also be used for chrysotile asbestos exposure and asbestosis although one might make the argument that a non-linear model is also appropriate for asbestosis. Stayner et al. (1997) evaluated this issue using data from the Dement et al. (1994) study and concluded that the association between chrysotile exposure and asbestosis appeared to be non-linear. Stayner et al. (1997) used a non-threshold, non-linear model and the estimates of asbestosis predicted from the model seem to fit very closely with point estimates for asbestosis from other studies of chrysotile exposed populations as mentioned in my responses to Questions 3(c) and 4(a).

5.323 An analysis by Peto et al. (1985) of chrysotile asbestos textile workers shows that a linear model fits the data for mesothelioma with the cube of time since first exposure. In this non-threshold model, the response is linear with dose of asbestos, but exponential with time since initial exposure. The predicted number of mesotheliomas by dose and time since first exposure was in reasonable agreement with the observed number. According to the authors, however, there were too few cases to test the model stringently and they did not attempt to fit other models to their data. Nevertheless, given the consistent observations of the long latency period between initial exposure to various forms of asbestos and the clinical manifestation of mesothelioma, it seems reasonable to use a model that is linear with exposure and exponential with time from initial exposure for chrysotile asbestos and mesothelioma.

Dr. Musk:

5.324 It is my opinion that the linear relationship model is the most appropriate one.

4.(d) Are there scientifically acceptable methods other than the linear relationship model which could be used to assess the risk to human health at low levels of exposure? What results do they suggest?

Dr. de Klerk:

5.325 While a threshold model suggests a lack of risk below a fixed level, it is unlikely that this risk would be completely zero, so that if applied to a much larger population, such a risk could lead to cases of disease.

Dr. Henderson:

5.326 I am not aware of any other methods that have met with broad scientific acceptance or a consensus. It has been suggested that an S-shaped curve might be more appropriate, but I have not seen any data on what the form of the S-curve might be; in other words, the S-shaped model appears to presuppose the existence of a threshold, but no such threshold has been established to the best of my knowledge.

5.327 The problem with arguing that there exists a practical threshold level for lung cancer and mesothelioma induction is that it is impossible to delineate such a threshold in numerical terms, because of a lack of observational data. (Please see also my answer to Q.5(c)).

Dr. Infante:

5.328 From the public health perspective, it has been the convention to use non-threshold linear models for estimating cancer risk to humans. This is particularly the case for substances known to cause cancer in humans. One might deviate from this concept if the mechanism(s) by which the substance causes the cancer were known. This is not the case with chrysotile, or any other form of asbestos. In the particular case of chrysotile asbestos, Stayner et al. (1997) selected several Poisson regression models to explore the shape of the exposure-response relationship between chrysotile asbestos exposure and risk of death from lung cancer. The models were capable of reflecting a wide range of exposure response patterns, including linear, sublinear and supralinear relationships. They also considered a threshold model to determine whether there was evidence that exposures below a certain exposure concentration were equivalent to zero, i.e., that a threshold was present. As mentioned above, for lung cancer, a linear model gave the best fit; for asbestosis, the response preferred was that based on a non-linear, non-threshold model. In both cases, the models did not provide any support for the existence of a threshold. Thus, in my opinion, these models are appropriate to assess risk for these diseases as a result of occupational exposure to chrysotile asbestos. With regard to lung cancer and asbestos, I am not aware of any public health organization, or governmental agency that has ever used a non-linear model to estimate risk. During the hearings held by the U.S. Occupational Safety and Health Administration (OSHA) as part of its rulemaking related to the standard promulgated for asbestos in 1994, numerous scientists were of the opinion that a non-threshold linear model was the preferred model to use for estimating the relationship between asbestos exposure and lung cancer. It is my opinion that a non-linear model is <u>not</u> an acceptable model to use in estimating dose response for asbestos exposure and risk of death from lung cancer. For mesothelioma, I would favor a non-threshold model that incorporates a linear relationship with exposure.

Dr. Musk:

5.329 I believe that there is no reason to discard the linear model as no threshold for any carcinogen is known to exist.

4.(e) To what concentration of chrysotile fibres and for how long must a person be exposed in order to be considered at risk of developing a chrysotile asbestos-related disease (lung cancer, mesothelioma or other asbestos-related pathology)?

Dr. de Klerk:

5.330 A person is "at risk" of developing a chrysotile asbestos-related disease after any exposure to chrysotile asbestos, the lower the amount of exposure, the lower the risk. For example, it could be estimated that there was a 50-50 chance that exposure to 1 fibre of crocidolite could cause 1 case of mesothelioma among the whole population of the world (including all those who have ever lived), i.e. a very small probability, but still greater than zero.

Dr. Henderson:

5.331 This question iterates the issue of a threshold exposure. The answer is essentially the same as for Questions 4(a)-4(d) in the absence of exposure-response data at low levels of exposure.

Dr. Infante:

5.332 The answer to this question depends upon the amount of risk that is considered unacceptable by a particular country. It is a matter of health policy. In the United States, the Environmental Protection Agency (EPA) regulates risk to a level below one extra death in a population of 100,000 people over its entire lifetime. I have already provided estimates for excess risk of death from lung cancer and asbestosis from chrysotile exposure. These risk estimates, however, are average risks to a group of individuals that are based on maximum likelihood estimates (MLEs) and they do not incorporate statistical uncertainty in terms of variability, e.g., they are not based on upper 95 per cent confidence limits as is usually the health policy when estimating adverse health effects to a group of individuals at risk from exposure to an environmental insult. In addition, the risk estimates may only be appropriate to workers' health risks. They are derived from a group of healthy adults, who were able to pass a physical in order to gain employment. They are not representative of individuals in the general population who may be exposed to asbestos and have a compromised immune system, or be exposed to other conditions which may exacerbate their risk of contracting the various diseases related to chrysotile asbestos as estimated from a healthy worker population. There will always be some risk from exposure to asbestos and the degree of that risk will depend upon the amount of asbestos exposure in relation to the susceptibility of the individuals exposed in terms of their health status and other factors that interact to produce clinical manifestation of disease.

5.333 It is noteworthy, as mentioned in my response to Question 1(a) above, that the population surrounding the Quebec mining and milling operation (Begin et al., 1992) that was exposed to background levels of chrysotile asbestos, developed mesothelioma at an incidence of 62.5 cases per million population per year, or 0.625 per 10,000 per year. This risk level translates to 0.5 per cent of the population developing mesothelioma over an 80-year lifetime from this background exposure. This estimate may well represent an underestimate of risk since the identification of cases was based on a workman's compensation board review, and additionally, out-migration of inhabitants would also result in loss of some cases. In the same report, it was pointed out that the largest increase in the mesothelioma rate in Quebec was among individuals that had occupations where their exposure would be occasional only, and that 33 per cent of these cases were exposed for less than a 5-year period. When one adds to this information to additional cases of mesothelioma reported in the literature that are associated with standby exposure to chrysotile, it leads one to the conclusion that occasional exposure for a short period of time, or constant low level exposure to chrysotile asbestos leads to death from mesothelioma (and lung cancer and asbestosis). [Note: while an excess of lung cancer was not identified in the Camus et al. (1998) study of women in the same Quebec population, the study had limited power to detect an excess of lung cancer; it did, however, demonstrate an excess of asbestosis and mesothelioma even though out-migration may have resulted in the loss of all three of these diseases in the study.]

Dr. Musk:

5.334 In my opinion any level of exposure to chrysotile (or other form of asbestos) constitutes some risk and that the level of "acceptable risk" is not a scientific issue but an issue for society to debate and determine at different times according to the evidence as they perceive it.

Question 5:

Canada states that, with controlled use, "health risks associated with occupational exposure throughout the life-cycle of chrysotile asbestos can be reduced to acceptable levels already recognized as such by competent international organizations. The European Communities questions this assertion and says that "les données scientifiques disponibles montrent que l'utilisation dite "sécuritaire" de l'amiante chrysotile ne permet pas d'empêcher un grand nombre de cas d'exposition entraînant des pathologies mortelles". ["available scientific evidence shows that so-called "controlled" use of chrysotile asbestos does not make it possible to prevent many cases of exposure causing fatal pathologies"]

5.(a) Is there a generally agreed methodology applicable to any use of chrysotile-cement products and other high-density chrysotile products throughout their life-cycle that can be referred to as "controlled use"? Is it embodied in international standards?

5.335 This is rather outside my areas of expertise. It does however appear theoretically feasible but practically very unlikely given the problems with "downstream" use described above.

Dr. Henderson:

5.336 In principle, regulation and control of chrysotile and high-density chrysotile products is feasible at some points of the life-cycle (manufacture and disposal), but in reality not others (please see following discussion).

5.337 The manufacture of high-density products is usually carried out under closed conditions with dust extraction. As one example, the manufacture of chrysotile friction materials in Australia involves the following processes: following transfer of other ingredients required for the product mix, unopened 50 kg plastic bags of raw chrysotile are placed in the mixer and opened under dust extraction. The empty bag is then delivered into a second plastic bag attached to the mixer. When full, this second bag is sealed and taken to a controlled disposal site. Mixing is a closed process. After mixing, the material is emptied under dust extraction before decanting into smaller buckets for weighing and use in moulding and finishing processes. The moulding is a hot process and when complete, the moulded product undergoes finishing processes that include grinding, grooving and drilling — all carried out under dust extraction. The finished disc pads and commercial vehicle brake blocks and linings are then wrapped and packed into sealed containers.

4.338 The potential for exposure includes opening and emptying chrysotile bags into the mixer, the moulding and finishing processes, and handling of damaged bags containing raw chrysotile. The workforce amounts to a few hundred workers, and the maximum exposures per employee vary from minimal, to the largest group involved in the processing operations. Airborne asbestos fibre levels are assessed by personal monitoring. About 84 per cent of 461 samples between 1992 and 1997 were < 0.1 f/ml; 10 per cent ≥ 0.01–≤ 0.2 f/ml; 6 per cent were ≥ 0.02–< 0.5 f/ml, and < 1 per cent were ≥ 0.5 f/ml. The manufacture of compressed asbestos fibre sheeting — most for export and the remainder processed into finished cut gaskets for industrial applications is also a closed process carried out under similar conditions to the manufacture of friction products (please see NICNAS 99, pp 32-34). A total of 232 personal samples between 1991 and 1996 showed similar low airborne fibre

concentration (58 per cent < 0.1 f/ml and only one sample ≥ 0.5 f/ml). Static samples recorded during guillotine and trimming activities were all ≤ 0.05 f/ml.

5.339 Although controlled use of this type is feasible for these manufacturing processes, and for disposal of materials left over (e.g. empty polythene bags), it is my perception that, historically and in reality, it is almost impossible to extend analogous controlled and regulated use to the end-users of asbestos products such as workers involved in building construction and demolition (e.g. builders' labourers, carpenters, electricians, painters, plasterers and plumbers), or to individuals who carry out maintenance or renovation work on their own homes, or to brake mechanics (please see AMR 99). This is because these groups add up to a large population of disparate and varied workers; many such individuals work for small businesses or are self-employed, so that it is difficult or impossible to extend controlled use or training to all of them.

5.340 Some of the supporting documentation submitted to the WTO refers to ILO recommendations, but it is also worth emphasizing that prohibition or regulation of asbestos-containing products varies from one nation to another, with different upper limits of airborne fibre concentrations (e.g. < 1 f/ml or < 0.1 f/ml). These are summarized in Tables 27 and 28 and Appendix 7 in NICNAS 99.

5.341 From the literature cited throughout this report and the reasons discussed, it is my perception that broad agreement exists among experts that controlled use of chrysotile (or other varieties of asbestos) is not a feasible option in the real world for certain worker groups, notably those involved in construction trades (e.g. see EHC 203).

Dr. Infante:

5.342 I am not familiar with any "agreed upon" methodology applicable to chrysotile-cement products and other high-density chrysotile products related to "controlled use" in the sense that these products could be used without harm to human health. Perhaps the consensus is that when using asbestos, the exposure should be controlled, and various countries have developed programmes or standards that recommended, or require, specific engineering controls, work practices, training and education and personal protective equipment to control exposures to asbestos to the extent feasible. This, to me, is different from the concept of "controlled use" in the dialogue being used by Canada, which seems to imply that using or manipulating asbestos or asbestos containing products can be done in such a manner that people are not exposed, or that the risk from such exposure is *de minimus*.

5.343 I also am not aware of international standards related to "controlled use" of asbestos products. What you may be referring to here are recommendations from international organizations, or recommendations or regulations (in the context of being enforceable by law) from various countries. These documents, however, should not be considered as international standards that lead to the "controlled use" of asbestos. For example, in 1994, the United States, promulgated a new standard for occupational exposure to asbestos which required the permissible exposure limit (PEL) to be no higher than 0.1 f/cc as an 8-hour time-weighted- average (TWA). In the opinion of OSHA, workers exposed to this PEL over an occupational lifetime (45 years) are still at a significant risk of developing asbestos related diseases. Therefore, the Agency included in the standard several provisions ancillary to the PEL. One could argue that the PEL plus the ancillary provisions constitutes one of the best examples of the concept of "controlled use" of asbestos as I understand it in the concept being brought forward by Canada. Yet, in the United States, the PEL for asbestos as well as the ancillary provisions that include training and education about the health hazards of exposure, work practices, requirements for personal protective equipment, medical surveillance, etc. are not complied with for various reasons in a large number of workplaces. Based on the observations of violations of several provisions of the asbestos standard in the United States, discussions with occupational safety and health personnel from other countries and my review of the literature, it is my opinion that a controlled use concept for chrysotile asbestos is not realistic in workplace situations. It would be much less realistic as applied

to non-occupational situations where individuals would make repairs involving the manipulation of asbestos products in their homes.

5.344 I am not aware of any international standard that embodies "controlled use" of asbestos in the context that the manipulation of asbestos, or asbestos containing products will result in exposures that will not result in harm to many of those exposed. Furthermore, it should be recognized that programmes to control asbestos in many countries are "agreements" and as such, they are not enforceable by law. Even more disconcerting is the observation that countries like the United States that promulgated stringent requirements to control asbestos find that their standards are often violated. A general downfall with the concept of "controlled use" is that it relies upon human behaviour, which cannot be controlled in too many situations. Hence, it is unreliable.

Dr. Musk:

5.345 In my opinion "controlled use" of asbestos is theoretically possible but not practically feasible. The second half of the question is not within my area of expertise.

5.(b) To what extent is controlled use feasible in terms of the training of those involved in such use, implementing process changes, monitoring, etc.? Have there been studies conducted in this regard and what do they show?

Dr. de Klerk:

5.346 This is definitely outside my area of expertise.

Dr. Henderson:

5.347 In theory, training of specific workers (e.g. products manufacture) and some other personnel in the controlled use of chrysotile ought to be feasible (as for other potentially hazardous materials such as radioactive materials used in nuclear reactors). As a matter of common sense, training is most likely to be effective when there is a small and cohesive workforce using materials that are not accessible to most other workers who have limited or no training, and when the workers have a clear understanding of the hazards and risks of the materials handled.

5.348 However, training of this type becomes less feasible or impossible in practice when there is a large and non-cohesive workforce and when there is general accessibility to the materials in question (e.g. builders' labourers, carpenters, electricians, plumbers and so forth at building sites, and brake mechanics).

5.349 Even so, I am sceptical about the consistent and universal effectiveness of training programmes in the real world, even when the workforce is small and cohesive, and involved in the handling of materials that present a clear hazard (e.g. radioactive isotopes). For example, following the recent mishap at a nuclear reactor in Japan, a BBC report broadcast by ABC News Radio on Sunday 31 October 1999 pointed out that the workers at the Japanese nuclear plant had been poorly trained, with a poor understanding of the risks.

5.350 An analogous report was printed in *The Guardian Weekly* (October 28-03 November 1999, p. 9):

> "Britain's key nuclear warheads factory this week admitted to more than 100 breaches of safety in the past year but ... the Director of Communications at the Atomic Weapons Establishment in Aldermarston ... branded claims that only luck had prevented an accident worse than that in Japan as 'irresponsible scaremongering'. ... The Plant's emphatic denials came after The Observer newspaper

> published details of a leaked report highlighting more than 100 dangerous incidents since September last year. ... Among these were eight breaches of the 'criticality' rules ... and eight instances of environmental contamination outside the site. There were also eight occasions when materials — including plutonium — were incorrectly packaged or labelled, and 19 highly serious health and safety incidents, including all fire-fighting pumping appliances being unfit to service. ... The lead-in of the catalogue of breaches comes as the environment agency prepares to decide whether to prosecute the privatised Aldermarston for dumping tritium, a radioactive substance, in a stream from which Reading's drinking water is sourced ... it also follows the imposition of a £22,000 fine on the company after two workers breathed in radioactive particles from plutonium that had escaped from a laboratory in August last year. ... The establishment insisted it was 'regulated up to the eyeballs' by external agencies and said it was penalised for its 'openness and transparency' in reporting breaches ...".

Dr. Infante:

5.351 Training is beneficial in reducing worker exposure to toxic substances in some circumstances, but minimizing exposure to asbestos to the extent that a significant amount of disease will not occur, is not one of these circumstances because of the extent of the training provisions necessary to reduce exposures, the lack of ability to reach all of the potentially exposed populations, and the wide-spread use of chrysotile asbestos. Training would be relatively better achieved in the manufacturing sector where the employed population is relatively more stable as compared to the construction sector wherein many workers are transient employees. Because of the transient nature of the workforce and the cost involved to train workers, there is a tendency to not train those who will only be employed for short periods of time.

5.352 In terms of studies related to the feasibility of using chrysotile asbestos in a "controlled manner" OSHA health compliance data may offer some insight. The United States has an asbestos standard that includes training requirements that are enforceable by law, and violations of which are punishable by monetary penalties. Yet, improper work practices (presumably a reflection of lack of training) and violations of the permissible exposure limit continue to be identified. Since 1980, OSHA compliance officers have identified almost 14,000 violations among establishments for failure to comply with provisions of its asbestos standard. During the recent 3-year period of 1996-98, over 4,000 violations have been cited. Because of the small number of OSHA compliance staff in relation to the number of facilities in the United States, it has been estimated that compliance officers are able to visit industrial workplaces an estimated one time in every 84 years. Thus, the non-compliance with provisions of the United States asbestos standard as identified by its compliance officers, represents a "tip of the iceberg" in identifying non-compliance with provisions of the standard that are thought necessary to control asbestos exposure in the workplace. As difficult as this situation is in the occupational setting, I am inclined to believe that training leading to "controlled use" of chrysotile would be even more difficult to achieve outside of the occupational setting.

Dr. Musk:

5.353 As above in my opinion controlled use of chrysotile is theoretically feasible but probably not practically possible. The second question part of the question is not in my area of expertise.

5.(c) Can controlled use, when properly applied, reduce exposure levels to chrysotile fibres to below 0,1 f/ml[26]? Can controlled use provide the assurance that there will be no peaks above this figure for any type of use of high-density chrysotile products? For workers or other persons exposed to chrysotile asbestos at this level, can you quantify the risk?

[26]Maximum exposure limit which was authorized in France before the ban.

Dr. de Klerk:

5.354 See Table in paragraph 5.197 above.

Dr. Henderson:

5.355 When properly applied, controlled use in specific situations (e.g. friction products manufacture) can reduce airborne chrysotile concentrations to < 0.1 f/ml for most of the time: e.g. as mentioned in my answer to Question 5(a), at the Australian friction products factory in Victoria, 84 per cent of 461 samples (1992-1997) showed an airborne fibre concentration < 0.1 f/ml; however, the remainder showed airborne fibre levels above this figure, although the concentrations were still low. This also demonstrates that one cannot always guarantee that fibre concentrations will never exceed 0.1 f/ml, even in highly regulated circumstances such as the manufacture of high-density chrysotile products. For the reasons discussed in preceding sections of this report, it is not possible to quantify the risks (e.g. lung cancer or mesothelioma) from occasional peak exposures > 0.1 f/ml, because these risks necessarily depend upon fibre type, the intensity of the exposure, and the frequency and duration of exposure; in addition, quantification of the risk necessarily involves extrapolation from a linear dose-response model, which is the subject of dispute, because there are no observational data on risks from low-level chrysotile exposure.

5.356 Tables 12 and 13 above (see my response to Question 1(d)) give some estimates of lung cancer and mesothelioma risk at various levels of exposure to chrysotile.

5.357 Finally, occasional bursts or peak concentrations of fibres can be released from buildings by catastrophic and uncontrollable events that include, for example, destruction by fire [244-247], earthquake, or explosions [246], including war (e.g. bombing of cities). Although disasters like these are infrequent — and the fall-out from fires is probably of little consequence to nearby residents or the public in general [247] — they pose a potential health risk for some occupational groups likely to encounter asbestos fall-out and debris more often, such as fire fighters and those involved in clean-up operations.

Dr. Infante:

5.358 Since I believe that "controlled use" is a misnomer in relation to potential for exposure to asbestos, I prefer to answer this question in the context of whether a stringent standard for the control of asbestos in the workplace can reduce exposures to below 0.1 f/cc. In many situations, when standards are properly applied, or adhered to, it is possible to maintain exposures below 0.1 f/cc. However, in many situations today, even in the presence of a stringent standard to control exposure, the 0.1 f/cc level for asbestos is exceeded, specified work practices and housekeeping provisions that are required to reduce exposures are not adhered to, communication of hazards is not provided, and appropriate personal protective equipment is not used. As a result, both average exposures and peak exposures above 0.1 f/cc will occur. With regard to high density chrysotile products specifically, over 2,000 violations of the OSHA asbestos standard have been identified in standard industrial classification (SIC) sectors where potential for exposure to chrysotile asbestos would occur, namely: wrecking and demolition work, asbestos products manufacturing, roofing, siding and sheet metal work, manufacturing of gasket, packing and sealing devices and automotive repair shops.

5.359 In addition to the above examples, in my opinion, many work practices are simply not good enough in some situations to reduce exposures below 0.1 f/cc. For example, even though asbestos cement products may be "pre-sized" in manufacturing, cement sheets need to be modified, drilled, cut and ground to fit them into specific areas. Although wetting may be used in some of these situations for cutting asbestos cement, the material dries and the dust becomes airborne resulting in uncontrolled asbestos dust being released into the work environment. Even in such situations where workers are

provided with respirators to prevent exposure, the respirators supplied for the situation are often the wrong ones. In addition, respirator effectiveness depends upon how well the masks fit the face, how often they are replaced, cleaned and repaired and how well the employees are trained to select, clean and repair their respirators. In spite of rules requiring good respirator practices, employers often simply do not comply with the regulations.

5.360 In a more general sense, non-compliance with regulations that could assist in the control of asbestos to exposure levels below 0.1 f/cc is often the result of human error, (not recognizing that asbestos is present, not understanding the requirements to protect workers from exposure in specific situations), wilful non-compliance, poor judgement, accidents, inability to adequately reach the potentially exposed population with proper training and education of the health hazard, etc. Based on my experience in occupational health and the results of OSHA compliance data and the literature, it is my opinion that it is impossible to use asbestos and assure that exposures can be kept below 0.1 f/cc in a great number of situations.

5.361 Regarding health risks from chrysotile exposure to 0.1 f/cc, as mentioned in my answer to Question 3, the risk assessment conducted by Stayner et al. (1997) based on the study by Dement et al. (1994) provides a good estimates of disease risks from exposure to chrysotile asbestos which are not much different from those provided from other studies. The analyses estimate that exposure to 0.1 f/cc of chrysotile asbestos for an occupational lifetime of 45 years, e.g., 4.5 f/cc-years of cumulative exposure, results in five extra deaths from lung cancer and two extra deaths from asbestosis per 1000 workers. The analysis did not include mesothelioma because there were too few deaths from this cause in the study to provide estimates of risk. I have not seen risk assessments for mesothelioma based on chrysotile exposure. Thus, I cannot provide a quantitative estimate of risk for this cause of death.

5.362 Of these diseases, the risk of developing asbestosis is most likely underestimated. This underestimation is a reflection of the fact that most risk assessments are based on mortality studies and individuals diagnosed with asbestosis often die from other causes. For example, in the study by Finkelstein (1982), of 24 individuals with certified asbestosis, who had died, 14 (58 per cent) died from lung cancer or mesothelioma and three (12.5 per cent) died from ischemic heart disease. Thus, 70 per cent of the individuals with asbestosis who died would not have been identified from a mortality study of this population of exposed workers. Asbestosis may also be underestimated in a study because it may be confused clinically with other non-malignant lung diseases. Therefore, the risk of death from asbestosis based on mortality studies may usually be underestimated. I am not familiar with quantitative estimates of risk from other pathologies related to chrysotile asbestos.

Dr. Musk:

5.363 The question is not within my area of expertise except that risks from exposure could be calculated if exposure levels are known.

5.(d) Is it possible to control the risks to human health presented by exposure to high-density chrysotile products, in particular chrysotile-cement, throughout the life-cycle of the product? Is controlled use a feasible and practicable option in everyday life for workers who are exposed occasionally to potentially high levels ("peaks of exposure") of chrysotile asbestos (such as plumbers, electricians, maintenance, repair, insulation, demolition, waste management and "handyman" type persons)?

Dr. de Klerk:

5.364 See my response to Question 5(a).

Dr. Henderson:

5.365 From my perspective, these questions are crucial to the dispute before the WTO. In my opinion, the answer to both questions is NO. I do not see how asbestos in place — or existing chrysotile products — can be controlled at every point of end-use. For example, EHC 203 indicates repeatedly that exposure is most likely to affect workers involved in building construction or demolition; this is because of the large number of these workers involved in myriad different tasks; in addition, these various workers represent a non-cohesive workforce, many self-employed or working as part of "small business".

5.366 My perception is also based on studies such as that reported by Kumagai et al. [4] on Japanese workers involved in the repair of asbestos-cement pipes, where fibre concentration for fibres > 5 µm in length ranged from 92 f/ml inside the hole where this work took place (range 48-170 f/ml) and up to 15 f/ml outside the hole; the final sentence of the Abstract for this Report indicates that only about 18 per cent of the workers used a protective respiratory device. In addition, a survey in Finland found occasional high fibre concentrations inside personal protectors during asbestos removal work, suggesting that these devices are not always effective.

5.367 Another factor that merits consideration in some societies such as Australia, is poor worker compliance with controls. For example, I am aware of non-compliance in the use of protective equipment (despite penalties), because respiratory protective devices may be cumbersome and uncomfortable — especially in hot climates like Australia — with skin irritation from sweat accumulating within them.

5.368 From the literature cited throughout this report and the reasons discussed, it seems clear that there is a broad consensus among experts that controlled use of chrysotile (or other varieties of asbestos) is not feasible in practice for certain worker groups, notably those involved in construction trades (e.g. see EHC 203).

Dr. Infante:

5.369 As mentioned in my responses to several previous questions, in my opinion, it is not possible to control the risk to human health posed by exposure to chrysotile asbestos throughout its life cycle. "Controlled use" is not a feasible and practical option in everyday life for workers. While "controlled use" is relatively more achievable in the manufacturing sector, violations of regulations enforceable by monetary fines still occur. In the construction sector, control of exposure to asbestos is much more difficult to achieve as compared to manufacturing. Workers who have jobs as plumbers, electricians, maintenance personnel, repairmen, insulators, demolition, waste management and handymen will most likely experience intermittent peak exposures to asbestos. These exposures result from lack of awareness of the hazard, lack of recognition of the hazard, lack of personal protective equipment, lack of training on the maintenance of the protective equipment, etc. as mentioned in responses to other questions above.

Dr. Musk:

5.370 In my opinion controlled use is probably not practically possible but this is not an area of my expertise.

5.(e) Is it possible to control the risks to human health presented by exposure to high-density chrysotile products, in particular chrysotile-cement, in non-occupational circumstances, such as intervention on these products by private individuals (cutting, sawing, removal, etc.)? Is controlled use a feasible and practicable option for this category of the population?

Dr. de Klerk:

5.371 See my response to Question 5(a).

Dr. Henderson:

5.372 As a follow-on to my answer to the preceding question, my answer to both of these questions is also NO. However, the risks from occasional or infrequent interventions on chrysotile-only products (e.g. by home "handymen") - although not quantifiable because of absence of data - must be very small for lung cancer and mesothelioma, and non-existent for asbestosis.

Dr. Infante:

5.373 As difficult as it is to control exposure to chrysotile asbestos during intervention with cement products in the occupational setting, it is much more so in non-occupational circumstances because there is no effective means of identifying the potential population at risk. As a result, there is a lack of awareness of the hazard, lack of recognition of the hazard, lack of personal protective equipment, lack of training on the maintenance of the protective equipment, etc. as mentioned in responses to other questions above. Therefore, in my opinion, it is not possible to limit exposure in such circumstances.

Dr. Musk:

5.374 Controlled use is probably not practically possible, in my inexpert opinion.

Question 6:

The parties disagree as to the relative pathogenicity of chrysotile fibres vs. substitute fibres, in particular cellulose fibres, para-aramid fibres, glass fibres and polyvinyl alcohol (PVA) fibres. Canada considers that, overall, substitute fibres have not been demonstrated to be less toxic than chrysotile fibres, and that, by banning chrysotile, France has replaced the "much studied but nonetheless undetectable risk associated with modern uses of chrysotile with the unknown, and perhaps greater risk associated with the use of substitute fibres" [Premier exposé oral du Canada, paragraph 90]. On the other hand, the European Communities argues that none of the substitute products -fibrous or non-fibrous- for chrysotile, and in particular none of the substitutes for chrysotile-cement, has been classified as a proven carcinogen to humans; hence, overall, substitute products present less of a risk to human health than chrysotile asbestos [see Deuxième soumission écrite, pp. 10-15].

6.(a) Is it correct to argue that non-fibrous substitutes are safe or less hazardous than chrysotile and that concern over potential health risks should be focused on fibrous ones? In this context, could you elaborate upon the "effet fibre" ["fibre effect"] of substitute fibres? What general conclusions can be drawn as to the respirability and biopersistence of substitute fibres?

Dr. de Klerk:

5.375 As outlined above, the pathogenicity of fibres is related to their size, shape, durability and quantity. Thus, all the parts to this question can be answered in the same way. The argument here is whether it is safer to stick with the well-studied chrysotile that has a semi-quantifiable and definite carcinogenic risk, than to use other substances which have the potential to increase risk in an unquantifiable way, ie. the "better the devil you know" principle. For example, para-amid fibres have recently been classified by IARC in Group 3, that is, 'not classifiable as to its carcinogenicity'.

5.376 Substitutes need to be compared to chrysotile in terms of the parameters listed above, namely, size, shape, durability and quantity. These are all properties of fibres and therefore "concern should be focused on fibrous substitutes". Substitute fibres can then be compared with chrysotile on the four parameters. I am inexpert in commenting on the "extent to which hazardous concentrations can be controlled" but it is my understanding that all four substitutes mentioned involve less dusty operations than equivalent ones involving chrysotile. As far as the other three parameters are concerned: all four substitutes except glass fibre produce a larger proportion of non-respirable fibres than chrysotile does, but respirable fibres are similar for all substances and glass fibre is the least durable; all four except cellulose are less durable than chrysotile, but cellulose is much less dusty and has also been in use for a long while without evidence of ill effect.

5.377 On balance, the substitute fibres appear less likely to cause adverse effects (from their fibres) than chrysotile.

Dr. Henderson:

5.378 Current thinking on this issue indicates that the bio-hazards — specifically the carcinogenic risks - of all fibres are determined by the three Ds: dose, fibre dimensions and durability (bio-persistence) [248-250]. Therefore, substitute materials that have engendered most concern are fibrous materials as opposed to non-fibrous substances (non-fibrous materials may or may not show different effects in terms of toxicology, but this discussion focusses on carcinogenic risks). For example, refractory ceramic fibres (RCF) are a cause for concern [251] because they may have dimensions similar to those of the amphibole varieties of asbestos and RCF have been reported to induce mesothelioma in experimental animals.

5.379 In a 1995 review, de Vuyst et al. [248] concluded that:

> "The group of man-made mineral or vitreous fibres (MMMFs or MMVFs) includes glass wool, rock wool, slag wool, glass filaments and microfibres, and refractory ceramic fibres (RCFs). Experimental observations have provided evidence that some types of MMVF are bioactive under certain conditions. The critical role of size parameters has been demonstrated in cellular and animal experiments, when intact fibres are in direct contact with the target cells. It is, however, difficult to extrapolate the results from these studies to humans since they bypass inhalation, deposition, clearance and translocation mechanisms. Inhalation studies are more realistic, but show differences between animal species regarding their sensibility to tumour induction by fibres. Fibre biopersistence is an important factor, as suggested by recent inhalation studies, which demonstrate positive results with RCF for fibrosis, lung tumours and mesothelioma. There is no firm evidence that exposure to glass-, rock- and slag wool is associated with lung fibrosis, pleural lesions, or nonspecific respiratory disease in humans. Exposure to RCF could enhance the effects of smoking in causing airways obstruction. An elevated standard mortality ratio for lung cancer has been demonstrated in cohorts of workers exposed to MMVF, especially in the early technological phase of mineral (rock slag) wool production. During that period, several carcinogenic agents (arsenic, asbestos, polycyclic aromatic hydrocarbons (PAH)) were also present at the workplace and quantitative data about smoking and fibre levels are lacking. It is not possible from these data to determine whether the risk of lung cancer is due to the MMVFs themselves. No increased risk of mesothelioma has been demonstrated in the cohorts of workers exposed to glass-, slag- or rock wool. There are in fact insufficient epidemiological data available concerning neoplastic diseases in RCF production workers because of the small size of the workforce and the relatively recent industrial production" [abstract].

5.380 In a 1999 review published in French, Boillat et al. [250] came to similar conclusions:

> "The group of man-made mineral fibres includes slagwool, glasswool, rockwool, glass filaments and microfibres, as well as refractory ceramic fibres. The toxicity of mineral fibres is determined by several factors such as the diameter (< or = 3-3.5 microns) and the length of the fibres (< 100 microns), their biopersistence, which is much shorter for man-made mineral fibres than for asbestos fibres, their

> physicochemical structure and surface properties, and the exposure level. The chemical composition of the various types of man-made mineral fibres depends directly on the raw material used to manufacture them. While naturally occurring fibres are crystalline in structure, most man-made mineral fibres are amorphous silicates combined with various metal oxides and additives. Observations using intracavitary administration have provided evidence that some types of man-made mineral fibres are bioactive in cellular and animal experiments and may induce lung tumours and mesothelioma. It is difficult to extrapolate these results to humans since they bypass inhalation, deposition, clearance and translocation mechanisms. Inhalation studies show more realistic results but differences are observed between animal species regarding their sensibility to tumours. There is no firm evidence that exposure to various wools is associated with lung fibrosis, pleural lesions or nonspecific respiratory disease in humans. A possible exception may be mentioned for refractory ceramic fibres. A slightly elevated standard mortality ratio for lung cancer has been documented in large cohorts of workers (USA, Europe and Canada) exposed to man-made mineral fibres, especially in the early technological phase. It is not possible to determine from these data whether the risk of lung cancer is due to the man-made mineral fibres themselves, in particular due to the lack of data on smoking habits. No increased risk of mesothelioma has been demonstrated in these cohorts. Epidemiological data are insufficient at this time concerning neoplastic diseases in refractory ceramic fibres" [abstract].

5.381 In one study on RCF, Glass et al. [252] reported that:

> "In recent inhalation experiments conducted with both rats and hamsters ... at the highest dose tested ... there was an increased incidence of tumours in both species. Lower doses were only examined in the rat and at these doses there was no significant excess of lung tumours. Epidemiological investigations of workers engaged in the manufacture of ceramic fibres have shown a small excess of pleural plaques. This phenomenon is being further investigated but could be due to confounding exposures. The populations available for study are small and their exposures fairly short, but it is considered prudent that they should remain under surveillance for some time to come. This is despite the fact that present exposures in the ceramic fibre industry are low (< 1 f/ml) and are being reduced" [abstract].

5.382 Okayasu et al. [253] also found that RCF-1 fibres were less cytotoxic and mutagenic than chrysotile:

> "Cytotoxicity and mutagenicity of tremolite, erionite and the man-made ceramic (RCF-1) fibre were studied using the human-hamster hybrid A(L) cells. Results from these fibres were compared with those of UICC Rhodesian chrysotile fibres. The A(L) cell mutation assay, based on the S1 gene marker located on human chromosome 11, the only human chromosome contained in the hybrid cell, has been shown to be more sensitive than conventional assays in detecting deletion mutations. Tremolite, erionite and RCF-1 fibres were significantly less cytotoxic to A(L) cells than chrysotile. Mutagenesis studies at the HPRT locus revealed no significant mutant yield with any of these fibres. In contrast, both erionite and tremolite induced dose-dependent S1- mutations in fibre-exposed cells, with the former inducing a significantly higher mutant yield than the latter fibre type. On the other hand, RCF-1 fibres were largely non-mutagenic. At equitoxic doses (cell survival at approximately 0.7), erionite was found to be the most potent mutagen among the three fibres tested and at a level comparable to that of chrysotile fibres. These results indicate that RCF-1 fibres are non-genotoxic under the conditions used in the studies and suggest that the high mesothelioma incidence previously observed in hamster may either be a result of selective sensitivity of hamster pleura to fibre-induced chronic irritation or as a result of prolonged fibre treatment. Furthermore, the relatively high mutagenic potential for erionite is consistent with its documented carcinogenicity" [abstract].

5.383 An important consideration is that fibre dimensions for some substitute materials (e.g. fibreglass) can be varied according to the manufacturing processes employed, so that they can be designed to have fibre characteristics and dimensions different from asbestos, or similar to asbestos: as one example, the dimensions of fibreglass can be varied and when implanted into experimental animals, fibres of the "right" size can induce mesothelioma.

5.384 For this reason, testing of substitute materials with fibre dimensions similar to those of asbestos should be carried out before these materials are used in products available to the general

public (e.g. testing for toxicology, clastogenicity, DNA strand breaks, mutagenicity and free radical generation using *in vitro* systems and/or testing *in vivo* — such as the intraperitoneal test in rats) [248, 249, 251-256].

5.385 Nonetheless, it is my perception that lumping all substitute fibres together is as erroneous as lumping amphibole and chrysotile fibres into the same category. For example, RCF are the subject of continuing concern, but other substitute fibres such as cellulose fibres, para-aramid fibres and polyvinyl alcohol (PVA) fibres appear to be different from chrysotile, in terms of fibre dimensions and especially bio-persistence.

5.386 NICNAS 99 summarizes these considerations in the following terms:

> "Any substitution of chrysotile should be with a less hazardous substance. There has been ongoing debate regarding the health effects of alternatives, such as synthetic mineral fibres (SMF), natural organic fibres and synthetic organic fibres.
>
> In general, less data on health effects of alternative materials (in comparison to asbestiform fibres) are available and because of this, it is difficult to make an assessment of the pathogenicity and potential carcinogenicity of many substitutes.
>
> Although not the only determinant of potential pathogenicity, fibre dimensions (length, width and aspect ratio) are considered to be [some] of the most important factors associated with carcinogenic (lung cancer and mesothelioma) potential ... The commonly accepted 'peak hazard' dimensions ... are > 5 µm long (length) and < 3 µm wide (diameter).
>
> The most commonly used alternatives in Australia (and overseas) for friction materials are aramid fibres, attapulgite, fibreglass, refractory ceramic fibres (RCF), semi-metallics, mineral wool, steel wool, cellulose, titanate fibres and wollastonite, and for gaskets are glass fibre, carbon fibre and aramid fibre.
>
> ... It should also be noted that ... differences in fibre length, diameter and surface properties may lead to entirely different toxicological profiles.
>
> A recent report by EC concludes that the available data are generally supportive of the conclusion that PVA, cellulose, p-aramid, glass wool and slag wool are likely to be safer in use than chrysotile. However, RCFs are the subject of ongoing concern ..." [p 125].

Dr. Infante:

5.387 I have not seen any information that indicates that non-fibrous substitutes for chrysotile are carcinogenic, or cause non-malignant lung diseases. I would focus attention on the fibrous substitutes in terms of their ability to reach lung tissue (respirability) and their known toxicity. Clearly, if the substitute fibres are not respirable, there is little concern for their "potential" to cause lung diseases. (Attention would then focus on adverse effects from exposure to the skin and eyes.) If the substitute fibres are respirable, then attention needs to focus on their toxicity relative to that of chrysotile in their ability to cause lung cancer, non-malignant lung diseases and mesothelioma.

5.388 The data I have reviewed in this area of investigation appear to indicate that polyvinyl alcohol fibres (PVA) are mostly in the range of 10-16 microns in diameter and hence are too large to respirable and thus cause lung disease. In terms of biopersistence, if they were respirable, they would degrade very slowly. Para-aramid fibres are also generally 10-12 microns in diameter and they also would have little chance of being respired. These fibres, however, contain fibrils of about 0.2 microns in diameter that can be liberated with high energy input and they would be respirable. P-aramid fibrils greater than 5 microns in length are less biopersistent than chrysotile fibres greater than 5 microns in length (Searl, 1997). Data for dimensions of cellulose fibres show a median length and diameter of about 7.5 and 1.50 microns, respectively, which indicates that they are in the respirable range (Muhle

et al. 1997). In terms of biopersistence, cellulose fibres had a mass half time in the rat lung of 72 days and bioaccumulated in the lungs. Data on the distribution of glass fibres indicates that the majority are in the respirable range, but the fibre size distribution of glass filaments indicates that a small portion are in the respirable range. Glass fibres are less biopersistent than chrysotile fibres. In general, in terms of the combination of respirability and biopersistence, with the exception of cellulose fibres, it appears that the substitute fibres would have less bioaccumulation in the lung than chrysotile fibres because they are either less respirable, or they are not as biopersistent.

5.389 The role of biopersistence in relation to toxicity is complicated. Chrysotile fibres are less biopersistent than amphibole fibres, yet experimental data demonstrate a similar potency for lung cancer, mesothelioma and fibrosis.

Dr. Musk:

5.390 I agree with the Canadian argument philosophically. However there is no evidence that I know of carcinogenicity of substitutes in animal studies and only rockwool has been associated with increased lung cancer risk in epidemiological studies.

6.(b) To what extent do physical characteristics and chemical properties of substitute fibres determine their toxicity? Is it correct to say that man-made fibre substitutes are superior to natural fibre ones in terms of the extent to which exposure to hazardous concentrations can be controlled during the various stages of production? Is your opinion based on one or more of the following evidence: (i) chemical/physical characteristics of the substitute fibres, (ii) epidemiological data, (ii) in vitro evidence, (iv) in vivo evidence?

Dr. de Klerk:

5.391 See my response to Question 6(a).

Dr. Henderson:

5.392 These questions are covered to a large extent in my answer to the preceding question. Again, dose, fibre dimensions (including surface chemistry) and bio-persistence appear to represent the properties that determine the toxicity and carcinogenicity of fibres of any type. The issue of controllability during various stages of production is an engineering and industrial question, and falls outside my expertise.

5.393 My opinions concerning the potential bio-hazards of these fibres are based on the physical characteristics of the substitute fibres, *in vivo* evidence (tumour induction in experimental animals) and *in vitro* studies (mutagenicity analogous that reported for other known carcinogens). To the best of my knowledge, there are no large-scale epidemiological studies on cellulose fibres, para-aramid fibres or PVA fibres; two large epidemiological investigations on slag wool fibres in both Europe and the United States did show an increase in the relative risk for lung cancer among the production workers, but this effect may have been explicable by other confounding factors involved in the manufacture of these materials.

Dr. Infante:

5.394 As a matter of general toxicology, I would focus concern on the "potential" for adverse health effects from any fibrous material of dimensions and aerodynamic diameter that will result in its being respirable. This is discussed in my response to Question 6(a) above. The toxicity of the substitute fibres and whether that information was determined on the basis of epidemiological or toxicological evidence is discussed in Question 6(c). The role of the chemical properties of fibres to induce cancer

is not clear to me. The nature of the production process makes the substitute fibres more amenable to control than asbestos fibres.

Dr. Musk:

5.395 I do not know: but it is my broad understanding that the physical and chemical properties of the substitute fibres suggests less risk of disease.

6.(c) The parties focus part of their arguments on cellulose fibres, para-aramid fibres, glass fibres and polyvinyl alcohol (PVA) fibres. What evidence exists with respect to the toxicity and health risks of these substitutes? Does the existing evidence suggest that these products are less/equally/more toxic than chrysotile asbestos fibres?

Dr. de Klerk:

5.396 See my response to Question 6(a).

Dr. Henderson:

5.397 In experimental studies on para-aramid fibres in comparison to chrysotile, Warheit et al. [12, 257] found that p-aramid is bio-degradable in the lungs of exposed rats, with faster clearance than long chrysotile fibres which showed greater bio-persistence. In their 1996 study, these authors [12] found that:

> " ... p-aramid is biodegradable in the lungs of exposed rats; in contrast, the clearance of long chrysotile fibres was slow or insignificant, resulting in a pulmonary retention of long chrysotile asbestos fibres. The dimensional changes of asbestos fibres as well as the pulmonary cell labelling data indicate that chrysotile asbestos fibres may produce greater long-term pulmonary effects when compared to inhaled para-aramid fibrils" [abstract].

5.398 The present status of knowledge has been summarized by Harrison et al. [19] in a recent review of the comparative hazards of chrysotile and its substitutes:

> "There are now practicable substitutes for the major remaining uses of chrysotile. Although lack of a full health and toxicological data set precludes a comprehensive assessment of the safety of substitute fibers, the application of basic principles of fiber toxicology enables a pragmatic decision to be made on the relative safety of potential substitutes. Our judgement is based on relative considerations of the intrinsic properties of fibers, on the pathogenicity of chrysotile in comparison with that of substitute fibers, and on the potential for uncontrollable exposures. The three parameters of dose, dimension (especially diameter), and durability are key to determining the differential hazards. Due consideration of these factors leads us to the following conclusions regarding chrysotile and its main substitutes.
>
> Chrysotile per se can cause lung cancer and asbestosis; it is less clear that chrysotile alone can cause mesothelioma in humans, and indeed it may not, whereas tremolite and other amphiboles certainly can do so. There is no definitive evidence for a threshold exposure level for lung cancer induction, although some studies suggest that a threshold does exist.
>
> The intrinsic hazardous properties of chrysotile can never be 'engineered out', and the potential for harm will always remain. Prevention of ill health will thus always rely on the control of exposure, something that history has shown cannot be guaranteed.
>
> Unlike chrysotile, substitute fibres can often be designed or selected to have particular characteristics. Criteria for the substitution of asbestos by other fibers include a) the substitute fibers are not in the respirable range, do not readily fibrillate, and/or are less durable than chrysotile; b) other materials that must be incorporated into the replacement product do not, in combination with the replacement fiber,

produce more harm overall than chrysotile alone; c) the replacement product has an equivalent or acceptable performance; and d) substitution would result in overall lower fiber exposures during manufacture and use and disposal, taking into account likely exposures. The same general principle can be applied to substitute fibers others than those considered here.

We judge that PVA fibers will pose less risk than chrysotile because they are generally too large to be respirable, do not fibrillate, and the parent material causes little or no tissue reaction. Aramid fibers have a reduced potential for exposure when compared to chrysotile because they are generally of high diameter and the production of respirable fibrils is energy intensive. The fibrils are less pathogenic than chrysotile, are less biopersistent, and are biodegradable. Cellulose has the benefit of long experience of use in a variety of industries without having raised significant concern. The potential for the generation of respirable fibers seems to be less than is the case for chrysotile, although fibrillation is possible. Cellulose is durable in the lung, and its biological properties should therefore be investigated further. However, exposure levels for current uses are low, and it is biodegradable in the environment.

We believe that the continued use of chrysotile in asbestos-cement products is not justifiable in the face of available and technically adequate substitutes. Likewise, there seems to be no justification for the continued residual use of chrysotile in friction materials" [pp 610-611].

5.399 From known past uses of asbestos and surveys of current uses in Australia, it is evident that alternatives have replaced chrysotile to a large extent for the following products [NICNAS 99, p 111]:

"Products where chrysotile use has been completely replaced:

- Cement sheeting, tubes and piping.
- Roofing tiles.
- Textiles.
- Fibre insulation.
- Railway brake blocks.
- Brake disc pads in new automotive vehicles (only 1 new vehicle model was identified as being supplied with asbestos pads in Australia).

Products where a major proportion of chrysotile use has been replaced:

- Clutch facings (in automotive vehicles and industrial machinery e.g. tractors, centrifuge drives).
- Brake disc pads (in older taxi and courier vehicles, and industrial machinery).
- Gaskets, such as spiral wound and head gaskets.
- Washers.
- Packing material.
- Rotor blades (e.g. in high vacuum pumps)".

5.400 It is notable that chrysotile is no longer used for brake linings in new passenger cars produced in Australia by most manufacturers, having been replaced by substitute materials: NICNAS 99 comments that:

"Out of 26 companies, 25 stated that they are using non-asbestos original equipment in all current models. One company (Ford Motor Australia) reported that they are still using asbestos parts in two current models: asbestos head gaskets for the Econovan and asbestos rear brake linings for the Ford utility. Ford Australia introduced non-asbestos components for their most popular models (e.g. Laser, Falcon and Fairlane) between 1989 and 1995. Other current models manufactured by Ford have been asbestos-free since their introduction. ... Asbestos parts are imported by 6 of the 26 companies (BMW, Ford, Mazda, Mitsubishi, Nissan and Toyota) with five companies using asbestos parts for superseded vehicles and one company (Ford Australia) using asbestos parts in superseded and current models ... the majority of the vehicle manufacturing companies stated that they have had policies in place in regard to not using asbestos components in new vehicles for the last 5 to 10 years" [p 22].

5.401 This trend to use of brake linings free of asbestos is shown in the following Table 15 — in comparison to the usage of asbestos brake linings — between 1994 and 1998 (asbestos-containing brake linings appear to be used primarily on older and superseded vehicle models).

TABLE 15: IMPORTS OF ASBESTOS AND NON-ASBESTOS BRAKE LININGS INTO AUSTRALIA, 1994-1998

	Number of Articles				
Import	**1994**	**1995**	**1996**	**1997**	**1998 (Jan-Aug)**
Asbestos brake linings, passenger cars	492,295	47,735	43,087	771,182	(548,692)
Non-asbestos brake linings, passenger cars	70,109	321,472	485,812	2,084,963	(4,057,143)

Source: NICNAS 99.

Dr. Infante:

5.402 There is no information to my knowledge that cellulose fibres, para-aramid fibres or ploy vinyl alcohol (PVA) fibres are carcinogenic. Cellulose fibres have not been studied experimentally for carcinogenicity. It is noteworthy, however, that cellulose has been used in the paper industry for hundreds of years and to date an elevated risk of death from lung cancer and mesothelioma has not been observed. Excess incidences of pharyngeal and/or laryngeal cancers were reported in two studies, but these observations have not been corroborated in other studies (IARC, 1987). Wood dust is associated with sino-nasal cancer, but not with lung cancer or mesothelioma. A relatively greater risk appears to be associated with hard woods as compared to soft woods, which suggests that the cellulose may not be the primary factor in the induction of these cancers. Workers exposed to cotton dust also do not demonstrate an excess of lung cancer or mesothelioma even though they develop byssinosis. The debate as to whether this disease is due to cotton dust per se, or to contaminants of the cotton fibre, however, is not resolved.

5.403 Para-aramid fibrils have been studied for carcinogenicity in experimental animals by inhalation and by intra-peritoneal injection. No cancer response was observed. As concluded by IARC (1997), there is inadequate evidence for the carcinogenicity of para-aramid fibrils in experimental animals. The carcinogenicity of para-aramid fibrils has not been evaluated in humans. Likewise, IARC (1987) concluded on the basis of its review of animal cancer tests that there is no evidence for the carcinogenicity of PVA fibres. PVA fibres have not been evaluated for carcinogenicity in humans. It is also my opinion that there is no evidence that these fibres present any risk of cancer to humans.

5.404 With regard to glass fibres, IARC (1988) concluded there was sufficient evidence for the carcinogenicity of glass wool in experimental animals and that there was inadequate evidence for the carcinogenicity of glass wool to humans. Subsequent to the IARC (1988) review, my colleagues and I have reviewed the toxicological and epidemiological studies related to exposure to glass fibres. In our opinion, there is conclusive evidence from implantation and inhalation studies that glass fibres are carcinogenic in experimental animals (Infante et al. 1994). Studies of workers exposed to glass fibres also demonstrate a significantly elevated risk of death from lung cancer. It is our interpretation of these studies that employment in the manufacturing of glass fibres carries with it an elevated risk of death from lung cancer. Is it proven beyond a doubt through epidemiological study that fibrous glass is a human carcinogen? In my opinion, it is not. However, given the positive animal cancer test results, knowledge that these fibres can be inhaled and retained in the lungs, evidence that workers

employed in the manufacturing of these fibres die at a significantly elevated rate of lung cancer, it is my opinion that it is more likely than not that glass fibres are carcinogenic to humans and that employment in this industry carries with it an elevated risk of death from lung cancer.

5.405 It is also my opinion that glass fibres are not as potent as chrysotile asbestos in causing disease. With regard to the capability of glass fibres to cause lung cancer, I have previously published the opinion that on a fibre-per-fibre basis, glass fibres may be as potent or even more potent than asbestos in causing lung cancer. This opinion was based on epidemiological studies which generally demonstrated 10 per cent to 20 per cent elevation in the relative risk of lung cancer (the 1987 study of Canadian workers by Shannon demonstrated a 2-fold risk) as a result of exposures to glass fibres that were reported to be fairly low. Within the past year, however, I have had the opportunity to discuss occupational exposures during glass fibre manufacturing with workers formerly employed at the Canadian facility that manufactured fibrous glass. According to several workers, they were also exposed to crystalline silica many times over the permissible limit through the dumping of sand into the hopper that was used to feed the furnace for melt down. They were exposed to asbestos that lined the furnace when they removed the insulation from the oven doors by hand, or chiselled it away in the absence of respiratory protection; they would then add water to asbestos fibre to make "asbestos mud" that was applied to the oven doors by hand, or by trowel. Workers were so uninformed of the hazard that they sometimes would throw "asbestos mud balls" at each other. The workers at this facility were also exposed to phenol formaldehyde resin that was used as a binder for the glass fibres; they were also exposed to tar that was applied to paper that was then applied to the glass fibre pack. Exposures to glass fibres only is mentioned in the study of these workers that was published by Shannon (1987).

5.406 Furthermore, there is less evidence from epidemiological studies that exposure to glass fibres is associated with a pneumoconiosis as compared to the data for chrysotile asbestos exposure and asbestosis. There is no evidence that exposure to glass fibres is associated with mesothelioma. For the few cases of mesothelioma that have been identified among workers exposed to glass fibres to date, there is claim that they also had been exposed to asbestos fibres. Therefore, it is difficult to attribute these cases of mesothelioma to the glass fibre exposures. Therefore, the totality of disease related to chrysotile asbestos exposure would be greater than that related to a similar amount of exposure to glass fibres.

5.407 In conclusion, only one of the fibres (glass fibres) that may play any significant role in substitution for chrysotile asbestos demonstrates evidence of being carcinogenic. Data for the total toxicity related to these fibres, however, is less than that for chrysotile asbestos fibres. Cellulose fibres have not been tested for carcinogenicity in experimental animals, but epidemiological studies of workers exposed to cellulose in three separate industries, i.e., furniture manufacturing, cotton textile manufacturing and the paper products industry, have not demonstrated an elevated risk of contracting lung cancer or mesothelioma. Regarding non-malignant lung disease among cotton dust exposed workers, it is not known whether the cotton dust per se, or contaminants of the cotton fibre, are responsible for the byssinosis observed in these workers.

Dr. Musk:

5.408 I understand that substitutes have been shown to be less toxic in animals.

3. Summary Comments by Dr. Henderson

5.409 In-place asbestos is widely distributed in industrialized societies and much includes mixtures of chrysotile and amphiboles — although chrysotile has been the predominant type of asbestos used throughout Western Europe for many years (about 94-97%).

5.410 Lung cancer and mesothelioma are the most important bio-hazards from asbestos in place and the continued use of asbestos.

5.411 Because of the prolonged lag-time between exposure and the subsequent development of either lung cancer or mesothelioma, most mesotheliomas in the 1990s and beyond can be attributed to exposures sustained decades before; the mesothelioma "epidemic" predicted for Europe over the next three decades can be attributed to exposures before, during and after the 1960s and 1970s, especially to one or more of the amphibole varieties.

5.412 For the amphibole forms of asbestos and mixtures of asbestos types, a linear dose-response relationship has been found at high levels of exposure; a dose-response relationship with an increase of the relative risk of mesothelioma to > 2.0 has also been observed at low levels of exposure, in the order of 0.5-1.0 fibre-year (which overlaps with non-occupational environmental exposures). No lower threshold dose for mesothelioma induction has been delineated for the amphiboles.

5.413 Chrysotile also has the capacity to induce mesothelioma, although it is less mesotheliomagenic than the amphiboles (my estimate is $1/10^{th}$-$1/30^{th}$).

5.414 Commercial Canadian chrysotile on average contains trace quantities of tremolite, including fibrous tremolite (< 1%).

5.415 Tremolite — a non-commercial amphibole — also has the capacity to induce mesothelioma.

5.416 The carcinogenicity of Canadian chrysotile may be attributable to the trace tremolite content, but it is not possible to separate the dose-response effects for the chrysotile and the tremolite.

5.417 At high levels of exposure to Canadian chrysotile, a linear dose-response relationship has been observed.

5.418 To the best of my knowledge, there are no epidemiological or observational data on dose-response effects of chrysotile only at low levels of exposure.

5.419 No lower threshold dose for the carcinogenic effects of chrysotile has been identified (EHC 203).

5.420 To the best of my knowledge, there are no observational data on the potential carcinogenic effects of inhaled chrysotile when superimposed upon a pre-existing burden of amphiboles ± chrysotile in lung tissue.

5.421 Although the amphiboles are far more potent than chrysotile for mesothelioma induction, this differential in carcinogenicity may be less obvious or absent for lung cancer induction, but this is still the subject of some dispute; chrysotile is associated with a low risk of lung cancer among Canadian chrysotile miners and millers, but the highest risk for lung cancer induction has been observed for South Carolina asbestos textile workers who used Canadian chrysotile almost exclusively.

5.422 A linear dose-response relationship has also been observed for the risk of lung cancer versus cumulative asbestos exposure. Although some authorities favour a linear no-threshold model for lung cancer induction, others suggest that a threshold may exist, but this has not been delineated in numerical terms.

5.423 In contrast, asbestosis is a dose-dependent non-cancerous disorder, with clear evidence of a threshold effect, although the threshold may be lower than previously supposed, at least for

histological asbestosis; there is no risk of asbestosis at low levels of chrysotile exposure.

5.424 Although reduction of airborne asbestos fibre concentrations in the mining and manufacturing industries has been achieved, it is too early to evaluate the effects of these reduced exposures, because no epidemiological data are available; however, with reduction of cumulative exposures, a reduction in the incidence of both asbestos-related mesothelioma and asbestos-related lung cancer can be expected.

5.425 The risks from low-level occupational exposure to chrysotile, or from occasional peak concentrations, have not been delineated but are predictably small.

5.426 Carcinogenic hazards from ultra-low levels of atmospheric chrysotile fibres (e.g. simple occupancy of public buildings) appear to be minuscule, negligible or undetectable.

5.427 Therefore, health concerns over chrysotile dust exposure narrow down to a workplace issue.

5.428 There is evidence of an increased incidence of mesothelioma among, say, brake mechanics in Australia exposed to chrysotile derived from brake blocks and lining.

5.429 With the reductions of airborne fibre concentrations in the asbestos mining, milling and manufacturing industries, construction trades workers constitute the group of workers at greatest risk from exposure to asbestos-cement products (e.g. builders, builders' labourers, carpenters, electricians, plumbers and roofing workers). This group constitutes a large, disparate and non-cohesive workforce for which controlled use of asbestos is not achievable, for the reasons discussed earlier in this report.

5.430 Therefore, chrysotile asbestos should not be used in building materials, because of the hazards imposed by installation, maintenance and removal operations (EHC 203); these risks may be compounded for some groups by catastrophic events affecting buildings — e.g. fires (with a burst of asbestos fibres into the atmosphere and the necessity for clean-up operations), and other disasters.

5.431 Substitutes for chrysotile are available for many applications (e.g. cellulose fibres, para-aramid fibres and polyvinyl alcohol); evidence indicates that these fibres are less bio-persistent than chrysotile and, therefore, national health authorities (EHC 203, NICNAS 99) have recommended phasing out or prohibition of chrysotile whenever safer substitute materials are available.

5.432 Therefore, from a perspective of caution and prudence for occupational health and safety, it follows that chrysotile should either:

(a) Be restricted to only a few and well-defined applications so that it is inaccessible to the great majority of workers and is available for use by only small and cohesive specialized worker groups that can be trained effectively in its controlled use (e.g. analogous to nuclear fuels); in effect, this means that chrysotile should not be used in building products (e.g. high-density fibro-cement materials such as asbestos-cement sheets) or friction products.

OR

(b) It should be made inaccessible to everyone, by prohibition, unless the alternatives pose equal or greater hazards and equal or greater problems with control.

5.433 These views are also expressed in EHC 203, wherein it is stated:

"a) Exposure to chrysotile asbestos poses increased risks for asbestosis, lung cancer and mesothelioma in a dose-dependent manner. No threshold has been identified for carcinogenic risks.
b) Where safer substitute materials for chrysotile are available, they should be considered for use.
c) Some asbestos-containing products pose particular concern and chrysotile use in these circumstances is not recommended These uses include friable products with high exposure potential. Construction materials are of particular concern for several reasons. The construction industry workforce is large and measures to control asbestos are difficult to institute. In-place building materials may also pose risk to those carrying out alterations, maintenance and demolition" … [p 144]
d) The combined effects of chrysotile and other insoluble respirable particles needs further study.
e) More epidemiological data are needed concerning cancer risks for populations exposed to fibre levels below 1 f/ml, as well as continued surveillance of asbestos-populations" … [p 145]

5.434 NICNAS 99 sets out a similar set of recommendations:

- "Chrysotile is a known human carcinogen.

- Prudent OHS [occupational health & safety] policy and public health policy favours the elimination of chrysotile wherever possible and practicable.

- The main exposure to Australian workers arises from manufacture, processing and removal of friction products and gaskets. Home mechanics are also exposed during 'do-it-yourself' replacement of brake pads/shoes. ... . In Australia, chrysotile is no longer used in high density materials such as chrysotile-cement.

- Current overseas experience with the phasing out of chrysotile products indicates that a range of alternatives is available to suit the majority of uses. Good OHS practice dictates that use of chrysotile products should be restricted to those uses where suitable substitutes are not available, and alternatives should continue to be sought for remaining uses".

5.435 Whether the objective of removal of chrysotile from the workplace and the general environment is achievable by enforcement of controlled use for a few restricted applications — or by prohibition — is essentially a societal question and a public health policy issue. For the reasons discussed in this report, a complete ban is more certain to accomplish this objective (paragraph 5.432(b)). Therefore, as a cautious and prudent approach to national occupational health policy, a complete ban is neither unreasoned nor unreasonable; on the balance of prevailing scientific evidence and uncertainties discussed in this report, such a policy seems defensible and, arguably, justifiable as a national health measure. Perhaps it is best to let Bradford Hill have the last words:

"All scientific work is incomplete — whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone action that it appears to demand at a given time."

4. Endnote by Dr. Henderson

5.436 Wishing to add two further pertinent references after completing his Report, Dr. Henderson attached the following Endnote. These references[27] deal with the following:

5.437 Clearance of chrysotile fibres from human lung tissue: In the past, the kinetics of chrysotile clearance from lung tissue have been investigated mainly in experimental models using rodents. In an autopsy study published in 1999, Finkelstein and Dufresne [1] investigated clearance of chrysotile

[27]For complete references, see Annex III to this Panel Report.

from the lung tissue of 72 Quebec chrysotile miners and millers in comparison to 49 control subjects, using regression analyses, with the following findings:

- There was a significant association between the duration of occupational exposure and the tissue burdens of chrysotile and tremolite.

- The concentration of chrysotile decreased with time after exposure ceased but the concentration of tremolite did not.

- The clearance rate varied inversely with the length of chrysotile fibres. For fibres > 10 μm in length - i.e. fibre lengths in the reported range for carcinogenicity - the clearance half-time was estimated to be eight years. In other words, the tissue bio-persistence of chrysotile fibres in this study seems substantially more prolonged than in rodent experiments, and presumably corresponds to persistent high chrysotile fibre concentrations for many years after cessation of occupational exposure in humans, as discussed in paragraphs 5.112 - 5.113. It is also notable that the concentration of 6,250,000 chrysotile fibres mentioned in those paragraphs (for an individual but by no means unusual patient) is probably above the level at which Rogers et al. [2] identified an odds ratio for mesothelioma of > 8.5 (even allowing for differences in fibre size between the two different laboratories), and even the duration of 16 years after exposure stopped (as opposed to its commencement: 24 years) falls into the lag-time range lung cancer induction by asbestos.

- Studies like this suggest that clearance mechanisms can be overwhelmed and break down at occupational levels of exposure in humans, with the existence of a long-term sequestered fraction of chrysotile fibres.

5.438 Mesothelioma rates in men and women in Sweden: attached to this Endnote is a recent paper by Jarvholm et al. [3] on trends in mesothelioma incidence in Sweden, which re-emphasizes some of the points made earlier in this report.

D. COMMENTS BY THE PARTIES ON THE RESPONSES FROM THE EXPERTS

1. Canada

5.439 Canada is pleased that the experts agree with Canada on certain crucial aspects of the debate in this case. Most importantly they opine that:

- Chrysotile is significantly safer than amphibole asbestos (three of the four experts agree);

- there is no risk to the public from low-level environmental exposure to chrysotile or from exposure in buildings that contain chrysotile (all of the experts agree);

- there is no risk to workers in mines or factories where use of chrysotile is controlled (three of the four experts agree); and

- there is no risk to "handymen" or "do-it-yourselfers" who disturb chrysotile products, because their exposure is intermittent and thus inconsequential (three of the four experts appear to agree).

5.440 In short, although the experts agree on the inadequacy of a data (statistical limitation to support a threshold), their findings are consistent with the view that low levels of exposure to

chrysotile asbestos create no detectable health risks. Indeed, the only population that the experts view as having problematic exposure is tradesmen, e.g., plumbers, electricians and mechanics, who disturb or modify chrysotile cement and friction products. At this point, the experts and Canada diverge; also, at this point, the experts stray beyond their specialities (as several admit). Canada maintains that adequate controls for these exposures can be developed and applied and has set forth such controls in Comments to Experts' Answers to Question 5.

5.441 Several other aspects of the experts' answers require comment. Some of the responses of the experts appear not to distinguish between chrysotile and amphibole exposure, and between modern uses (e.g., chrysotile friction and cement products) and historical uses (e.g., insulation containing amphiboles). In many places, for example, the experts appear to draw conclusions regarding chrysotile based in part or in whole on data from individuals exposed to amphiboles and/or amphiboles and chrysotile. This is of greatest concern to Canada regarding the experts' conclusions on tradesmen; as the experts no doubt agree, the greatest risk to tradesmen is not exposure to modern chrysotile products, but the disturbance of flocking or insulation containing amphiboles. Similarly, the experts do not always distinguish peak and cumulative exposures. For the purposes of defining health risks, the cumulative measure, not the peak measure, is key.

5.442 It is crucial that this proceeding forms on the pertinent issues. The key issue is whether exposure to modern uses of chrysotile can be controlled to ensure worker safety or if a total ban is required to achieve an equivalent level of safety. The experts' answers help to focus the proceeding on tradesmen exposure.

Question 1(a)

5.443 Canada believes that the Panel should take note of the clarifications to this question proposed by Drs. de Klerk and Musk. The former writes that "the more relevant question here is: who is likely to receive the most exposure and therefore have the greatest risk of disease". Dr. Musk rephrases the question in almost identical terms, taking the expression "risk of exposure" to mean "who is most likely to receive the most exposure and therefore be at the greatest risk of developing asbestos-related disease". In Canada's view, because the evidence suggests different risk per unit fibre exposure in different sectors, it is the combination of level of exposure, duration of exposure and risk per unit fibre exposure that is important.

5.444 The experts have confirmed that any risk from exposure to chrysotile will depend on the nature of an individual's specific occupational setting and the risk per unit fibre exposure in that setting, certain sectors being the subject of more stringent controls than others. For example, the experts echo the Parties' agreement to the effect that the mining and manufacturing sectors have successfully controlled the risks to which their workers had previously been exposed. Certain settings pose lower risk per unit fibre exposure than others do.

5.445 Canada does not disagree with the statement that the so-called secondary user sector is the most diverse. Canada nevertheless understands that the experts do not believe that the diversity of this particular workforce is to be considered the only factor that may contribute to a greater likelihood of exposure; rather, as Dr. Musk puts it, "the risk of developing asbestos-related disease [...] (also) depend(s) on [...] the type of asbestos being produced or used or otherwise encountered. It would also depend on the conditions of work such as indoors versus outdoor etc." As the Panel also knows, the specific uses or products also entail more or less risk.

5.446 Canada does not believe that the diversity of this workforce precludes effective control. The diversity of a specific workforce is not indicative of the quality of the work practices actually observed by the members of that workforce. A typical construction site offers numerous examples of sound safety practices: from hard hats to proper footwear, from the use of common sense to following

trade-specific work practises, measures are taken to insure safety and avoid trauma.

5.447 Canada notes that the experts have not commented on the assertion by the European Communities that there is a correlation between the amount of chrysotile used by France and the incidence of asbestos-related disease. Clearly no such correlation can be made, in logic or in fact. The logic on which the European Communities purports to base this assertion is a sophism, and should be dismissed accordingly. From a factual point of view, the following factors suggest that the correlation is false: the relative difference in potency and in biopersistence of amphiboles and chrysotile, the historical uses of each fibre type, and the differences in risk per unit fibre exposure in different sectors.

5.448 Canada notes that Dr. Infante assimilates friable amphibole or mixed fibre type exposure circumstances to those of high-density chrysotile products, thereby answering the wrong question. He correctly identifies worker contact with insulation as being the "typical scenario" in which exposure to asbestos will occur. But most insulation is friable, as opposed to high-density, and most friable insulation products contained amphiboles or mixed fibre types. It is not clear how this answer based on friable mixed asbestos products responds to a question relating solely to safety of high-density chrysotile products.

Question 1(b)

5.449 Canada takes note that the experts have indicated that the risk of human health associated with the various uses of chrysotile throughout its life cycle is overwhelmingly a workplace issue, and therefore not related to the "handyman".[28]

Question 1(c)

5.450 The answers given by the experts indicate that, on their own, chrysotile cement products do not pose a health risk because of their normal weathering, erosion or general degradation, and that "there is little or no dispute among experts on this issue".[29]

5.451 Canada wishes to draw the attention of the Panel to the results of the investigation carried out by the Western Australia Advisory Committee on Hazardous Substances (WAACHS), cited by Dr. Henderson.[30] This report contains different sections describing asbestos cement products, their production and use and their health effects, as well as surveys of schools and other relevant measurements of asbestos concentrations. In addition to pertinent recommendations, the report contains several appendices, including one on the *Effects of Asbestos Cement Products – A Review of the Literature* and another on *Acceptable Air Concentrations of Asbestos Fibres in the General Environment*, both prepared by one of the experts to this Panel, Dr. de Klerk.

5.452 On low level air concentrations, Dr. de Klerk writes: "[M]ost of these estimates are on or below the level of what the Royal Society would consider acceptable [...] The 1986 IPCS report did not even bother to estimate such risks and summarised the risk exposure unrelated to occupation as being undetectably low".[31] Indeed, the executive summary of the WAACHS report indicates: "[...] [T]he level of risk is low enough to be considered to be negligible relative to these other risks in our

[28]Canada notes that, according to Dr. Henderson: "[f]rom my perspective, this is overwhelmingly a workplace issue […]".

[29]Henderson, answer to Question 1(d).

[30]Henderson, p. 54, citing Multiple Authors, *Asbestos Cement Products. Report by the Western Australia Advisory Committee on Hazardous Substances*, Perth, 1990, hereinafter the WAACHS Report.

[31]De Klerk, N., *Acceptable Air Concentrations of Asbestos Fibres in the General Environment. A Review of Scientific Evidence and Opinion* in the WAACHS Report, Appendix 3, p. 10.

society".[32] Similarly, in his report to the Panel, Dr. Henderson underlines that compared to the fibre concentrations observed in the vicinity of asbestos-cement roofing, "a greater risk to health would arise from [workers] falling from or through the roofs".[33]

5.453 High-density chrysotile on buildings has been extensively studied. Indeed Teichert found the following: "the study of emission conducted on coated and uncoated roofing materials revealed low asbestos fibre concentrations, even though severe corrosion was observed on uncoated asbestos cement roofs and a considerable quantity of material containing asbestos could be removed by blowing or suction. The asbestos fibre concentrations that were measured in populated areas are well below the level considered acceptable by the Health Authorities of the Federal Republic of Germany, i.e. clearly below 1000 fibres/m^3 (or 0.001 f/ml)".[34] Felbermayer and Ussar, for their part, write: "a comparison of the asbestos fibre concentrations in those areas with and without asbestos-cement roofing (...) lead to the conclusion that there is no statistical significant connection between the use of asbestos-cement materials and the asbestos fibre concentrations found in the various measurement areas."[35]

5.454 Finally, Canada would like to bring to the Panel's attention the following recommendation of the WAACHS report, which is: "[A]n asbestos cement roof, which has not deteriorated to an extent where physical safety or structural integrity is of concern, should not be replaced. In addition, an asbestos cement roof should not be treated with a coating on the basis of risk to health. Other asbestos cement products are generally less prone to deterioration and do not require attention for health purposes".[36] Nonetheless, many chrysotile-cement products are coated with protective sealant agents.

Question 1(d)

5.455 The experts agree that the degree of risk to the health of workers intervening on high-density chrysotile cement products will depend on the manner in which an intervention is carried out. As noted by Dr. Infante in his response to question 1(e), "the extent of the exposure to the worker (...) would depend on the nature of the intervention, e.g., the circumstances under which the chrysotile asbestos product is manipulated in terms of work practices, the controls, or lack of controls in place and the type of personal protective equipment provided to the worker". Dr. Henderson illustrates this proposition when he writes that "cutting (chrysotile-cement) with hand saws produced lower concentrations."

5.456 Canada accepts that abrasion and cutting of high-density chrysotile products can release materials. However, the degree of exposure, if any, will depend on the methods and controls used. Canada notes that the experts disagree as to the exact composition of the materials that would be released by such interventions (see question 1 (f)), although there is apparent agreement that cutting chrysotile cement releases crystalline silica, an IARC Class 1 carcinogen.[37] Cutting chrysotile cement using simple work practices such as those outlined in ISO Standard 7337 will therefore provide protection from any potentially harmful material contained in such a product. Wetting the product before cutting and/or using commonly found suction attachments when sawing are techniques that can be used as added, but perhaps unnecessary, precautions. A final safety barrier would be for the worker to wear a facemask: this step would render it virtually impossible for the worker to inhale dust.

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[32]WAACHS Report, p. 2.

[33]Henderson, answer to Question 1(b).

[34]Teichert, U., *Immissionen durch Asbestzement-Produkte*, (1986) Teil 1 Stub Reinhaltung der Luft, Vol. 46, No. 10, pp. 432-434.

[35]Felbermayer, W., Ussar, M. B., *Research Report: Airborne Asbestos Fibres Eroded from Asbestos Cement Sheets*, (1980) Institut für Umweltschutz und Emissionesfragen, Leoben, Austria.

[36]WAACHS Report, p. 4.

[37]Infante, answer to Question 1(f).

5.457 Neither the European Communities nor the experts have demonstrated that such practices would subject workers to cumulative exposures presenting health risks. An American survey estimated that a worker would spend less than 1/16th of his work time on tasks that would involve aggressive interventions on chrysotile-cement of the type susceptible of releasing any substantial amount of dust.[38] Canada submits that the European Communities have not identified any population of workers that would be subject to a detectable risk because of professional contact with high-density chrysotile cement. The European Communities' contentions *vis-à-vis* the "handyman" are therefore even less convincing (see next answer).

Question 1(e)

5.458 Canada agrees with Dr. Henderson's conclusion that "occasional interventions (...) would predictably produce low cumulative exposures, with a lower risk (...)". Dr. Henderson also affirms that for "electricians, carpenters, plumbers, insulation workers and so forth", "it is acknowledged that most if not all these mesotheliomas are a consequence of exposure to (...) a mixture of asbestos types, including chrysotile and one or more of the amphiboles."

5.459 The Panel has not been presented with evidence that contradicts Canada's assertion that occasional interventions do not pose a risk that is significantly different from zero (statistically). Therefore, the experts have not validated the EC's claim that an alleged risk for workers or the "handyman" is something more than undetectable.

5.460 Nor has the Panel been presented with evidence or expert opinion that supports the European Communities' claim with respect to the "handyman". Given that cohorts exposed to relatively high concentrations of chrysotile over entire occupational lifetimes show no increase of disease, it is unlikely that occasional interventions by a "handyman" would produce more than an equally undetectable risk. Obviously the "handyman" or *bricoleur du dimanche* will not encounter high-density chrysotile-cement products on a daily basis, nor devote his "handiwork" exclusively or principally to cutting such products. Rather, the typical "handyman" will rarely, if ever, come into contact with chrysotile cement products, let alone be sawing them.

5.461 The Panel should note that no evidence has been presented that shows any fatality in workers, let alone in "handymen", who would have been subject to any form of exposure, high or low, from contact with chrysotile cement products; the argument presented by the European Communities has been based entirely on hypothetical scenarios.[39]

Question 1(f)

5.462 There is debate in the scientific community and among the experts appointed by the Panel as to the exact physical and chemical composition of what is contained in dust from certain interventions on chrysotile cement products. Dr. Infante writes, however, that this dust (indeed, all cement dust) will contain "crystalline silica", a known IARC Class 1 carcinogen found in all cement.

5.463 A 1992 IARC publication determined that "in asbestos-cement products, the asbestos fibres usually represent 10-15 per cent of the total weight and are embedded in the cement. Therefore, it is not certain a priori that dust generated from asbestos-cement products will have the same effect as dust from pure chrysotile. [I]n asbestos-cement dust most of the asbestos fibres form aggregates with cement particles ... [t]hose which do not form aggregates ... appear to be coated with a calcium-containing layer. In absorption experiments, the asbestos-cement dust behaves more like cement dust

[38]CONSAD Research Corporation, 1990, No. 8282.
[39]See Canada's Comments to Questions 5(c) and (e).

than like asbestos dust."[40] Because the surface properties of asbestos fibres are altered by certain heating, pH, and abrasion conditions[41], it can be deduced that the composition and effect of the final aerosol would be different than that suggested by studies of concentrations of fibres alone. And again, controlled use procedures limit release, and proper breathing equipment precludes exposure.

Question 1(g)

5.464 Canada believes that the Panel was not presented with any quantification of this risk, or indeed its existence. Dr. Infante describes how the removal of chrysotile cement panels can be accomplished with negligible release of respirable fibres. Most other chrysotile cement products are found in the form of underground water pipes. Studies show that these products remain intact for decades after installation.[42] Hence, very little of this product will need to be disturbed. Moreover, the excavation and removal of pipes is not executed by manual labour, the bulk of any removal being done by heavy machinery.

5.465 The Panel should also note that the removal of chrysotile cement products does not generally entail crushing. Rather, if and when necessary, chrysotile cement products can be removed, transported, and disposed of by means that do not constitute a detectable risk to human health. The French Circulaire 97-15 accomplishes this goal for the high-density products at issue in this proceeding.[43] Also, if France is ensuring the safe removal and disposal of friable asbestos materials[44] known to contain amphiboles or mixed fibre types, the Panel should conclude that the removal and disposal of high-density chrysotile cement products can be accomplished even more safely, since high-density materials are indisputably recognised, even by France, as much easier to manage than anything in friable form.[45]

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[40]*Characterization and Proprieties of Asbestos-Cement Dust,* in Biological Effects of Mineral Fibres, Vol. 1, IARC Scientific Publications No. 30, Lyon, 1980, pp. 43, 49 and 50.

[41]Henderson, answer to Question 2.

[42]Canada notes that a study of 15 water supply systems in the State of Illinois U.S.A., where some asbestos-cement pipes were up to 40 years old, and where the water was non-aggressive to moderately aggressive, shows no significant differences in the water before and after passing through the asbestos-cement pipe network: Hallenbeck, W. H., et al., *Is Chrysotile Asbestos Released from Asbestos Cement Pipe into Drinking Water*, (1978) Journal of the American Water Works Association 70 (2): 97-102.

[43]Circulaire no. 97-15 du 9 janvier 1997 *relative à l'élimination des déchets d'amiante-ciment générés lors des travaux de réhabilitation et de démolition du bâtiment et des travaux publics, des produits d'amiante-ciment retirés de la vente et provenant des industries de fabrication d'amiante-ciment et des points de vente ainsi que tous autres stock.*

[44]Circulaire no. 96-60 du 19 juillet 1996 *relative à l'élimination des déchets générés lors des travaux relatifs aux flocages et aux calorifugeages contenant de l'amiante dans le bâtiment.*

[45]Canada notes that French regulations indeed recognize a difference in disposal proscriptions between "les matériaux friables" and "l'amiante liée" – see Note DPPR/SDPD/BGTD/LT/LT no. 97-320 du 12 mars 1997 relative aux conséquences de l'interdiction de l'amiante et à l'élimination des déchets, which is as follows:

> *"III. – Quelles sont les fillières d'élimination des déchets contenant de l'amiante?*
>
> *"Deux circulaires ont été diffusées, l'une le 19 juillet 1996 pour les déchets issus des travaux relatifs aux flocages et aux calorifugeages, l'autre le 9 janvier 1997 pour les déchets d'amiante-ciment.*
>
> *"Les fillières d'élimination des déchets contenant de l'amiante autres que ceux qui ont fait l'objet des deux cricularies précitées peuvent être déterminées par analogie aux prescriptions de ces deux circulaires:*
>
> - *Les matériaux friables, c'est-à-dire les matériaux susceptibles d'émettre des fibres sous l'effet de chocs, de vibrations ou de mouvements d'air, sont assimilables aux flocages et aux calorifugeages. Ils devront être éliminés dans des installations de stockage des déchets industriels spéciaux ou dans l'unité de vitrification;*
> - *pour les déchets contenant de l'amiante liée, trois cas sont envisageables:*

Question 1(h)

5.466 See comments on previous question.

Question 1(i)

5.467 Canada wishes to add the following comments on the answers to this question. Once removed from a building, a chrysotile cement panel, even if broken into several pieces, remains as intact as when it formed part of that building. Studies referred to above indicate that chrysotile cement roofing does not contribute (< 0.001 f/ml) to the levels of chrysotile occurring naturally in the environment. Likewise, chrysotile cement piping is generally found below ground, and therefore does not contribute to the levels of chrysotile naturally occurring in the atmosphere. If removed from roofing, or if excavated and removed from a water system, chrysotile cement products are transported to a landfill and buried anew beneath a layer of earth. Consequently, Canada is of the view that used chrysotile cement products can be eliminated safely.

5.468 Canada also notes that recent technology has enabled safe (in some cases, on-site) disposal of chrysotile products. For example, chrysotile can be treated with chemicals and/or subjected to high temperatures so as to render the end product entirely harmless and, in fact, suitable for enhancing the quality of soils. For example, in the United States, a foam has been developed that eliminates the risk associated with removing asbestos from buildings; when this product is sprayed onto asbestos fireproofing, the fibres turn into harmless globs of magnesium silica. A U.S. building contractor recycles asbestos by subjecting it to a chemical bath and high temperatures resulting in a totally inert end-product suitable for soil improvement. A Japanese company, responding to a government law mandating pollution-free disposal of asbestos, melts asbestos into harmless glass.[46]

Question 2

5.469 Canada has advocated the use of chrysotile in high-density products only; textiles are not of that category, and had been banned in France prior to the adoption of the measure that is the subject of this dispute. Friction materials using chrysotile have not been shown to constitute a risk to human health.[47] Indeed, the contrary is probably true: lesser braking action of linings manufactured without

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- *Si les déchets sont composés d'amiante associée uniquement avec des matériaux inertes, ceux-ci pourront être éliminés conformément à la circulaire du 9 janvier 1997 relativement à l'élimination des déchets d'amiante-ciment;*
- *si l'amiante est associée avec des matériaux, qui lorsqu'ils deviennent des déchets, sont classés déchets ménagers et assimilés, c'est par exemple le cas des dalles vinyl-amiante, ils pourront être éliminés dans des installations de stockage de déchets ménagers et assimilés;*
- *si l'amiante est associée avec des matériaux, qui lorsqu'ils deviennent des déchets, sont classés déchets industriels spéciaux, ils devront être éliminés soit dans des installations de stockage de déchets industriels spéciaux, soit dans l'unité de vitrification.*

"Dans tous les cas, l'industriel ou l'entreprise devra fournir des éléments permettant de caractériser les déchets afin de déterminer les filières d'élimination adaptées."

[46]*Acid v. Asbestos*, Discover, Information Access Company, No. 7, Vol. 20, July 1, 1999, p. 102.; *Contractor Recycles Asbestos for Re-Use in Construction*, Air Conditioning, Heating & Refrigeration News, Business News Publishing Company, Vol. 194, No. 2, January 9, 1995, p.1*; Kent Firm Fires up New Asbestos-Disposal System*, Puget Sound Business Journal, Vol. 13, No. 14, August 21, 1992, p. 9; *Japanese Plant Turns Asbestos into Glass*, American Metal Market, Vol. 100, No. 145, July 28, 1992, p. 4.

[47]Appendix A on Control Use in the Friction Industry, Canada's Comments to Question 5(a), contained in Annex IV to this Report.

chrysotile is cited by France as the safety concern for which it exempted certain military vehicles from the purview of the Decree.[48]

Question 3(a)

5.470 Three of the four experts concur with the position of Canada and the WHO that a clear distinction must be made between chrysotile and amphiboles. Dr. Musk believes that "there is a need to distinguish chrysotile asbestos from amphiboles based on the epidemiological data at least" and that the relative pathogenicity of some amphiboles to chrysotile may, in some cases such as mesothelioma, be 100 to 1. Dr. de Klerk affirms that the "epidemiological evidence is clear that, for a given quantity (intensity and duration) of exposure, chrysotile imparts less risk than amphibole fibres." The difference in pathogenicity is, according to Dr. de Klerk, up to 50-fold in the case of lung cancer and up to 100-fold for mesothelioma. Dr. Henderson concludes that: "a clear distinction should be made between chrysotile and the amphibole forms of asbestos."

5.471 Domestic legislation and international standards have long recognized the relative pathogenicity of different asbestos fibre types by permitting higher exposures to chrysotile than to amphiboles. In the European Communities in 1998, for example, the maximum exposure level for amphiboles was 0.3 f/ml, whereas it was 0.6 f/ml for chrysotile. In Canada (Quebec), it is 0.2 f/ml for crocidolite and 1 f/ml for chrysotile. Similarly, international instruments such as the ILO's *Convention 162* and *Recommendation 172* advocate an outright ban on crocidolite, while recommending replacing chrysotile if and only if safer substitutes exist.

5.472 Dr. Infante acknowledges epidemiological data to the effect that chrysotile is less dangerous than amphiboles, but sees no basis for distinguishing between asbestos fibre types. Dr. Infante's dissident view to the question of relative pathogenicity between asbestos fibres – one which echoes the European Communities' argument but simply begs the question – is that because amphiboles and chrysotile are both classified as carcinogens, no distinction should be made.

5.473 In 1998, the WHO affirmed that a distinction should be made between chrysotile and amphiboles because using data from exposures to amphiboles "contribute[s] less to our understanding of the effects of chrysotile, due to concomitant exposure to amphiboles."[49] The distinction between chrysotile and amphiboles is crucial in this instance since the current problem of asbestos in France is due to past uses of friable materials, high-level exposures, and the use of amphibole fibres. The distinction between chrysotile and amphibole asbestos is also important because the extrapolations made by INSERM to assess the risks associated with chrysotile are based on exposures to amphibole fibres in proportions of up to 100 per cent in circumstances which have nothing to do with the current uses of chrysotile.[50]

Question 3(b)

5.474 Physical properties, as well as chemical properties that determine biopersistence, are identified as relevant factors of pathogenicity by Drs. Musk, Henderson and de Klerk and by the WHO.[51]

5.475 Dr. de Klerk, for example, has written that:

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[48]Article Ier 2a) *Arrêté du 17 mars 1998 relatif aux exceptions à l'interdiction de l'amiante*.

[49]WHO, *IPCS Health Criteria 203 on Chrysotile*, WHO, Geneva, 1998, p. 107.

[50]See notably INSERM Report, p. 213.

[51]WHO, *IPCS Health Criteria 203 on Chrysotile*, WHO, Geneva, 1998, p. 51: "[I]t is considered that the potential respiratory health effects related to [...] airborne concentrations, patterns of exposure, fibre shape, diameter and length (which affect lung deposition and clearance) and biopersistence."

> "[T]he important carcinogenic properties of asbestos are related to the physical properties of size and shape of the fibers, and to their quantity. To cause any harm, fibers must be able to reach the target organs [...]." […]
>
> "[I]n all occupationally exposed series of mesotheliomas, none have occurred in cohorts where amphibole asbestos has never been used or detected. Chrysotile asbestos has not been directly implicated in any case of peritoneal mesothelioma. [...] The main differences between the effects of chrysotile and amphibole fibers are:
>
> 1. Industries using a mixture of asbestos types have higher rates of disease than similar industries using only chrysotile.
> 2. Chrysotile fibers are eliminated more readily from the lungs than are amphibole fibers.
> 3. Much smaller doses of amphibole fibers than chrysotile fibers can induce mesothelioma."[52]

5.476 All four experts recognize the lower biopersistence of chrysotile. INSERM, citing numerous studies, also acknowledges the lower biopersistence of chrysotile:

> "Les études expérimentales ont montré que la biopersistance des fibres de chrysotile était inférieure à celle des amphiboles (Wagner et al., 1974; Davis et al.; Davis and Jones, 1988, Churg et al., 1989; Churg, 1994)."[53]

5.477 Dr. Infante identifies the physical characteristics as also relevant to the relative pathogenicity of asbestos fibre types, but, unlike the three other experts and the WHO, believes that the role of biopersistence, through the element of solubility, "is not so clear."

5.478 Chrysotile fibres are "curly" and downy while amphibole fibres are straight and rigid like needles.[54] Drs. de Klerk and Musk both specifically address the "straightness" element. The WHO has observed that:

> "Inhalation of respirable straight fibres [amphiboles] is reported to be associated with greater penetration to the terminal bronchioles than in the case of 'curly' fibres [chrysotile]."[55]

5.479 Once they have entered the respiratory tract, chrysotile asbestos fibres, because of their curly shape, are more easily cleared by the mucociliary process than are straight and rigid amphibole fibres.[56] Dr. Henderson writes: "[I]t is well known that chrysotile fibres are cleared more rapidly than amphiboles, especially in long-term studies (Churg, 1994)."[57] This is confirmed by a 1994 European study by Dr. Albin: "[A]dverse effects are associated rather with the fibres retained (amphiboles), than with the ones being cleared (largely chrysotile)."[58]

5.480 For chrysotile fibres that do nonetheless manage to become lodged in the lungs, the solubility of the fibres and the action of macrophages come into play to make chrysotile a much less potent fibre. First, as the WHO recognizes, chrysotile has a lower resistance than amphiboles in acidic

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[52]de Klerk, N.H. and Armstrong, B.K., *The Epidemiology of Asbestos and Mesothelioma* in Malignant Mesothelioma, Henderson, D.W. et al., eds. Hemisphere Publishing, New York, 1992, 223 at p. 230.

[53]INSERM Report, p. 92.

[54]WHO, IPCS Health Criteria 203 on Chrysotile, WHO, Geneva, 1998, p. 11.

[55]WHO, IPCS Health Criteria 203 on Chrysotile, WHO, Geneva, 1998, p. 11.

[56]Kumar, V., Cotran, R. and Robbins, S., *Basic Pathology*, 6th Ed., London, Saunders Co., 1997, p. 228.

[57]Henderson, see above para. 5.112.

[58]Albin, M., *et al., Retention Patterns of Asbestos Fibres in Lung Tissue Among Asbestos Cement Workers* (1994) 51 J. of Occupational Environmental Medicine 205.

environments such as the lungs.[59] Second, the macrophages responsible for eliminating fibres from the lungs are able to deal more easily with chrysotile fibres than with amphibole fibres. A 1997 report of the French Government (G2SAT) referred to by the European Communities, recognizes that as a result of the chemical dissolution process that takes place in the lungs, carcinogen activity is subsequently practically nil:

> "Il a été démontré que le chrysotile est nettement plus facilement éliminé du poumon humain que les autres formes [amphiboles]. Par ailleurs, il ne présente pratiquement plus d'activité cancérogène (par injection intra-cavitaire) après attaque acide, laquelle dissout la majorité du magnésium."[60]

5.481 Dr. Wagner, in his 1988 study of asbestos-related diseases, concluded:

> "Chrysotile is the least harmful form of asbestos in every respect and [...] more emphasis should be laid on the different biological effects of amphibole and serpentine asbestos fibre."[61]

5.482 It should also be noted that gravimetric comparisons between amphiboles and chrysotile – widely used in the past in experimental work – tend to grossly misrepresent the relative pathogenicity of the fibres. According to the WHO, chrysotile "may contain more than 10 times more fibres per unit weight."[62] Recent studies that use both the fibre mass and the number of fibres as dose units confirm that, on a per fibre basis, amphiboles are far more pathogenic than chrysotile.[63]

Question 3(c)

(i) Asbestosis

5.483 Dr. Henderson asserts that: "[T]he amphibole varieties of asbestos appear to be substantially more pathogenic than chrysotile for the induction of asbestosis and mesothelioma." According to Dr. Henderson, "[A]sbestosis is a dose-dependent disorder with a threshold effect [...] There is widespread agreement that asbestosis in general is a consequence of high intensity exposure (or lower intensity but more prolonged exposure)."

5.484 INSERM also supports the existence of a threshold for asbestosis,[64] and according to INSERM, current low-level exposures to chrysotile pose no threat of asbestosis: "les expositions actuellement relevées dans les industries directement utilisatrices d'amiante devraient conduire à la disparition des cas d'asbestose confirmée (Doll et Peto, 1985)."[65] It is clear, therefore, that asbestosis is not relevant to this dispute.

(ii) Lung Cancer

5.485 Dr. Musk believes that lung cancer risks are more than ten times greater in the case of amphiboles than in the case of chrysotile asbestos. Dr. de Klerk suggests the difference may be up to 50-fold.

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[59]WHO, *IPCS Health Criteria 203 on Chrysotile*, WHO, Geneva, 1998, p. 4. Kumar, V., Cotran, R. and Robbins, S., *Basic Pathology*, 6th ed., London, Saunders Co., 1997, pp. 227; INSERM Report, p. 396.

[60]INRS, *Rapport du Groupe scientifique pour la surveillance des atmosphères de travail (G2SAT)*, 1997, p. 47.

[61]Wagner, J.C. et al., *Correlation between Fibre Content of the Lung and Disease in East London Asbestos Factory Workers*, (1988) 45 British Journal of Industrial Medicine 305.

[62]WHO, IPCS Health Criteria 203 on Chrysotile, WHO, Geneva, 1998, p. 69.

[63]See WHO, *IPCS Health Criteria 203 on Chrysotile*, WHO, Geneva, 1998, p. 69 and 81; INSERM Report, Table 2, p. 196; EPA, Integrated Risk Information System, *Asbestos*, Document No. CASRN 1332-21-4 on-line: EPA, <http://www.epa.gov/ngispgm3/iris/subst/0371.htm> (access date: June 10, 1999).

[64]INSERM Report, p. 327.

[65]INSERM Report, p. 327.

5.486 Dr. Henderson states that the "greater carcinogenicity of the amphiboles [...] appears not to extend to the induction of lung cancer"[66] but he admits that "chrysotile is implicated in one of the lowest rates of asbestos-associated lung cancer (in Quebec chrysotile miners and millers)."[67] Dr. Henderson's reluctance to conclude the greater carcinogenicity of amphiboles seems to be caused by the results of Dr. Dement's study of the Charleston, South Carolina asbestos textile industry.[68]

5.487 The Charleston data has recently been revisited by Bruce Case, André Dufresne, A.D. McDonald, J.C. McDonald and Patrick Sébastien in a study released in Maastricht in October 1999 at the *VII*th *International Symposium on Inhaled Particles*, a symposium attended by some of the world's leading experts. This study shows that a significant amount of crocidolite and amosite fibres was found in the textile workers' lungs. This analysis sheds new light on the issue and explains the extreme results of the original study by Dr. Dement[69] and the subsequent study by Dr. Stayner.[70] These studies of textile workers exposed to crocidolite and amosite can thereby no longer be used to demonstrate the risks associated with chrysotile fibres.

5.488 The seminal findings of Case et al. may cause Dr. Infante to reconsider his view – based principally on the studies by Dement and by Stayner – that "chrysotile may be more potent in causing lung cancer."

(iii) Mesothelioma

5.489 On the relative risks of mesothelioma, Dr. Henderson observes that: "[T]here is general though not universal agreement of a differential potency between the amphiboles versus [chrysotile] for mesothelioma induction." He believes amphiboles may be greater than 60 times more likely than chrysotile to induce mesothelioma.[71] Drs. Musk and de Klerk estimate that the potency of amphiboles may be 100 times greater. And although Dr. Infante also concedes that "amphiboles may be more potent in causing mesothelioma", he fails to conclude from this that a distinction exists between chrysotile and amphibole fibres.

5.490 This distinction is also emphasized in pathology medical reference books:

> "It is important to make the distinction between various forms of amphiboles and serpentines, because amphiboles, even though less prevalent, are more pathogenic than the serpentine chrysotile, particularly with respect to induction of malignant pleural tumors (mesotheliomas). Indeed, some studies have shown the link is almost invariably to amphibole exposure."[72]

(iv) Other Diseases

5.491 Dr. de Klerk links other asbestos-related diseases such as pleural plaques and pleural thickening more with amphiboles than with chrysotile: "[P]leural plaques appear to be more common among anthophyllite workers than others while crocidolite workers have more diffuse pleural

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[66]Henderson, see above paragraph 5.146.
[67]*Ibid*.
[68]*Ibid*.
[69]Dement, J.M., Brown, D.P. and Okun, A. , *Follow-Up Study of Chrysotile Asbestos Textile Workers: Cohort Mortality and Case-Control Analyses,* (1994) 26 American J. of Industrial Medicine 431.
[70]Stayner, L., Smith, R., Bailer, J., Gilbert, S., Steenland, K., Dement, J., Brown, D., Lemen, R., *Exposure-Response Analysis of Risk of Respiratory Disease Associated with Occupational Exposure to Chrysotile Asbestos,* (1997) 54 Occupational Environmental Medicine 646.
[71]Henderson, see above para.5.103.
[72]See Kumar, V., Cotran, R. et Robbins, S., *Basic Pathology*, 6th Ed., London, Saunders Co., 1997 at pp. 227-28.

thickening, and benign asbestos pleurisy also seems to be more common after crocidolite exposure." Dr. Henderson also raises the issue of types of fibres in dealing with parietal pleural plaques.

Question 4(a)

5.492 Drs. de Klerk and Musk agree that the existing epidemiological data show no excess health risks at low-level chrysotile exposures. Dr. Henderson is not aware of exposure-response data for low-level exposures. Dr. Infante again relies heavily on Stayner's study, a study on one single cohort of textile workers now known to be based on textile workers exposed to amphiboles as well as to chrysotile.[73] Newhouse and Sullivan studied exposures to chrysotile in the manufacturing setting: "[I]t is concluded that with good environmental control, chrysotile asbestos may be used in manufacture without excess mortality."[74]

5.493 Thomas et al. concluded similarly for an asbestos cement factory: "[T]hus the general results of this mortality survey suggest that the population of the chrysotile-cement factory studied are not at any excess risk in terms of total mortality, all cancer mortality, cancers of the lung and bronchus, or gastrointestinal cancers."[75]

5.494 There is clearly no increased risk of lung cancer in the friction products manufacturing industry at levels below 356 f/ml-years. This means that there was no chrysotile-related increase in lung cancer risk for persons exposed to the equivalent of up to 8.9 f/ml for 40 years. Even if we allowed a 10-fold protection factor this would be 0.9 f/ml for 40 years for lung cancer.[76] More recently in 1997, McDonald et al. concluded from the analysis of a cohort of 10,000 asbestos workers with average exposures to 45 f/ml over 20 years that: "[...] from the point of view of mortality [...] exposure in this industry to less than 300 mpcf.years [approximately 45 f/ml over 20 years] has been essentially innocuous."[77] This unequivocal data comes from the longest term study of the largest group of chrysotile workers ever conducted. A review of eight studies of cohorts exposed to chrysotile only led its authors to conclude: "[T]he evidence for chrysotile shows that for lung cancer and mesothelioma there exist levels of exposure below which risks are for practical purposes zero."[78]

Question 4(b)

5.495 According to Dr. Henderson, whether a threshold exists generally is a much-debated issue. For the case at hand, i.e. low-level exposure to chrysotile, Dr. Henderson states that: "[I]f a threshold exists, it must lie somewhere in this area, between no exposure, low-level environmental exposure, and low-level occupational exposure." He also points out that, although no threshold has been identified, "[a]t the same time, no increase in risk of mesothelioma has been identified at very low-levels of exposures." Drs. Musk and de Klerk agree that the epidemiological data show an absence of risk at low exposure levels, but are unwilling to commit to the existence of a threshold. If there is

[73]See Canada's Comments to Question 3.

[74]Newhouse, M.L. and Sullivan, K.R., *A Mortality Study of Workers Manufacturing Friction Materials,* (1989) 46:3 British Journal of Industrial Medicine 176, p. 176.

[75]Thomas, H.F., Benjamin, I.T., Elwood, P.C. and Sweetnam, P.M., *Further Follow-Up Study of Workers From an Asbestos Cement Factory,* (1982) 39:3 British J. of Industrial Medicine 273, p. 275.

[76]Berry, G. and Newhouse, M.I., *Mortality of Workers Manufacturing Friction Materials Using Asbestos*, (1983) 40 British Journal of Industrial Medicine 1 at 6, p. 6.

[77]Liddell, F.D.K., McDonald, A.D. and McDonald, J.C., *The 1891-1920 Birth Cohort of Quebec Chrysotile Miners and Millers: Development from 1904 and Mortality to 1992*, (1997) 41 Annals of Occupational Hygiene 13, p. 13.

[78]Browne, K. and Gibbs, G., "Chrysotile Asbestos – Thresholds of Risk" in Chiotany, K., Hosoda, Y., Aizawa, Y., eds., *Advances in the Prevention of Occupational Respiratory Diseases*, Elsevier, Amsterdam, 1998 at p. 306.

agreement that low level exposures show no increased health risk, admitting the existence of a threshold is academic.

5.496 The extreme difficulty of proving a threshold scientifically is echoed by the European Communities' DG XXIV Report:

> "In fact, a threshold implies the demonstration that an effect does not occur at or under a given dose level. The unequivocal demonstration (i.e. identification) of a 'negative' is tantamount to impossible."[79]

5.497 The corollary to the proof of a threshold is the proof of the absence of a threshold. The proof that no threshold exists would need to explain the absence of an excess risk of lung cancer or mesothelioma in chrysotile-only cohorts, as well as the lack of any chrysotile-related increase in lung cancer mortality in workers exposed to less than 900 f/ml-years in the 10,000 miners and millers studied in Quebec.[80] Dr. Henderson does acknowledge the existence of a threshold for asbestosis in his answer to Question 3: "Asbestosis is a lung dependent disorder with a threshold effect [...] There is widespread agreement that asbestosis in general is a consequence of high intensity exposure (or lower intensity but more prolonged exposure)." INSERM also supports the existence of a threshold for asbestosis:

> "La plupart des données épidémiologiques recueillies dans des populations professionnelles exposées suggèrent que l'asbestose cliniquement et/ou radiologiquement caractérisée n'apparaît qu'à partir d'expositions suffisamment élevées [...] un seuil minimal de 25 f/ml-années a ainsi été avancé (Doll et Peto, 1985)."[81]

5.498 Why could there not be a threshold for other asbestos-related diseases? Dr. de Klerk asserts that:

> "[I]t is now widely believed that the risk for chrysotile workers in fibrous cement and friction product manufacturing is so slight as to be undetectable. It is widely held that this kind of negligible risk level 'threshold' exists at different levels for all types of asbestos for all relevant diseases."[82]

5.499 Some experts advising the EC believe there is a threshold for diseases other than asbestosis:

> "It is very likely that there is a practical level of exposure below which it will be impossible to detect any excess mortality or morbidity due to asbestos. [...] Thus, it is possible that there is a level of exposure (perhaps already achieved in the general public) where the risk is negligibly small."[83]

5.500 This links to Dr. de Klerk's observation that: "[T]he smaller the effect that needs to be demonstrated, the larger the study needs to be." Dr. Infante, who dismisses the Panel's question as "moot", points out that "it is not possible to determine thresholds from epidemiological studies because of the lack of statistical power to distinguish that the risk is virtually zero." Canada argues –

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[79]DG XXIV, *Opinion on a Study Commissioned by Directorate General III (Industry) of the European Commission on "Recent Assessments of the Hazards and Risks Posed by Asbestos and Substitute Fibres, and Recent Regulation on Fibres World-Wide"*, Environmental Resources Management, Oxford (opinion expressed on 9 February 1998).

[80]Liddell, F.D.K., McDonald, A.D. and McDonald, J.C., *The 1891-1920 Birth Cohort of Quebec Chrysotile Miners and Millers: Development from 1904 and Mortality to 1992*,(1997) 41 Annals of Occupational Hygiene 13.

[81]INSERM Report, p. 327.

[82]de Klerk, N.H. and Armstrong, B.K., *The Epidemiology of Asbestos and Mesothelioma*, in Malignant Mesothelioma, Henderson, D.W. et al., eds. Hemisphere Publishing, New York, 1992, 223 at pp. 230-31.

[83]CEC, *Report of the Working Group of Experts to the Commission of the European Communities: Public Health Risks of Exposure to Asbestos*, Oxford, Pergamon Press, 1977 cited in: WHO, *Environmental Health Criteria 53 for Asbestos and Other Mineral Fibres*, WHO, Geneva, 1986, p. 43.

epidemiological data in hand – just that low-level exposures to chrysotile pose a risk that is "virtually zero": "un risque indétectable". Dr. Infante uses Stayner's data once again to claim that the chrysotile data fit with a linear no-threshold model. With the new analysis on the Charleston cohort data discussed above, this argument does not hold.[84]

Question 4(c)

5.501 Drs. de Klerk and Musk agree that there is epidemiological data indicating no increased risk at low-level exposures, but the experts believe the linear model may be appropriate. However, "[W]hether or not it is a valid method is unknown."[85] According to international experts from the Health Effects Institute-Asbestos Review (HEI-AR), such as Julian Peto, David G. Hoel and W. Nicholson, the linear model is not used for its validity, but precisely because it tends to overestimate risk.[86] Dr. de Klerk shares this view and states that the model provides a "conservative estimate."

5.502 The limits of the linear model and the conditions under which extrapolations are made must be clearly set out. Extrapolations from high-level exposures and exposures to amphiboles should not be taken at face value to ban chrysotile in today's context of low-level chrysotile-only exposures. Canada's critical view of the linear model is supported by a 1999 report by the Australian National Industrial Chemicals Notifications and Assessments Scheme (NICNAS) cited by Dr. Henderson:

> "There are many problems associated with low-dose risk extrapolation, such as the assumption of a linear relationship. However, as insufficient data exist to indicate threshold exposure for effect, the linear extrapolation methodology provides a conservative worst-case scenario estimate of risk. Other confounding factors in estimating risks from epidemiological data are possible contamination by other fibre types and inaccurate estimates of historical exposures."[87]

5.503 Not only does the linear model provide a worst-case scenario, it provides a grossly exaggerated estimate of risk when "confounding factors", as Dr. Henderson calls them, are so clearly present. INSERM made extrapolations from high-level amphibole exposures to mixed fibre type exposures, as well as from exposures in the textile industry and during the installation of low-density products such as flocking.[88] Amphiboles are much more potent than chrysotile, and the risks in the textile industry cannot be compared with the risks in the high-density chrysotile products, as Dr. Henderson points out in citing Boffetta: "[I]n general, the risk of lung cancer ... is highest in studies of asbestos textile workers."[89]

5.504 Another important consideration is the human biological defence mechanisms that are naturally much more effective at low-levels of exposure, i.e. clearance, biopersistence and DNA repair mechanisms.[90] Given these mechanisms, the reasoning behind the threshold model is both intuitively

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[84]See Canada's comments to Question 3.

[85]Henderson, answer to question 4(c).

[86]Health Effects Institute-Asbestos Research, Asbestos in Public and Commercial Buildings: A Literature Review and Synthesis of Current Knowledge (Executive Summary), Cambridge, 1991, p. 6-62.

[87]Australia National Industrial Chemicals Notifications and Assessments Scheme (NICNAS), *Chrysotile Asbestos: Priority Existing Chemical No. 9 (Full Public Report)*, February 1999 at p. 72, cited by Henderson in his answer to question 4(c).

[88]INSERM Report, p. 213.

[89]Henderson, paragraph 5.149 above, citing: Boffetta, P., *Health Effects of Asbestos Exposure in Humans: A Quantitative Assessment,* (1998) 89 Med. Lav. 471.

[90]Voir Holland CD, Sielken RLJ., *Quantitative Cancer Modeling and Risk Assessment.* Englewood Cliffs, New Jersey: Prentice Hall, 1993; Sielken RL, Jr., Bretzlaff RS, Stevenson DE., *Incorporating Additional Biological Phenomena into Two-Stage Cancer Models* in: Spitzer HL, Slaga TJ, Greenlee WF, McClain M, eds. *Receptor-Mediated Biological Processes: Implications for Evaluating Carcinogenesis*. New York: Wiley-Liss, 1994;237-60. Stevenson DE, Sielken Jr. RL, Bretzlaff RS., *Challenges to Low-Dose Linearity in Carcinogenesis*

and scientifically sound, as well as epidemiologically validated. To illustrate this, consider the following illustration: the effect of 50 fibres in the lungs will be more than five times the effect of ten fibres.

5.505 According to Sir Richard Doll, who first demonstrated the link between asbestos and lung cancer (as well as between smoking and lung cancer), "[W]e have no real ground for postulating that a linear relationship for lung cancer can be extrapolated back to the levels of dose with which we are concerned in non-occupational settings."[91] Ames and Gold are of the same view: "[l]inear extrapolation from the maximum tolerated dose in rodents to low-level exposure in humans has led to grossly exaggerated forecasts in mortality." [92] Fournier and Efthymiou are even more categorical: "[L]inear extrapolation to zero is an unscientific methodology whose social consequences are so immense that it warrants unconditional elimination."[93] INSERM acknowledges the limits of the linear model's application when it states that it provides nothing more than food for thought: "cette extrapolation ne crée pas une information scientifiquement certaine, elle représente une aide à la réflexion en matière de maîtrise de risque."[94]

5.506 As Dr. de Klerk points out, "how one extrapolates risk assessment outside the range of available data is more of a societal decision than a scientific one."

Question 4(d)

5.507 Situations where there is no increased risk at low levels of exposure have been used by Stayner et al. to establish NOAELs [i.e. no observable adverse effect levels] for silica. A similar model is used for asbestosis. Canada believes that the use of such a model is warranted for other asbestos-related diseases, particularly since it has been acknowledged by Dr. Musk and Dr. de Klerk that epidemiological data exists to justify such an approach.

Question 4(e)

5.508 We concur with Dr. Henderson's view that "[t]his question iterates the issue of a threshold exposure." Canada nonetheless notes the use by Dr. Infante of a 1992 study by Bégin et al. to demonstrate the risks related to "background levels" is erroneous. As has been pointed out by Canada in its factual arguments,[95] this study is based on exposures to a mix of chrysotile and amphiboles in the manufacturing and construction industry, and therefore is not relevant to exposures from the current uses of chrysotile.

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from Interactions among Mechanistic Components as Exemplified by the Concept of 'Invaders' and 'Defenders'. BELLE Newsletter 1994;3(2):1-8. Stevenson DE., *Dose-Response Studies of Genotoxic Rodent Carcinogens: Thresholds, Hockey Sticks, Hormesis or Straight Lines? - Comment on the Kitchin and Brown paper*, BELLE Newsletter 1995;3(3):14-15.

[91]Doll, R., *Mineral Fibres in the Non-Occupational Environment: Concluding Remarks,* in Bignon, J., Peto, J. and Saracci R., eds., Non-Occupational Exposure to Mineral Fibres, IARC Scientific Publication N^{o} 90, 1989, pp. 516-17.

[92]Ames, B.N. et Swirsky Gold, L., *Causes and Prevention of Cancer: Gaining Perspectives on the Management of Risk,* in Risks, Costs, and Lives Saved: Getting Better Results From Regulation?, New York, OUP, 1996, p.6.

[93]Fournier, E. and Efthymiou, M.-L., *Problems with Very Low Dose Risk Evaluation: The Case of Asbestos,* in What Risk?, p.49.

[94]INSERM Report, p. 239 and 414.

[95] See above Section III.A.5.

Question 5(a)

5.509 Clearly the answers given by the four experts are based on their concept of what is meant by controlled use. It is also evident that the controlled use concept as espoused by Canada was not the approach that resulted in their answers. We must therefore respectfully disagree with the answers given by the experts in respect of controlled use of chrysotile and high-density chrysotile containing products. The fact that they agreed that controlled use of chrysotile and high-density chrysotile products is feasible at some points of the life cycle, but not in others, suggests that they are not far from the view of Canada. The only difference is that Canada believes that the experts misunderstand the controlled use principle and that, as properly understood and implemented, use can be controlled throughout the full life cycle of high-density chrysotile containing products. The basis for our view, with supporting evidence, is set out below.[96]

(i) Canada's understanding of the "Controlled use" principle

5.510 The Canadian government's review of the experts' reports and answers to the questions posed by the Panel reveals that there is one crucial issue, which seems to override all other issues. This is the question of whether the application of the controlled use principle is feasible and credible in all stages in the life cycle of a product. While there is a reasonably high degree of agreement among experts that controlled use can be a reality in the mining and manufacturing sectors, serious doubts are expressed that controlled use can be applied in a few sectors of use – installation, maintenance and demolition. However, the basis for this view is not documented, except by Dr. Infante and Dr. Henderson.

5.511 By "controlled use", the Canadian government means "stewardship" based on the total life cycle. This is outlined in the document *The Mineral and Metals Policy of the Government of Canada: Partnerships for Sustainable Development*.[97] With regard to asbestos, this "controlled use" is based on the following general principles:

- Only the chrysotile variety is used;
- only a limited number of well-defined product applications, where it has been demonstrated that they can be handled safely, are allowed (i.e. where the fibres are encapsulated in a matrix such as cement, bitumen, plastic, resin, etc.);[98] and
- new product applications may be introduced only after a strict evaluation to ensure that a certain level of fibre release is not exceeded during its life cycle.

[96]Canada notes that the "controlled-use" approach has been endorsed by the WHO in its 1998 *Environmental Health Criteria 203: Chrysotile Asbestos*, p. 144. "Control measures, including engineering controls and work practices, should be used in circumstances where occupational exposure to chrysotile can occur. Data from industries where control technologies have been applied have demonstrated the feasibility of controlling exposure to levels generally below 0.5 fibres/ml. Personal protective equipment can further reduce individual exposure where engineering controls and work practices prove insufficient."

[97]NRCAN, The Minerals and Metals Policy of the Government of Canada: *Partnership for Sustainable Development*, Public Works Canada, 1996. Canada notes that the "controlled-use" approach to regulating chrysotile asbestos is well researched as evidenced in the studies and conclusions referred to by Canada in its factual arguments (see above Section III.A.6).

[98]To illustrate this point, examples of "controlled use" of friction products and asbestos-cement are detailed in Appendices A and B respectively to these comments. (These Appendices can be found in Annex IV to this Report).

5.512 With regard to the downstream use sectors, "controlled use" implies that all distributors/manufacturers of asbestos will be required to have an import permit. This permit will be withdrawn if the company does not meet the following commitments:

- To distribute its products only to companies (users) licensed to purchase these products. Those companies must have workers trained and licensed to install products, and must be in compliance with regulations. Approved users shall not resell to third parties, and any unused materials must be returned to the manufacturer;

- to provide a list of users of products to the responsible government agency;

- to provide products cut to specification and to establish centres equipped to cut the products to size, and where persons cutting the products are trained and are licensed to work with asbestos; and

- to police the downstream users in co-operation with the government. The product manufacturer visits, monitors and reports on the performance of the downstream users at regular intervals. There are penalties for failing to provide this product stewardship.

5.513 While high-density products in most countries are not considered to pose any occupational or environmental health risk, disposal should only be undertaken by approved and appropriately trained persons.

5.514 Dr. Infante's description of the permissible exposure limit for chrysotile asbestos, as well as programmes or standards that recommend or require specific engineering control, work practices, training and education and personal protective equipment to control exposures to asbestos corresponds, to some extent, to Canada's approach. Dr. Infante seems to suggest that because some workers do not comply with standards and regulations on controlled use in the United States, controlled use is not feasible. As explained in Appendix A on friction material and Appendix B on asbestos cement, the controlled use approach can minimize, if not eliminate, workers' non-compliance.[99]

5.515 Canada does not propose that any chrysotile products produced, sold or used without the implementation and enforcement of very stringent control procedures. Taking into account the types of products being manufactured and used in France at the time of the ban, Canada does not advocate re-introducing any product that cannot be handled according to the safety criteria outlined above. Canada is not advocating the introduction anywhere in the world of manufacturing facilities of products for which the technology does not exist to protect workers from exposure to chrysotile at levels where risks would be above epidemiologically based practical thresholds.

5.516 The experts have indicated that the level of exposure is such that they are not concerned about asbestos-related disease for persons living in buildings containing chrysotile asbestos products, including friable insulation. As none of the chrysotile products that will be used in the future are friable, this conclusion would be further reinforced. If the procedures envisaged under the "controlled use" policy are followed by licensed practitioners, the public will not be placed under any practically determinable increased risk of disease as a result of the manufacture and use of chrysotile containing products. Unlike friable insulation products where janitorial staff, electricians, carpenters, and others may be required to work regularly in an environment where exposures to asbestos would occur, the nature of the high-density products will ensure that exposures are a much rarer event.

[99]Appendices A and B can be found in Annex IV to this Report.

5.517 Canada recognizes that the clock cannot be turned back. Friable mixed products produced in the past are now in place, and trades such as electricians or telephone engineers face situations where the potential health risk from exposure is considerably greater than any additional risk that new high-density chrysotile products would present. It is evident that the protection of workers who come into contact with friable products must be assured by the responsible jurisdictions through training in trade schools, appropriate information programmes by unions, and by governments and employers ensuring that the appropriate equipment and tools are made available to workers.[100]

5.518 Regarding high-density products, Canada believes that no less stringent measures should be required, even though the evidence shows that the risk from exposure to high-density chrysotile products is minuscule compared to the risk from friable products, in many cases containing mixtures of chrysotile and amphibole fibres. Furthermore, in the absence of sound scientific data to the contrary, the same criteria should be applied to the handling of all products in which respirable fibres, including asbestos substitutes, may be released.

(ii) International Standards

5.519 None of the experts acknowledges that controlled-use of chrysotile asbestos cement products and other high-density chrysotile products stems from international standards. Dr. Infante even denies the existence of international standards on controlled-use of high-density chrysotile products. Canada wishes to remind the Panel that international standards, as the term is defined in the Agreement on Technical Barriers to Trade, do exist. Regulatory developments on asbestos fibres have been guided by ILO Convention 162 concerning Safety in the Use of Asbestos.[101] ILO convention 162 provides for: (i) the prescription of adequate engineering controls and work practices; (ii) the prescription of special rules and procedures for the use of asbestos or certain types of asbestos or products containing asbestos or for certain work processes; (iii) where necessary to protect the health of workers and technically practicable, the replacement of asbestos or of certain types of asbestos by other materials or the use of alternative technology scientifically evaluated by the competent authorities as harmless or less harmful; and (iv) total or partial prohibition of the use of asbestos or of certain types of asbestos in certain work processes.[102]

5.520 The Code of Practice on Safety in the Use of Asbestos of the International Labour Office referred to by Canada in all its submissions is another international standard on controlled-use.[103] The objects of the Code are: (i) to prevent the risk of exposure to asbestos dust at work; (ii) to prevent harmful effects on the health of workers arising from exposure to asbestos dust; and (iii) to provide reasonably practicable control procedures and practices for minimising occupational exposure to asbestos dust. To do so, the Code gives detailed guidance on the limitation of exposure in respect of asbestos cement and friction materials. Finally, Canada has referred the Panel to International Standard ISO 7337: Asbestos Reinforced Cement Products – Guidelines for On-Site Work Practices.[104] This international standard gives guidelines for tools and working methods to be used on site with a view to maintaining the dust emission at the lowest practicable level. It applies to asbestos-cement products.

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[100]See Section III.A.5 of this Report and Camus M., *L'amiante et les risques pour la santé*, April 1999.

[101]Conférence internationale du travail, Convention concernant la sécurité dans l'utilisation de l'amiante (Convention 162), adoptée le 24 juin 1986, and Recommandation concernant la sécurité dans l'utilisation de l'amiante (Recommandation 172), adoptée le 24 juin 1986.

[102]According to Canada, the emphasis of ILO Convention 162 is on controlled-use and not on product prohibitions. The Convention calls for two specific prohibitions: crocidolite and all products containing crocidolite, and sprayed-on applications of asbestos.

[103]Recueil de directives pratiques du BIT sur la sécurité dans l'utilisation de l'amiante, Organisation internationale du travail, Genève, 1984.

[104]ISO, standard ISO-7337 1984.

5.521 The ILO Convention 162 and the Code of Practice on Safety in the use of chrysotile should be supplemented by a national policy on responsible use based on the recognition and acceptance of the principles that both international standards set forth.[105] As explained above, the objective of responsible use is to limit the handling of chrysotile to companies that comply with the national regulations or that have submitted action plans and formal commitments in writing with a view to bringing their activities into line with these regulations.

Question 5(b)

5.522 The experts recognize that training could be achieved in the manufacturing sector, where there is a small and cohesive workforce, but assert without support that it cannot be achieved in the construction sector, where there is a large and non-cohesive workforce. Dr. Infante wrongly equates non-compliance with regulated training requirements to non-feasibility of training for controlled-use of chrysotile asbestos.[106]

5.523 In Europe, as in other countries, there are now requirements for training workers. In Canada, both levels of government require training at all workplaces. It is possible for training to be made available by industry. In fact, information and training is one of the most important elements of a company's preventive control programme. In line with the controls suggested at paragraphs 5.511 and 5.512, France could require through legislation that all construction workers handling asbestos products attend training sessions. France could also require that only designated, properly trained workers be allowed to work with those asbestos products that need to fall under a controlled regime.

5.524 During manufacture, controls such as wet processes and exhaust ventilation, essentially eliminate all exposure. On the work site, process changes are reduced by the industry manufacturing products requiring no, or virtually no, modifications on site. The controlled use approach includes the use of pre-cut and pre-drilled asbestos cement products, and provides for designated locations where chrysotile asbestos cement sheets or pipes are cut and drilled and where the appropriate controls are in place. The monitoring process is similar to that for other workplaces: all complaints are submitted to governmental inspectors for evaluation. The supplier has the responsibility for ensuring that all companies to which they supply have in place the proper equipment and training to ensure safe use of the product throughout its life cycle. Finally, the removal of high-density chrysotile products is carried out in accordance with government codes.

Question 5(c)

5.525 Both Dr. Henderson and Dr. Infante agree that, in many situations, when standards are properly applied, it is possible to maintain exposure below 0.1 f/ml. Also, as explained in Appendix A on the friction industry and Appendix B[107] on the asbestos cement industry, experience shows that a level below 0.1 f/ml can be achieved because the technology and work practices exist to control exposure during manufacture. No guarantee can be offered that there would never be a situation in which 0.1 f/ml might be exceeded as a peak exposure. However, there is no evidence that occasional peak exposures increase the risk of lung cancer or mesothelioma in chrysotile exposed workers. For example, the health experience of brake mechanics, i.e. no evidence of an increased risk of mesothelioma or lung cancer, is based on exposures that involved peak exposures, such as occurred during the blowing out of brake wear debris and the occasional grinding of brake linings. These operations involved short exposures above 0.1 f/ml. The actual concentrations associated with various

[105]*Memorandum of Understanding between the Government of Canada and the Asbestos Industry on Responsible-Use of Chrysotile Asbestos*, 1997.

[106]Canada notes that it should be recalled that his basis for risk assessment is based on the textile industry.

[107]See Annex IV to this Report.

tasks have been reported by Kauppinen and Korhonen,[108] and by Rödelsperger.[109] In spite of these short-term peak exposures, the average exposure of auto mechanics was less than 0.05 f/ml.

5.526 A person repairing their own brakes periodically nowadays (using disc brake pads mainly) would have extremely low cumulative exposures compared to full time auto mechanics and there is no reason for them to have any, even short term, exposures exceeding 0.1 f/ml. The risks associated with cumulative exposure to chrysotile at these levels would not be epidemiologically detectable for handymen handling friction or asbestos cement products.

5.527 Rödelsperger[110] made dust measurements on about 40 buildings sites in Germany. He reported peak exposures of more than 100 f/ml in the vicinity of a grinding machine used to cut asbestos cement sheets. However, when he used the standardized work histories of 61 roofers, who had a mean duration of exposure of 16 years, he found that their mean cumulative exposure was 1.6 fibre-years/ml. These measurements were made 20 or more years ago, with the products and technology available then and for regular construction workers. It is evident that even under these circumstances, lifetime cumulative exposures were low. Thus, a handyman, even if he did not take proper precautions would still have a low cumulative fibre exposure because peak exposures are of short duration and he would be at a very low, undetectable risk of health effects.

5.528 It is generally agreed that at the levels of exposure associated with the use of the modern high-density products, they would not even put a full-time worker at increased risk of asbestosis and, therefore, this would not be of concern for a handyman working occasionally with the product. It has been amply demonstrated that the risk of lung cancer increases with increasing cumulative lifetime exposure that combines duration and level of exposure. A person exposed at 0.1 f/ml for 40 years has a cumulative lifetime exposure of 4 f/ml-years. If that person worked on a project only once each week for four hours for 40 years, he would not achieve the same lifetime exposure unless he was exposed to 1 f/ml continuously for the four hours of exposure every time he was exposed for 40 years. Thus occasional peak exposures of a few minutes contribute very little to cumulative lifetime exposure which is important in evaluating the risk of chronic diseases such as lung cancer or mesothelioma.

5.529 Gardner[111] found no increased risk of lung cancer or other asbestos-related disease in a chrysotile asbestos cement plant where exposures were less than 1 f/ml. This was in a cohort of workers employed between 1941 and 1983. It is evident that any risk would have been well below the detection limit at 0.1 f/ml. A study of chrysotile cement production workers by Thomas[112] and Neuberger & Kundi[113] identified no chrysotile-related increased risk of lung cancer and Weill,[114] while reporting an increased risk of lung cancer in asbestos cement workers, found the increased risk only in

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[108]Kauppinen, T. and Korhonen, K., *Exposure to Asbestos During Brake Maintenance Of Automotive Vehicles by Different Methods*, (1987) 48 Am. Industr. Hyg. Assoc. J, pp. 499-504.

[109]Rödelsperger, K. et al., *Asbestos Dust Exposure During Brake Repair*, (1986) 10 American Journal of Industrial Medicine, pp. 63-72.

[110]Rödelsperger, K., Woitowitz, H.J. and Krieger, H.G., *Estimation of Exposure to Asbestos-Cement Dust on Building Sites*, in Biological Effects of Mineral Fibres, Vol. 2, J.C. Wagner Editor, 1980, International Agency for Research on Cancer: Lyon, pp. 845-853.

[111]Gardner, M.J., Winter, P.D., Pannett, B. and Powell, C.A., *Follow-Up Study of Workers Manufacturing Chrysotile Asbestos Cement Products*, (1986) 43 British J. of Industrial Medicine, pp. 726-732.

[112]Thomas, H.F., Benjamin, I.T., Elwood, P.C. and Sweetman, P.M., *Further Follow-Up Study of Workers from an Asbestos-Cement Factory*, (1982) 39 British Journal of Industrial Medicine, pp. 273-276.

[113]Neuberger, M. and Kundi, M., *Individual Asbestos Exposure: Smoking and Mortality – A Cohort Study in the Asbestos-Cement Industry*, (1990) 47 British Journal of Industrial Medicine, pp. 615-620.

[114]Weill, H., *Biological Effects: Asbestos-Cement Manufacturing*, (1994) 41 Ann. Occup. Hyg., pp. 533-538.

those with asbestosis. In this study, there was little evidence of asbestosis below 30-40 f/ml-years of exposure. This is about 0,75-1 f/ml continuous exposure for 40 years. Thus, there is little evidence to support a detectable increase in risk of lung cancer in workers with a 40 years cumulative lifetime exposure at 4 f/ml-years.

5.530 Any risk estimates obtained by linear extrapolation from high exposures to such low exposures are somewhat hypothetical and both Lash[115] and Camus[116] have shown that the risk estimates made by the U.S. Government have overestimated lung cancer risks.

Question 5(d)

5.531 Canada disagrees with the views of Dr. Henderson[117] and Dr. Infante that controlled use of chrysotile asbestos is not feasible for workers involved in the construction trade and that service and maintenance workers such as carpenters, plumbers, and electricians will experience peaks of exposures to asbestos that place them at risk. The nature of high-density chrysotile asbestos products is such that few of the trades listed above will ever need to work on the products, with the possible exception of demolition workers. Again, there is evidence that during demolition exposure concentrations associated with chrysotile asbestos cement products is very low.[118] Today, with chrysotile cement products and controlled use procedures, health risks become insignificant.

5.532 Recommended installation methods can eliminate the need to cut or drill into chrysotile-based products at construction sites, since those products are distributed in a variety of pre-cut and pre-drilled sizes, according to buyers' specifications. In fact, many asbestos cement products are pre-formed ready for use. They are factory-made to the correct size and shape including holes so that a minimum of on-site preparations is needed. Once installed, chrysotile asbestos cement pipes are below ground and pose no risk to workers. Even if dug up, they pose no risks unless comminuted, ground or sawed, and, when this is necessary, the use of appropriate tools and controls will keep the release of dust and exposure well within the level considered safe by the WHO. Chrysotile asbestos cement sheets are used for roofing and exterior building walls. Once installed, there is no need to modify the roof until the life of the product is over. Similarly, there is no need to modify chrysotile asbestos sheets used as walls once they have been installed. The product can be painted without fibre release.

5.533 Chrysotile cement products are unlikely to release fibres into the environment or breathing zones of workers such as janitors, plumbers, electricians, repair men, etc., unless these workers have to actually cut or drill the product. Unlike insulation products, there will rarely be a need for anyone to perforate, saw, or grind installed chrysotile cement products. Where cutting or drilling is required, hand tools and low speed power tools are recommended in combination with wetting to keep dust levels to a minimum. Dust levels for various types of on-site working have been measured both in laboratories and in the field and these facts showed that risks could be maintained below detection limit.

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[115]Lash, T.L., Crouch, E.A.C. and Green, L.C., *A Meta-Analysis of the Relation between Cumulative Exposure to Asbestos and Relative Risk of Lung Cancer*, (1997) 54 Occupational and Environmental Medicine, pp. 254-263.

[116]Camus, M., Siemiatycki, J. and Meek, B., *Nonoccupational Exposure to Chrysotile Asbestos and the Risk of Lung Cancer*, (1998) 338 N. Eng. J. Med., 1565.

[117]Henderson, answers to Questions 5(a) to (d).

[118]Hoskins J.A., *Chrysotile in the 21st Century*, UK, 1999, p.12.

Question 5(e)

5.534 Dr. de Klerk and Dr. Musk wrote that efficiency of controlled-use in the case of home handymen is outside their area of expertise. However, both Dr. Henderson and Dr. Infante have concluded that it is not possible to control exposure to chrysotile asbestos high-density products in non-occupational circumstances (occasional interventions by home handymen). Neither bases his conclusion on data. Dr. Henderson adds to his answer that although such risks are not quantifiable because of absence of data, these risks must be very small for lung cancer and mesothelioma, and non-existent for asbestosis.

5.535 Controlled use will reduce and even eliminate risks. The risk of chrysotile-related health effects is tied to cumulative exposure, that is, duration and level of exposure. Rarely will an individual under non-occupational circumstances achieve the exposure of a full-time worker. Occasional uncontrolled exposures for a handyman would not result in appreciable cumulative exposure. Data published by Brown[119] showed time-weighted average (TWA) levels during demolition of weathered asbestos-cement roofing between 0.3 and 0.6 f/ml. One can likely guess that a handyman would not practice such an activity more than 40 hours in 25 years. This would average out to a TWA of 0.015 f/ml for the year of this activity, and a TWA of 0.0006 f/ml each year of the worker's adult life. This is 1 million times less than past asbestos workers are. It is equivalent to exposure levels in schools containing ACM.[120]

5.536 Based on INSERM[121] and HEI-AR risk tables, which are based on mixed asbestos exposures, the resulting lifetime cancer risk would be between 10 and 20 in a million depending on the time occurrence of this exposure scenario. More accurately however, the lifetime risk would be near zero per million, based on chrysotile friction workers who were exposed to similar fibres (species and dimension wise), and about 1 in a million, based on the risks of past chrysotile miners and millers. The casual user of a high density product, even if the product were weathered, is not likely to be at any increased risk of an asbestos related disease. If the supplier follows through on the requirements of controlled use, the casual purchase of chrysotile asbestos-cement products by the handyman will not be possible. However, there is probably no way of stopping any individual from doing something to any product if they can obtain it. This is a problem that exists for any product many of which pose serious health risks if abused.

Question 6(a)

5.537 Canada respectfully disputes the conclusions of the experts regarding the risk from substitute fibres, and with respect to one expert, the ability of substitutes to serve as suitable replacements to chrysotile. Canada notes that the treatment of the issue by two of the experts is terse, comprising only several sentences. To their credit, Drs. de Klerk and Musk indicate that the use and control of substitute fibres is not within their areas of special expertise. They offer some responses nonetheless. Canada is concerned, in particular, by their lack of familiarity with the relevant studies and actual modes of production, use and disposal of substitute fibres. For example, they apparently are unaware of research conclusively demonstrating the significant health risks from exposure to refractory ceramic fibres (RCF), which are discussed below.

5.538 This concern applies to Dr. Infante as well. Dr. Infante further appears unaware of (or ignores) recent research demonstrating that chrysotile is less biopersistent than many substitute fibres.

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[119]Brown, S.K., *Asbestos Exposure During Renovation and Demolition of Asbestos-Cement Clad Buildings*, (1987) 48 Amer. Ind. Hyg. J., pp. 478-486.

[120]Health Effects Institute – Asbestos Research, *Asbestos in Public and Commercial Buildings: A Literature Review and Synthesis of Current Knowledge (Executive Summary)*, Cambridge, 1991, pp. 1-11.

[121]INSERM Report.

Dr. Infante also ignores the population the experts agree are most at risk from exposure to any fibre – tradesmen – when he concludes (without support or, even, explanation, Canada notes) that the "nature of the production process makes substitutes more amenable to control than asbestos fibres." Assuming he is not again conflating chrysotile with amphiboles when referring to "asbestos," his point, were it true, would be irrelevant. The experts agree that chrysotile and chrysotile products can be safely mined and produced. The key is exposure to tradesmen. And, for that exposure, no rationale exists suggesting that the ability to impose effective controls differs based on the type of the fibre.

5.539 Dr. Henderson, for his part, recognises that, as with all fibres, the pathogenicity of substitutes is defined by the "3Ds" (dimension, dose, durability). He seems also to understand that, due to the (lack of) historical use of substitutes, we cannot fully know the risks of using them.[122] However, he then seems to ignore the importance of these facts.

5.540 All of the experts fail to take into account several very important factors. First, the chrysotile products at issue in this proceeding are quite few. Second, the exposure levels during the manufacture, use and disposal of these products are extremely low. Third, the data demonstrate that these few products have been and can be used without detectable health effects in humans. Moreover, in order to assess whether a substitute is safer to use than chrysotile in a product: (i) it is fundamental that the characteristics of the fibres being compared be those of the fibres as they are used in the product or as they are released from the product throughout the product's lifecycle; (ii) it is essential that data on at least the key parameters (exposure, biopersistence and dimensions) be available to make this assessment. Unfortunately, the experts have not addressed these topics. In short, the experts have based their opinions on very limited, if any, data. While the experts reach conclusions that various substitutes (PVA fibres, glass fibres, cellulose and para-aramid fibres) are safer to use than chrysotile, they provide no systematic comparison of risks and very limited, questionable scientific data in support of their opinions.

5.541 Canada presents below a survey of the studies and concepts that the experts ignored. These studies give a picture of risks from substitute fibres starkly different from that suggested by the Panel's experts. As demonstrated below, the situation concerning risk from substitute materials is as Canada set out in its factual arguments.[123]

(i) The Fibres to Compare

5.542 Experimental data for a wide range of fibres have shown that the physical characteristics (diameters, lengths, density) of fibres are important in determining their respirability, when they are deposited in the respiratory system, and their capacity to induce fibrosis and cancers. Further, the risk of effects also depends on dose (exposure). Thus, differences in the risk of disease in various industrial sectors would be expected to occur because of differences in these, as well as other factors. As the characteristics of chrysotile and any substitute fibres are likely to be dictated by the product in which they are used, it is not appropriate to assess the risks associated with friction products or asbestos cement products using data from other industrial sectors. The data that should be available and used for the purpose of comparing risks should be those for the fibres as used in the specific products under review. Canada's presentation proceeds on this basis.

5.543 Davis[124] pointed out that while materials like wool, cellulose and other fibres have in some cases been used for many years, they are now being used in quite different applications, about which

[122]Henderson, response to Question 6(b).
[123]See above Section III.A.6.
[124]Davis, J.M.G., *The Toxicity of Wool and Cellulose*, (1996) 12 J. Occ. Health and Safety Australia and New Zealand, pp. 341-344.

knowledge is very limited. As a consequence, the characteristics of the fibres used in the newer applications may not be the same as those in the conventional products manufactured in the past. Such changes can modify the respirability and biological activity of the materials. There is a further complication for substitutes that is not addressed by the experts. This is the fact that substitution does not always involve replacement of chrysotile by a single fibre, but often by several different materials or substitute fibres. For example, cocktails of fibres are needed to meet technical requirements in friction products. In addition, when substituting for chrysotile, other materials such as silica or other fibres, fire retardants or biocides must often be added. These agents may themselves be toxic or carcinogenic, and may act synergistically.

(ii) The Outcomes to be Measured

5.544 While it is reasonable to compare the risks of lung cancer and mesothelioma between the various fibre types, it must be remembered that different sized fibres may lead to fibre deposition at different locations in the respiratory system. For example, if more fibres of one material than another are likely to be deposited in the nasal passages, one should consider the possibility of an increased frequency of nasal cancer in evaluating the substitute. Dr. Infante mentioned the increased risk of nasal cancer in woodworkers, which has been well established.[125] This might raise a question concerning the sources of the cellulose used as a substitute and whether controls are in place to avoid exposure to cellulose from woods that have caused such cancers. Also, some materials may cause dangerous allergic responses. Certain glass fibres cause skin irritation. Harrison[126] notes that there are indications of an accumulation of oligomers in the kidney in some circumstances, so that attention should be given to the molecular weight of PVA used "especially if a smaller diameter material were to be produced."

5.545 In considering risks, the composition of the dusts and fibres to which workers are exposed when handling the "raw substitute" materials, manufacturing the product, cutting, grinding, manipulating or disposing of the product also must be considered. For example, it is important to know whether the fibres of para-aramid, PVA or cellulose are opened (fibrillised) or comminuted during preparation or manufacture of the product? Does manipulation, sawing or drilling of the product give rise to narrower diameter respirable "fibres" such as result with polyester fibres during weaving? Do these fibre fragments have biological significance? What are actual use concentrations? It must be remembered throughout that there exists a substantial body of information concerning chrysotile. Unfortunately, in the case of substitutes, there are rarely any human epidemiological data available and even experimental data are limited. Perhaps this fact led Dr. de Klerk to conclude that "[G]iven the comparative lack of knowledge about the health effects of substitute materials, the continued use of chrysotile under [controlled] circumstances seems sensible.[127]

(iii) The Essential Data

5.546 The data that need to be compared in an evaluation of the relative safety of chrysotile and substitutes include the following:

- Epidemiological data that provide direct evidence of the risks associated with the products.

[125]Infante, answer to Question 6(c).

[126]Harrison, T.W., Levy, W.S., Patrick, G., Pigott, G.H. and Smith, L.L., *Comparative Hazards of Chrysotile Asbestos and its Substitutes: A European perspective*, (1999) Environmental Health Perspective, 107.

[127]de Klerk, N.H. and Armstrong, B.K., *The Epidemiology of Asbestos and Mesothelioma", in Malignant Mesothelioma*, Henderson, D.W. et al., eds Hemisphere Publishing, New York, 1982, p. 231.

- Experimental data by inoculation of fibres or by inhalation experiments in experimental animals.

- Dimensions of fibres in the respirable airborne dust during the manufacture of the product.

- Dimensions of fibres in the respirable airborne dust during the use of products containing the fibre.

- Dimensions of fibres in the lungs of workers engaged in the manufacture of products containing the fibre.

- Dimensions of fibres in the lungs of persons exposed during the use of products containing the fibre.

- Dimensions of fibres in the respirable airborne dust and in the lungs following exposure during the disposal of the fibre or products.

- The biopersistence of the fibres in humans and animals.

- The cumulative exposure (i.e.: concentration x time) of workers engaged in all phases of manufacture, use and disposal of the product.

- Data on alterations or modification of the fibres chemically, physically and biologically during their life cycle that might affect their potential to cause health effects.

5.547 Even if one were to narrow the requirements to a smaller number of key parameters such as fibre dimensions, biopersistence and exposure-response, the available data are still inadequate to provide a credible basis for an adequate comparison. Thus, the unqualified wholesale affirmation that "substitutes are safer than chrysotile" is not well founded and potentially very dangerous. For example, prior to the finding of a very high risk of mesothelioma for persons exposed to very low concentrations of fibrous zeolite erionite in Turkey, there had been no indications world-wide that such fibres might after 30 years from first exposure at such very low levels produce such a high rate of mesotheliomas in humans. In South Africa, crocidolite had been used for about 60 years before Wagner[128] reported that mesotheliomas were associated with crocidolite exposure. In humans, mesotheliomas do not occur until 40-60 years after first exposure. Thus, caution is needed in the absence of data regarding substitute fibres. As one expert stated: "better the devil you know" than the devil you do not know.[129]

Question 6(b)

(i) Dimensions

5.548 The experts present no data that show that the dimensions of all fibrous substitutes are outside the respirable size range during the substitute product's lifecycle. This is because no such data exist.

[128]Wagner, J.C., Newhouse, M.L., Corrin, B., Possister, C.E. and Griffiths, D.M., *Correlation between Fibre Content of the Lung and Disease in East London Asbestos Factory Workers*, (1988) 45 British J. of industrial Medicine, 305.

[129]de Klerk, answer to Question 6(a).

(ii) PVA & Aramid Fibres

5.549 Views from the experts appear to be mixed. Dr. Henderson quotes Harrison's review stating that PVA and aramid fibres are too large to be respirable. Dr. de Klerk states that all substitutes except glass (cellulose, aramid, PVA) produce a larger proportion of non-respirable fibres than chrysotile but respirable fibres are similar for all substances. Dr. Musk offers no opinion. Dr. Infante states that PVA fibres are "mostly" in the size range 10-16 µm and aramid fibres 10-12 µm. However, he notes, quite correctly, that, as mentioned below, the aramid fibres can and do split into fibrils of about 0.2 µm in diameter.

5.550 In assessing fibre respirability, none of the experts accounts for the fact that respirability depends on density as well as fibre diameter. The densities of PVA and para-aramid fibres are both considerably less that that of chrysotile. This means that much larger diameter substitute fibres would be respirable. In fact, the upper limits of diameters that are respirable for these fibres, as reported by Harrison[130], are approximately 7 µm and 6-7 µm respectively. The equivalent upper level diameter for chrysotile is about 3-3.5 µm. Thus, fibres of much greater diameter can penetrate into the alveolar region of the lung. A review of the available information in the literature is that there is a general opinion without data that the respirable fraction of PVA fibres is small. However, there do not appear to be any data on the dimensions of airborne fibres during mixing with cement or other materials, or as released from the products during processing and use.

(iii) Glass and Cellulose Fibres

5.551 As far as cellulose and glass fibres are concerned, none of the experts provided any actual measurement data on the sizes or respirability of the fibres. Also, the dimensions of fibres at various stages of the processing, use and disposal of cellulose have not been reported. The actual dimensions of fibres in the airborne dust will depend on the specific glass fibres used and how they were prepared.

(iv) Biopersistence

5.552 It is well known that biopersistence is a key parameter. Indeed, the human evidence for chrysotile indicates that it is likely to be one of the main reasons why chrysotile is less dangerous than the amphiboles in respect to mesothelioma risk. This is clearly recognized by three of the four experts, as well as by INSERM.[131]

(v) Cellulose

5.553 Drs. Infante, Henderson and de Klerk recognise that cellulose is durable in the lung. In fact, the data show that some cellulose fibres have half lives of about 1000 days in the lung, which are many times longer than even those published data for amphibole fibres, much less chrysotile fibres.[132]

(vi) PVA

5.554 Dr. Musk and Dr. Henderson had no comment on PVA durability. Dr. de Klerk presented no data, but expressed the view that PVA was less durable than chrysotile. Davis, in a review in 1998, found no published data on the biopersistence of PVA fibres. Data was not published until 1999,

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[130]Harrison, T.W., Levy, W.S., Patrick, G., Pigott, G.H. and Smith, L.L., *Comparative Hazards of Chrysotile Asbestos and its Substitutes: A European perspective*, (1999) Environmental Health Perspective, 107.

[131]See Canada's comments on Question 3.

[132]Muhle, H., Ernst, H. and Bellman, B., *Investigation of the Durability of Cellulose Fibres in the Rat Lungs*, (1997) 41 Ann. Occup. Hyg., pp. 184-188.

when Harrison [1999] reported that PVA "will degrade very slowly, if at all in the lung."[133] There do not appear to have been any systematic studies of the biopersistence of PVA fibres, a crucial parameter in assessing the hazard associated with PVA fibres.

(vii) Para-aramid Fibres

5.555 Based on a study by Searl,[134] who compared chrysotile and para-aramid fibres, the general view of the experts is that para-aramid fibres are less biopersistent. However, Searl failed to check the lung tissue to confirm that the retained fibres were chrysotile. Based on studies using a standard protocol, Dr. David Bernstein has found that the biopersistence of chrysotile is in fact less than that of para-aramid fibres.[135]

(viii) Glass Fibres

5.556 Drs. Musk, de Klerk and Henderson presented no data on the biopersistence of glass fibres. Dr. Infante, without identifying the specific glass fibres, reports that glass fibres are less biopersistent than chrysotile. In fact, the recent work by Dr. Bernstein, in which the same protocol was used as for synthetic fibres, found that long [i.e.: > 20um] pure chrysotile fibres are removed from the lung faster than most, if not all, of the glass fibres reported in the published literature.[136]

(ix) Chrysotile

5.557 As far as chrysotile is concerned, it is well accepted that chrysotile is readily removed from the lung. This is why the lungs of chrysotile millers and miners, exposed to chrysotile, have been found at autopsy to contain more tremolite (an amphibole asbestos mineral) than chrysotile.[137] The chrysotile cleared, but the tremolite fibres remained in the lung because of their much greater biopersistence. There are various estimates of the half time for chrysotile clearance. Oberdöerster[138] studied baboons and estimated a 90-110 day half time for chrysotile fibres. The study by Searl was mentioned above. The estimates by Dr. Bernstein are even shorter (< 10 days).[139] For direct comparison purposes, the clearance rates for fibres in the same ranges of dimensions must be studied. In addition, it is crucial that the fibres be tested using the same methodology. The studies by Bernstein best fit these criteria and show that, size for size, chrysotile has a very short half-life.

Question 6(c)

(i) Exposure-Response

5.558 In the absence of exposure-response data, it is not possible to quantify the risks associated with the various fibres. The question to be addressed is not: is one material more dusty than another? Nor is it: is the concentration higher when working with one material compared to another? Rather,

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[133]Davis, J.M.G., *The Biological Effects of Fibres Proposed as Substitutes for Chrysotile Asbestos: Current State of Knowledge*, 1998.

[134]Searl, A., *Clearance of Respirable Para-Aramid from Rat Lungs: Possible Role of Enzymatic Degradation of Para-Aramid Fibrils*, (1997) 41 Ann. Occup. Hyg., pp. 148-153.

[135]Bernstein, D.M., Graph on Biopersistence of p-Aramid Fibres.

[136]Bernstein, D.M., *Summary of the Final Reports on the Chrysotile Biopersistence Study*, Geneva, 1998, document submitted to the Panel by Brazil as a Third Party (see above Section IV).

[137]Rowlands, N., Gibbs, G.W. and McDonald, A.D., *Asbestos Fibres in the Lungs of Chrysotile Miners and Millers – A Preliminary Report*, (1982) 26 Ann. Occup. Hyg., pp. 411-415.

[138]Oberdörster, G., *Macrophage-Associated Responses to Chrysotile*, (1994), 38 Ann. Occup. Hyg., pp. 601-615.

[139]Bernstein, D.M., *Summary of the Final Reports on the Chrysotile Biopersistence Study*, Geneva, 1998, document submitted to the Panel by Brazil as a Third Party (see above Section IV).

the question that must be asked is: what is the risk for workers manufacturing or using the product? The decision on which fibre is safer has to be made on the basis of an assessment of the risk of disease for workers when manufacturing and using a product containing chrysotile compared to that when manufacturing and using the same product containing the substitute when subjected to the same or equivalent handling.

5.559 Three sources of data might be considered: experimental animal studies; human (epidemiological) studies; and *in vitro* studies. The latter (*in vitro*) are of little value for estimating risk as they only involve tests of, for example, biological activity in cells isolated from the processes which occur in a complete organism. Thus, they are an inadequate basis of comparison to the effects of inhalation on animals, much less humans.

(ii) Animal Studies

5.560 The first approach involves the exposure of animals to fibres of well-defined characteristics and concentrations by inhalation and following them for their lifetimes. Such studies have been done for a wide range of synthetic mineral fibres. Problems with this approach are many, as has been demonstrated in the considerable work done in recent years on synthetic mineral fibres. First, the animal species may have a limit on the size of fibre that it can inspire. Second, there are marked differences in the sensitivity of different animal species. For example, a refractory ceramic fibre (RCF) which produced one or two mesotheliomas in rats, produced mesotheliomas in 40 per cent of the hamsters exposed. Third, the lifetime of rats is about two years. In order to produce an effect within the lifetime of the animals they are subject to enormous exposures. Such exposures can produce the abnormal situation of lung overload so that the real reason for any biological effect is not clear. Fourth, an animal must produce an effect within two years (before it dies of natural causes). If biopersistence is important, fibres that are readily removed in humans over the course of a human's life are not removed from the lung of an experimental animal because of the high exposures and shorter life. Fifth, the interpretation of much of the experimental work must be done with caution, because until recently, fibre exposures were reported on mass not number basis. As the materials tested can have quite different dimensions, the same mass can lead to exposures involving considerably different concentrations of fibres on a number basis.

(iii) PVA

5.561 There are no studies relating the long-term effects of exposure to PVA fibres.

(iv) Cellulose

5.562 Studies that have been done with cellulose have shown that it initiates a severe inflammatory response[140] and fibrosis.[141] Unfortunately, no chronic exposure data have been published.

(v) Glass Fibres

5.563 While there have been many studies of glass fibres, the only study in which the same methodology was applied to the study of synthetic mineral fibres and chrysotile asbestos is that of Hesterberg.[142] He found that while there is an increased risk of lung cancer identified at high

[140]Hadley, J.G., Kotin, P. and Bernstein, D.M., *Subacute (28 Day) Repeated Dose Inhalation of Cellulose Building Insulation in the Rat*, (1992) The Toxicologist, 225 (abstract).

[141]Muhle, H., Ernst, H. and Bellman, B*., Investigation of the Durability of Cellulose Fibres in the Rat Lungs*, (1997) 41 Ann. Occup. Hyg., pp. 184-188.

[142]Hesterberg, T.W., Miller, W.C., Theveney, Ph. and Anderson, R., *Comparative Inhalation Studies of Man-Made Vitreous Fibres: Characterization of Fibres in the Exposure Aerosol and Lungs*, (1995) 39 Ann. Occup. Hyg., pp. 637-653. Hesterberg exposed rats to a concentration of 10,000 WHO fibres/ml of chrysotile,

concentrations (as for glass and other fibres) the animal data suggest that at low level exposure, the risk associated with the chrysotile exposure is considerably less than that associated with the synthetic mineral fibres tested.

(vi) Para-aramid Fibres

5.564 While in recent years the information base concerning aramid fibres has increased greatly, there remain several issues. The only data are those derived from experimental studies in animals. While studies of biopersistence suggest that long fibres are shortened by enzymes in the lungs of animal experiments (Searl) and hence removed from the lung, the situation in humans is not known. Two researchers (Davis[143] and Pott[144]) have produced mesotheliomas by intra-peritoneal injection of these fibres, so their potential to produce mesotheliomas cannot be dismissed. The interpretation of "proliferative keratin cysts" observed during inhalation experiments remains unclear.[145] Minty et al., in a criteria document for an occupational exposure limit (OEL) in the UK, summarized what was known about the para-aramid fibres at that time and drew several parallels with chrysotile. For example they state that "[T]he balance of evidence suggests that respirable aramid fibres possess a low potential to produce mesothelioma which is likely to be at least as low as with chrysotile.[146]

5.565 Referring to chrysotile, they conclude that mesothelioma "would only be detectable following very heavy and prolonged exposures." The recent evidence that the mesothelioma risk for chrysotile miners and millers is associated with tremolite, will render the threshold of mesothelioma for downstream workers even more remote. These authors considered a clear no-effect level of 2.5 f/ml for pulmonary toxicity and a recommended OEL of 0.5 f/ml to allow for "uncertainties in interspecies differences."

(vii) Epidemiological Data

(i) PVA

5.566 Drs. Musk, de Klerk, Henderson and Infante did not identify any epidemiological studies of PVA fibre workers. In fact, there is one study involving a small number of PVA fibre production workers (about 400 exposed employees).[147] Even though the length of exposure thus far is quite short, already two lung cancer deaths have occurred in the cohort to date. Clearly a much longer follow-up is needed. Regarding mesothelioma, it must be noted that with such a small population, even if half were dead and there were one mesothelioma, the risk would be 0.5 per cent which is more than the risk of mesothelioma found in Quebec miners and millers exposed to tremolite contaminated

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which resulted in 18.9 per cent lung tumours. Rats exposed to 232 f/ml of one type of glass fibre resulted in 5.9 per cent lung tumours, with 4.4 per cent lung tumours reported with other man-made vitreous fibres and 13 per cent with a RCF sample. The air control resulted in 1-3 per cent tumours (At 1000 f/ml, the risk of lung tumours would be just under 2 per cent which is well within the rate of tumours in the control animals).

[143]Davis, J.M.G., *Carcinogenicity of Kevlar Aramid Pulp Following Intraperitoneal Injection into Rats*, (1987) Technical Memorandum No. TM/87/12 Published by the Institute of Occupational Medicine, Edinburgh, Scotland.

[144]Pott, F., Roller, M., Ziem, U., Reiffer, F.J., Bellman, B., Rosenbruch, M. and Huth, F., *Carcinogenicity Studies on Natural and Man-Made Fibres with Intraperitoneal Tests in Rats,* (1989) In: Non-Occupational Exposure to Mineral Fibres. J. Bignon, J. Peto, K. Saracci eds. IARC Scientific Publication No. 90 Publ. International Agency for Research on Cancer, Lyon, pp. 173-179.

[145]IARC International Agency for Research on Cancer (1997), Monographs on the Evaluation of Carcinogenic Risks to Humans. Vol. 68.

[146]Minty, C.A., Meldrum, M., Phillips, A.M. and Ogden, T.L., *P-aramid Respirable Fibres Criteria Documents for an Occupational Exposure Limit*, HMSO (1995).

[147]Morinaga, K., Nakamura, K., Koyama, N. and Kishimoto, T., *A Retrospective Cohort Study of Male Workers Exposed to PVA Fibres*, (1999) 37 J. Industr. Health, pp. 18-21.

chrysotile. (Also, the Panel should note that there were no mesotheliomas among 1267 deaths in chrysotile exposed friction product manufacturing workers exposed to chrysotile.) Thus, this study cannot detect either mesothelioma or lung cancer risks as low as at that already known for chrysotile. Clearly, there are no human data on which to assess risk to conclude that the risk is less than it is for chrysotile either per f/ml of exposure or globally from work with products manufactured using PVA fibres.

(ii) Cellulose

5.567 Dr. Infante states that there are three studies in which cellulose exposures have been investigated, but he does not identify them. The other two experts do not suggest any epidemiological data. Studies in which there is no overall increase in mortality from lung cancer are not adequate to investigate the risk of exposure. To assess this risk, the relationship between lung cancer and cellulose fibre exposures on a per fibre basis must be, but has not been, examined.

(iii) Para-aramid Fibres

5.568 None of the experts reported any epidemiological data. Clearly, para-aramid fibres can be inhaled, as experimental animals inhaled them. However, because para-aramid fibres have been used for such a short time, there are no data on the relationship between levels of fibre exposure and the risks of lung cancer, mesothelioma or other adverse effects for persons working with this substitute or products manufactured using it.

(iv) Glass Fibres

5.569 There have been several studies of workers exposed to glass fibres during fibre manufacture. Studies have also included rock [stone] and slag wool exposures. The latter were associated with an increased risk of lung cancer even at very low levels of exposure. Doll[148] concluded that the risks from such exposures were greater than those associated with chrysotile asbestos. Doll summarized the situation as follows: "an occupational hazard of lung cancer has been demonstrated in the rock and slag wool section of the industry and possibly the glass wool section." The human evidence since that time has not dispelled concern about the risks associated with these fibres. This question is still not resolved.

5.570 Dr. Infante[149] and co-workers once reached the same conclusion for glass fibre (although he has changed his opinion in his current report). In his report, Dr. Infante mentions that after speaking with workers, he now thinks that there was asbestos exposure at the plant studied by Shannon in Ontario, Canada, where a high level of risk of lung cancer was found in glass fibre workers. A recent discussion with Dr. Harry Shannon about his study of glass fibre workers reveals that to his recollection, no one had raised the question of asbestos as a potential confounder in his study. He noted that, as the study was published many years ago, it seems unlikely that this issue – if it actually existed – would not have been raised and studied, especially by the glass fibre industry.[150] Clearly, no new analyses have been done, so the impact of supposed asbestos exposure, if it took place, is not known. Dr. Infante's reversal of opinion does not seem justified, as no new data are presented. For example, it is not known whether the "asbestos exposed workers" had high or low glass fibre exposure. If they had low glass fibre exposure, then the risk associated with the glass fibre exposures

[148]Doll, R., *Mineral Fibres in the Non-Occupational Environment: Concluding Remarks,* in Bignon, J., Peto, J. and Saracci, R., eds., Non-Occupational Exposure to Mineral Fibres, IARC Scientific Publication No. 90, 1989, pp. 511-518.

[149]Infante, P.F. et al., *Fibrous Glass and Cancer*, (1994) 26 Am. J. Industrl. Med., pp. 559-584.

[150]Gibbs, G., Phone Communication.

might increase. Thus, without additional analyses, the best estimates at present are the original analyses by Shannon.[151]

5.571 It was noted earlier that exposure levels during production may not be the same as those during product use. While it has not been possible to find data on the use of glass fibres in chrysotile cement or friction products, there has been an estimate of the risk associated with glass fibres as installed in homes. In this study, Wilson[152] used animal data to derive lung cancer risk estimates for glass fibre exposure. They assumed an exposure of 1f/ml for one year based on available data and estimated that the lung cancer risk in smokers associated with blown glass wool without binder in a smoker without a respirator would be 2.4×10^{-4}. If one uses the same methodology as applied by them to derive a chrysotile estimate (based on epidemiological data), but for friction product manufacture, the risk would be very much lower: $0.12 \times 0.00058 = 0.00007$ or 7×10^{-5}. This is a lower risk than calculated for glass fibres. In fact, there is no demonstrated increased risk of lung cancer in the friction industry, so even this chrysotile risk is hypothetical and certainly an overestimate. Wilson acknowledges this in their paper.

5.572 In this light, it is safer to work with chrysotile in friction products than to work with glass fibres. While it might be argued that there has been no report of an increased risk of mesothelioma in humans as a result of manufacturing glass fibres, in the case of chrysotile, there is greater confidence concerning this lack of risk because there is no evidence of an increased risk of mesothelioma associated with friction products throughout their lifecycle, and the studies are far more voluminous and varied in approach. There are no systematically gathered data available concerning downstream risks for glass fibres as used as a substitute in cement or friction products. Similarly, with regard to the asbestos cement industry, Harrison[153] reports that most studies have not found an increase in mesothelioma; certainly this is true for chrysotile asbestos cement plants. Thus, it is evident that there are clear no epidemiological or experimental data to conclude that "glass fibres" are safer than chrysotile, indeed, there is evidence to suggest the contrary.

5.573 In summary, the experts have based their opinions on very limited, if any, data. The data that do exist suggest that the conclusions of the Panel's experts concerning the relative safety of the substitutes and chrysotile at low concentrations are incorrect.

2. The European Communities

(i) Introduction

5.574 Each of the four scientific experts appointed by the Panel has recently responded to the points which the Panel wished to clarify. The European Communities note that the four experts consulted unanimously and unambiguously corroborate the analysis that led France to adopt the Decree 96-1133 banning asbestos. This analysis was communicated to the Panel in the two written submissions of the European Communities of 21 May and 30 June 1999 and is based on the following points:

(a) All forms of asbestos, including chrysotile asbestos, are carcinogens, and there is no scientifically established threshold below which exposure to asbestos would be without risk for humans;

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[151]Shannon, H.S. et al., *Mortality Experience of Ontario Glass Fibre Workers – Extended Follow-Up*, (1987) 31 Ann. Occup. Hyg., pp. 657-662.

[152]Wilson, R., Langer, A.M. and Nolan, R.P., *A Risk Assessment for Exposure to Glass Wool*, 30 Regulatory Toxicology and Pharmacology, pp. 96-109.

[153]Harrison, T.W., Levy, W.S., Patrick, G., Pigott, G.H. and Smith, L.L., *Comparative Hazards of Chrysotile Asbestos and its Substitutes: A European Perspective*, (1999), Environmental Health Perspective, 107.

(b) exposure to asbestos, including chrysotile asbestos, is the cause of many cancers, the vast majority of which affect secondary users, particularly workers coming into contact with materials containing asbestos, including asbestos cement;

(c) so-called "controlled" use of asbestos is in fact impossible in practice;

(d) there are asbestos substitutes which are far less dangerous for human health.

5.575 In this document, the European Communities do not wish to make systematic and detailed comments on all the replies by the four experts consulted, but will simply refer to the main conclusions and give a summary of their replies in the annex.[154]

(ii) The four experts consulted agree that all types of asbestos, including chrysotile, are carcinogens and that there is no established threshold under which exposure to asbestos is without risk for humans

5.576 The four scientific experts unanimously consider that chrysotile asbestos, as well as amphiboles, can cause mesothelioma and lung cancer *inter alia*.

5.577 The four experts also unanimously agree that there is no scientifically established threshold below which exposure would not pose any risk of cancer for humans. All the experts state that the risk of cancer is proportional to the cumulative level of exposure and all consider that the non-threshold linear model is the most scientifically appropriate model for guaranteeing the level of health protection decided upon by France in this particular case. This explains and confirms that the non-threshold linear model has always been used, without exception, by the authorities in all those countries that have so far carried out scientific assessment of the cancer risk.

(iii) The four experts consider that exposure to asbestos, including chrysotile asbestos, is the cause of many cancers that mainly affect secondary users, particularly workers in contact with materials containing asbestos, including asbestos cement

5.578 The four experts consider that the vast majority of the risks concern so-called "secondary" users[155], in other words, workers making interventions (building workers, electricians, plumbers, maintenance workers, handymen, etc.) because of their large number and the nature of their activities, even if the individual risks are sometimes lower.

5.579 For example, most cases of mesothelioma now affect this category of workers in all the industrialized countries, including Canada (Quebec) and Australia, countries which produce asbestos. The four experts point out that the levels of exposure in the course of occasional contacts with asbestos cement products are very high, much higher than the levels at which a risk of cancer has been definitely and scientifically established.

(iv) The four experts consider that the so-called "controlled" use of asbestos is not practically possible

5.580 The four experts unanimously agree that so-called "controlled" use aimed at ensuring a constantly low level of release of the fibres into the atmosphere is absolutely impracticable in the vast majority of work situations where workers have to deal with friable or non-friable materials containing asbestos.

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[154]See Annex V to this Report.
[155] See factual arguments by the EC, Section III.A.4.

5.581 The four experts consider that it might be possible in very special situations where a small number of workers carry out a very precise task. They also indicate that interventions on materials such as asbestos cement can release very large quantities of asbestos fibres; that protective equipment is not or not always effective and not always used; that the recommended procedures are rarely or incorrectly followed in small enterprises such as those in the building sector; that it is quite impossible to apply them to non-professionals (for example, handymen, etc.).

E. SUPPLEMENTARY REMARKS FROM DR. HENDERSON[156]

1. Concerning the comments from the European Communities

5.582 The comments from the European Communities are very brief, occupying only four pages in English translation, so that only a short comment is needed. The tabular summary of the four experts' reports appears to represent a fair précis of my conclusions and opinions, if an oversimplification. In para. 5.579, the European response refers to Canada (Quebec) and Australia as countries that produce asbestos. As pointed out in para 5.27, Australia is no longer an asbestos producer.

2. Concerning the comments from Canada

5.583 At 62 pages and with over 50 Annexes, the comments from Canada are far lengthier than the response from the European Communities; the Canadian documents include new information, necessitating more extensive discussion. Some general comments follow; other issues are discussed later under specific sub-headings.

5.584 In para. 5.441, the comment is made that some of the answers from the experts "appear not to distinguish between chrysotile and amphibole exposure" or between "modern uses ... and historical uses ... ." Throughout my own Report, I tried to make this distinction wherever appropriate, and my answers to the Panel's questions deal almost exclusively with chrysotile (like EHC 203 [1]) -e.g. my discussion of the risks to brake mechanics[157] and the tabulation of risk estimates for lung cancer and mesothelioma (Tables 12 and 13 in paras. 5.203 and 5.205. At the same time, it seems worth reiterating that commercial chrysotile from Canada on average contains variable trace amounts (about <1 per cent) of tremolite (fibrous tremolite is a non-commercial amphibole; e.g. please see EHC 203). In relation to Canada's concerns about the "experts' conclusions on tradesmen" (e.g. building construction workers), my perspective seems to concur with the IPCS/WHO monograph on chrysotile (EHC 203):

> "... (c) Some asbestos-containing products pose particular concern and chrysotile use in these circumstances is not recommended These uses include friable products with high exposure potential. Construction materials are of particular concern for several reasons. The construction industry workforce is large and measures to control asbestos are difficult to institute. In-place building materials may also pose risk to those carrying out alterations, maintenance and demolition" ... [p 144].

5.585 My recognition that chrysotile is substantially less potent than the amphiboles on a fibre-for-fibre basis for mesothelioma induction - and that present exposures overall are substantially less than in the past - explains why my Report dwelt mainly on workplace exposures (e.g. to building materials and friction products). Non-workplace exposures (e.g. non-occupational exposures including household contact or neighbourhood exposures [2-4]) - and exposures to friable insulation materials - received less attention and were included mainly to put the present situation into historical perspective.

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[156]For complete references of the documents quoted in this Section, see Annex III to this Panel Report.

[157]For decades, brake blocks and brake linings used in Australia have contained Canadian chrysotile asbestos only, with no added amphiboles.

5.586 In para. 5.489, the Canadian comments state that: "... He [Henderson] believes amphiboles may be greater than 60 times more likely than chrysotile to induce mesothelioma ... ." In fact, in para. 5.103, I had stated that:

> "There is general though not universal agreement of a differential potency between the amphiboles versus chrysotile for mesothelioma induction; in this respect, the amphiboles are substantially more potent, with estimates ranging from 2-4X, to 10X, to 12X on a fibre-for-fibre basis, to 30X, to a 30-60X greater potency, or more (e.g. please see EHC 203)."

5.587 Later in my Report (paras. 5.141 and 5.413), I gave my estimate that chrysotile has a potency $1/10^{th}$-$1/30^{th}$ the carcinogenicity of crocidolite *for the mesothelium.* This estimate has not changed.

5.588 Some clarification of my answer to Question 1(b)[158] from the Panel seems necessary, taking into account Canada's quotation of my view and the comment that: "Canada takes note that ... [this is] ... overwhelmingly a workplace issue, and therefore not related to the 'handyman'." In my answer, I took "workplace" to refer to any situation where work of any type is carried out (e.g. cutting, sawing, drilling, grinding, rasping or sanding of asbestos-cement building products), whereas I interpreted the expression "a larger part of the population" to refer to general environmental exposure to asbestos (e.g. simple occupancy of buildings, or potential exposure of urban dwellers in general to asbestos derived from the brakes of passing vehicles). Obviously, any risks to handymen who carry out maintenance on homes only occasionally will be much less than the risks to professional tradesmen such as carpenters, who work day in, day out at building construction sites - because the frequency and duration of exposures for the handyman will be less (with lower cumulative exposures), assuming the types of asbestos to be the same. However, this may not always be so. For example, I know that some "handymen" in Australia specialize in buying and living in dilapidated houses, to carry out extensive renovations on these dwellings (e.g. throughout each weekend or more often) before selling them a year or more later; because the house qualifies as a principal place of residence, the profit is not taxable. The handyman then repeats this exercise on another "handyman special" house, and so on. Many such handymen also regularly carry out maintenance and renovation work on other homes, so that their exposures may approach those of professional tradesmen, but they style themselves as "home handymen". The activities of such handymen are virtually unregulated because they are self-employed and a number work on a "strictly cash" basis.

5.589 In commenting on the experts' responses to Questions 1(b), Canada reiterates the proposition that "chrysotile is readily removed from the lung", and estimates of the half-life of chrysotile are given as 90-110 days, and even a shorter estimate of < 10 days from Dr. David Bernstein. Canada goes on to state that "size for size, chrysotile has a very short half-life." I again draw attention to the 1999 study by Finkelstein and Dufresne [5], who found a lung tissue half-life of eight years for chrysotile fibres > 10 µm in length; this investigation was discussed briefly in the Endnote to my report (see Section V.C.4):

> " ... in the past, the kinetics of chrysotile clearance from lung tissue have been investigated mainly in experimental models using rodents. In an autopsy study published in 1999, Finkelstein and Dufresne [5] ... investigated clearance of chrysotile from the lung tissue of 72 Quebec chrysotile miners and millers in comparison to 49 control subjects, using regression analyses, with the following findings:
>
> There was a significant association between the duration of occupational exposure and the tissue burdens of chrysotile and tremolite.
>
> The concentration of chrysotile decreased with time after exposure ceased but the concentration of tremolite did not.

[158]Please see also my answers to Questions 1(e) and 5(a).

> The clearance rate varied inversely with the length of chrysotile fibres. For fibres > 10 µm in length - i.e. fibre lengths in the reported range for carcinogenicity - the clearance half-time was estimated to be eight years. In other words, the tissue bio-persistence of chrysotile fibres in this study seems substantially more prolonged than in rodent experiments, and presumably corresponds to persistent high chrysotile fibre concentrations for many years after cessation of occupational exposure in humans, as discussed on p 31. It is also notable that the concentration of 6,250,000 chrysotile fibres mentioned on p 31 (for an individual but by no means unusual patient) is probably above the level at which Rogers et al. [6] identified an odds ratio for mesothelioma of > 8.5 (even allowing for differences in fibre size in the counts by the two different laboratories), and even the duration of 16 years after exposure stopped (as opposed to its commencement: 24 years) falls into the lag-time range for lung cancer induction by asbestos.
>
> Studies like this suggest that clearance mechanisms can be overwhelmed and break down at occupational levels of exposure in humans, with the existence of a long-term sequestered fraction of chrysotile fibres."

5.590 This study seems to be of particular significance for the tissue bio-persistence of chrysotile fibres in comparison to substitute materials (please see below, paras. 5.642 to 5.652).

5.591 I also emphasize that some of the estimates given in my Report were conservative, with potential under-estimation of effects. For example, after discussing the incidence rate for spontaneous mesothelioma unrelated to asbestos as being in the range of 1-2 mesotheliomas per million person-years - whereas the likely true figure is probably less than one [4] - I nonetheless used the upper figure of two cases/million for comparison with mesothelioma incidence in some occupational groups (e.g. the incidence of mesothelioma among male automobile/brake mechanics in Australia; please see para. 5.253). In a similar way, I referred to a 30-fold differential rate for lung cancer among the South Carolina (Charleston) chrysotile textile workers in comparison to the Quebec chrysotile miners and millers, whereas others give the differential as up to "about 50 times higher in Charleston" [7].

5.592 I also draw attention to the occurrence of mesothelioma among various cohorts and studies other than the Quebec chrysotile miners/millers, as set out in paragraphs 5.124-5.141, and to the incidence of mesothelioma among mechanics in Australia as shown in the 1999 Report for the Australian Mesothelioma Register [AMR 99] and in NICNAS 99 (see my answer to Question 2).

5.593 In my Report, I discussed the limitations or deficiencies of those studies which reported an increased risk of lung cancer only among workers with pre-existing asbestosis (e.g. the Hughes-Weill study [8]) - and the uncertainties of the study by Camus et al. [9] on lung cancer risk from non-occupational exposure to chrysotile among females in Quebec[159] - but the comments from Canada (para. 5.529) reiterate the Hughes-Weill conclusion that an increased risk of lung cancer occurs "only in those with asbestosis." (Please see paras. 5.73-5.74 and 5.152-5.162 above; this subject was reviewed extensively by Henderson et al. [13] in 1997. Lung cancer risk among the South Carolina chrysotile textile workers versus the Quebec chrysotile miners/millers is also discussed in paras. 5.596 to 5.620 below).

[159]Canada's comments also refer to the meta-analysis of lung cancer risk reported by Lash et al., [10], which identified a low risk. Meta-analysis is a field that lies outside my expertise, but I understand that there are various models for meta-analysis and problems with this approach (e.g. see Blettner et al. [11] who state that "... Meta-analyses from published data are in general insufficient to calculate a pooled estimate since published estimates are based on heterogeneous populations, different study designs and mainly different statistical models [Abstract] ... Meta-analyses using published data are, therefore, restricted and seldom useful to produce a valid quantitative estimate or to investigate exposure relations such as dose-response [p 8] ..."). In a meta-analysis of 69 asbestos-exposed occupational cohorts, Goodman et al. [12] identified "... meta-SMRs of 163 and 148 [for lung cancer] with and without latency, with significant heterogeneity of results ..."

5.594 At various points (paragraphs 5.475, 5.498 and 5.545), the comments from Canada quote de Klerk and Armstrong [14], in a chapter on *The Epidemiology of Asbestos and Mesothelioma*, in the book *Malignant Mesothelioma,* for which I was the senior editor and a co-author. I shall leave it to Dr. de Klerk to respond.

5.595 In passing, I point out that *Malignant Mesothelioma* was published in 1992; the text for those chapters which I wrote was current up to September 1990, and the manuscript was sent to the publisher shortly thereafter. Much new information on asbestos-related diseases has accumulated since that time (e.g. references 15, 16, 113, 125, 126, 131-133, 140, 141, 170-172, 177-179, 181, 185-187, and 190-194 in my Report, to list but a few). My views on many aspects of asbestos-related disorders have changed very substantially since *Malignant Mesothelioma* was published (e.g. my views on asbestos and lung cancer - please see references [13, 15-18] in these Supplementary Remarks).

(a) Lung cancer rate among South Carolina (Charleston) chrysotile textile workers versus the Quebec chrysotile miners/millers

5.596 With respect to this question, Canada states (see paras. 5.485-5.486):

> "Dr Henderson states that the "greater carcinogenicity of the amphiboles [...] appears not to extend to the induction of lung cancer [p 40], but he admits that 'chrysotile is implicated in one of the lowest rates of asbestos-associated lung cancer (in Quebec chrysotile miners and millers)' [where I also stated that chrysotile is also implicated in the highest lung cancer rate]. Dr Henderson's reluctance to conclude the greater carcinogenicity of amphiboles seems to be caused by the results of Dr Dement's study of the Charleston, South Carolina asbestos textile industry [...]".
>
> "The Charleston data has [*sic*] recently been revisited by Bruce Case, André Dufresne, A.D. McDonald, J.C. McDonald and Patrick Sébastien in a study released in Maastricht in October 1999 at the *VIIth International Symposium on Inhaled Particles,* a symposium attended by some of the world's leading experts. This study shows that a significant amount of crocidolite and amosite fibres was found in the textile workers' lungs. This analysis sheds new light on the issue and explains the extreme results of the original study by Dr Dement [...] and the subsequent study by Dr Stayner [...]. These studies of textile workers exposed to crocidolite and amosite can thereby no longer be used to demonstrate the risks associated with chrysotile fibres."

5.597 Subsequently, the manuscript for a paper by Case et al. [19] entitled *Asbestos Fibre Type and Length in Lungs of Chrysotile Textile and Production Workers: A Preliminary Report* arrived by facsimile transmission. I offer the following comments on this document (and, later, on the Abstract for the corresponding presentation at the Maastricht meeting [20]):

5.598 A disclaimer beneath the title [19] indicates that this is a "DRAFT DOCUMENT: SUBJECT TO REVISION - NOT TO BE CITED". It is cited nonetheless. There is no indication that this document has gone through a process of peer review and been accepted for publication.

5.599 This study revisits the study reported in 1989 by Sébastien et al. [7], and the draft manuscript indicates that the same grids were examined (but fewer cases). The main difference between this investigation and the earlier study by Sébastien et al. [7] is that Case et al. [19, 20] analysed long fibres > 18 µm in length, whereas Sébastien et al. [7] studied fibres > 5 µm in length, with an aspect ratio > 3:1. (It is common practice for fibre burden analyses to focus on fibres ≥ 5 µm in length and there is no evidence that the carcinogenicity of asbestos fibres - in terms of lung cancer induction - is restricted only to fibres about 20 µm in length or more.)

5.600 Another study on the lung fibre content of the Charleston chrysotile textile workers was reported in 1997 by Green et al. [21]; this investigation studied all fibres resolvable by electron

microscopy and with an aspect ratio > 3:1. For this study, lung tissue was analysed from 39 textile workers versus 31 comparable controls matched closely for age (median age at death for the asbestos workers was 56.0 years, versus 59.0 years for the controls).

5.601 In the Green et al. [21] study, the Charleston chrysotile workers had a higher lung content of chrysotile in comparison to the controls (geometric mean = 33,450,000 versus 6,710,000 f/g dry lung), with a higher content of tremolite (3,560,000 *vs*. 260,000); the asbestos workers also had a slightly elevated mean amosite/crocidolite content of 470,000 fibres *vs*. 210,000 for the controls (please see Table 1).

TABLE 1: MINERAL FIBRE CONTENT OF LUNG TISSUE, SOUTH CAROLINA ASBESTOS TEXTILE WORKERS *VS.* CONTROLS (ALL COUNTS = FIBRES X 10^6 / G DRY LUNG)*

	Textile workers	**Controls**
Age at death (median; years)	56.0 (M); 57.0 (F)	59.0 (M); 62.5 (F)
Year of death (median)	1971 (M and F)	1972 (M); 1971 (F)
Chrysotile (fibres x 10^6/ g dry lung)	33.45	6.71
Tremolite	3.56	0.26
Amosite/crocidolite	0.47	0.21
Anthophyllite	0.16	0.13
Mullite	1.63	4.01
Other	1.02	1.9
All fibres	52.46	16.02

*Modified from Tables 1 and 3 in Green et al. [21]; M = men; F= females.

5.602 In the discussion section, Green et al. [21] commented that:

> "The population was exposed almost exclusively to chrysotile asbestos from Quebec. The native ore contained about 1% tremolite asbestos. The high concentrations of chrysotile and tremolite asbestos found in the lungs of the asbestos textile workers are also consistent with their exposure histories. Our finding on enrichment of tremolite relative to chrysotile in the lungs of asbestos workers is consistent with previous reports. The presence of crocidolite in some of the lungs of the asbestos workers is in keeping with the use of small quantities of crocidolite between 1950 and 1975, but the values were only slightly greater than those found in the control population. ... The increased risk of lung cancer in the asbestos textile workers is also unlikely to be due to differences in exposure to tremolite asbestos, as Sebastien et al. have shown that the textile workers had less tremolite asbestos in their lungs than miners and millers of the original ore after matching for exposure intensity. Differences in exposure to other commercial amphiboles (crocidolite and amosite) may have played a small part based on our own data ... and on the data of Sebastien et al., which showed a small excess of these amphiboles in the lungs of the textile workers compared with the miners; however, it is very unlikely that this is the whole explanation as commercial amphiboles formed a very small proportion of the total amphiboles in both studies. Moreover, review of the 10 cases with lung cancer in this study on whom lung fibre analyses were made, showed only one case with substantially increased (> 1 x 10^6 fibre/g dry lung) crocidolite or amosite".

5.603 In this study, it is also notable that the lung cancer cases on which fibre burden analysis was carried out were not representative of the cohort as a whole: e.g. autopsies were carried out on only about 10 per cent of all deaths in the cohort, and the mean lifetime cumulative exposure for the ten lung cancer cases was 94.6 fibre-years in comparison to 67 fibre-years for male lung cancer cases across the whole cohort [21, 22].

5.604 There are even greater concerns about the representativeness of the cases on which fibre burden analysis was carried out by Sébastien et al. [7]. For example, this study was confined to tissue from 72 autopsies among 857 deaths (8.4 per cent) among the Charleston cohort, and there were only seven lung cancer cases out of 66, whereas Case et al. [19] list 126 lung cancers, so that the fibre burden data reported by Case et al. [19] appear to deal with no more than 5.56 per cent of the Charleston lung cancers. It is also notable that the mean age at death in the Charleston group was about a decade younger than the age at death for the Thetford group which formed the basis for comparison in the 1989 study by Sébastien et al. [7][160]

5.605 In addition, as reported by Sébastien et al. (see Table 3 in reference [7]), those cases from the Thetford group that came to autopsy showed an over-representation of asbestos-related diseases (lung cancer, mesothelioma and pneumoconiosis) than the Thetford cohort overall - so that cases of lung cancer + mesothelioma + pneumoconiosis added up to 37 out of 89 autopsies (42 per cent), in comparison to 306 out of 4463 deaths across the whole cohort (7 per cent) [7]. For the Charleston cohort, the figures were more comparable, so that lung cancer + mesothelioma + pneumoconiosis cases added up to 13 out of 72 autopsies (18 per cent) in comparison to 10 per cent across the cohort [7].

5.606 In the more recent study from Case et al. [19], there is a further point on which the two study groups (Thetford versus Charleston) are not comparable: the time following cessation of exposure was a median of eight years for the Thetford group, in comparison to 20 years for the Charleston cohort (please see Table 2). Therefore, it is clear that those lung cancer cases on which fibre burden analysis was carried out from each cohort were not representative of each cohort, and that there were also substantial differences between the two cohorts for the same types of case. Finally, the manuscript from Case et al. [19] does not include a control group against which the two cohorts can be compared (the only one of the three investigations that does is the Green study [21]).

TABLE 2: COMPARISON OF THE SOUTH CAROLINA AND QUEBEC CHRYSOTILE WORKER COHORTS*

	South Carolina textile workers	**Quebec miners/millers**
Cohort number	3022	10,918
Cohort deaths	1258	8009
Age at death (years)	67 ± 10 (??)**	56 ± 6 (??)**
Lung cancers in cohort	126 [SMR 197]	657 [SMR 137]
Mesotheliomas in cohort	2	38
Years since cessation of exposure (median)	20	8
Geometric mean exposure (mpcfy)***	3.63	186
Subjects studied	64	43
Lung cancer cases studied	? (7/72 autopsies in ref [7])	? ("random" selection of 43 cases from 89 original cases that included 22 lung cancer cases - ref [7])
Chrysotile (fibres x 10^6/ g dry lung)	0.054	0.231
Tremolite	0.027	0.325

[160]There is a discrepancy between the ages at death in the original paper by Sébastien et al. [7] (i.e. mean = 55.8 ± 9.7 for the Charleston cohort vs 67.5 ± 9.7 for the Thetford group) and the follow-up study by Case et al. [19] (Table 1A, where the ages are reversed: 67 ± 10 for the Charleston group vs 56 ± 6 for Thetford). Clearly, one or the other must be wrong.

	South Carolina textile workers	Quebec miners/millers
Amosite/crocidolite	0.037	0.024
Total amphibole (tremolite + amosite/crocidolite)	0.064	0.349

*Modified from Case et al. [19]. Fibre counts represent geometric means; all expressed as fibres x 10^6/ g dry lung; **see footnote 160; ***mpcfy = millions of particles per cubic foot-years.

5.607 From the above Table, it is evident that the amosite/crocidolite content of lung tissue from the textile workers is slightly (< 2-fold) higher than the amosite/crocidolite in the lung tissue from the Quebec miners and millers (37,000 fibres > 18 µm in length versus 24,000). This difference in concentration seems to be insufficient to explain the "huge" [19] risk difference (about 30-fold) in the slope of the lung cancer dose-response line between the two groups. In addition, it is noteworthy that the tremolite content of lung tissue was higher in the Quebec miners and millers than the Charleston textile workers (325,000 versus 27,000 for fibres with a mean fibre length of 21.7 versus 21.9 µm). The point is that the total amphibole content (tremolite + amosite + crocidolite) is higher in the Quebec miners and millers at 349,000 f/g dry lung in comparison to a total amphibole content of 64,000 among the Charleston textile workers. In this respect, there is no evidence that tremolite is substantially less potent than the other amphiboles for lung cancer induction, as shown by the high lung cancer incidence (SMR = 285) among Montana vermiculite miners exposed only to tremolite/actinolite (please see paragraph 5.107-5.111).

5.608 From these studies, it appears that the amosite/crocidolite content of lung tissue among the Charleston textile workers may in part be a reflection of low level exposure to the small amount of crocidolite (< 1000 kg total) used in the plant from 1950-1975 to make an asbestos tape or braided packing. The material was received at the plant as a yarn ready for weaving, and no fibre preparation, carding, spinning or twisting was done using crocidolite. Packing workers were not included among the textile worker cohort, and analysis of lung cancer risk by operation in the plant shows all operations to be at about the same lung cancer risk after controlling for chrysotile exposure in a logistic model (Dement, personal communication, 1999).

5.609 A portion of the amosite/crocidolite content may also be explicable by general environmental (non-occupational) exposure, taking into account the small differences between the amphibole content in the textile workers versus the controls in the study reported by Green et al. [21]. In this respect, amphibole concentrations of up to 100,000-200,000 fibres per gram (f/g) dry lung tissue can be expected for about 5 per cent of the population in Germany [23]. Therefore, it seems that the amosite/crocidolite cannot explain the risk of lung cancer in the Charleston cohort in comparison to either matched controls (also matched for smoking) versus the Thetford miners and millers.

5.610 If major significance is to be assigned to the small difference in amosite/crocidolite content of lung tissue between the Charleston workers versus the Thetford miners/millers for lung cancer induction, a question that immediately arises is: *where are the mesotheliomas among the Charleston workers?* Case et al. [19] suggest that misclassification of mesotheliomas as lung cancers among the Charleston workers could have produced under-estimation of the true number of mesotheliomas "while having virtually no effect on the lung cancer excess or lung cancer exposure-disease slope of risk." No evidence in support of this proposition is adduced, and Case et al. [19] state that this is "speculation." The larger number of mesotheliomas in the Quebec cohort may be explicable in part by the higher mean total amphibole content for this group, but this still leaves unexplained the disproportionately larger numbers of lung cancers in the Charleston group (e.g. the ratio of lung cancers to mesotheliomas in the Thetford group is 657/38 = about 17:1, whereas the ratio for the Charleston group is 126/2 = 63:1).

5.611 Case et al. [19] are also rather more cautious in their interpretation than the propositions put forward in Canada's responses to the reports from the experts. For example, on the last page of text they state:

> "... comparison of groups of individuals using this technique is valid only insofar as those studied are representative of the larger groups ... from which they are derived. We cannot be certain to what degree our groups of chrysotile miners/millers and textile workers are representative of the cohorts from which they are derived[161] ... the two groups are not directly comparable in some ways: not only was exposure much higher in the miners/millers, but the interval between cessation of employment and death was shorter .... . Our results closely parallel those reported by Sebastien et al.. Any other result would be surprising since the subjects were drawn from the latter study. ... Caution remains in interpretation. ... One continuing mystery, given the apparent non-trivial long-fibre commercial amphibole exposures is the low level of reported mesotheliomas in this cohort ...".

5.612 Given the data on fibre lengths across the cohorts, in comparison to the data in Sébastien et al. [7], the difference in lung cancer rates between the two groups cannot be explained by differences in fibre length. This is stated explicitly by Case et al. [19].

5.613 However, on looking at the data, it seems that the differences between the two cohorts might be explicable in part by the exposure estimates. Differences in exposure assessment are not refuted by the "new" study reported in draft form by Case et al. [19] or by the earlier study reported by Sébastien et al. [7]: e.g. the difference between 20 years (Charleston) and eight years (Quebec) for clearance after exposure ceased could have a large effect. One can calculate the final exposure (end of exposure) (N_0) from the final fibre content in lung tissue at death (N), from the equation

$$N/N_0 = e^{-\lambda t}$$

where λ represents a clearance coefficient ($\lambda = 0.693 \div T_{1/2}$) and t = half-life in tissue ($T_{1/2}$). For $T_{1/2}$ = 8 years [5], $\lambda = 0.693/8$, so that for the chrysotile miners/millers, where N = 0.231, $N_0 = 0.462$. For the Charleston textile workers, where N = 0.054, $N_0 = 0.306$.

5.614 If $T_{1/2}$ is shorter (e.g. one year), then N_0 for the miners/millers = 59.2 and the corresponding N_0 for the textile workers = 56456.

5.615 Therefore, for a half-life of eight years, one would expect the ratios of exposure (exposure miners/millers ÷ exposure textile workers) to be 0.462/0.306 = 1.5. For a half-life of one year the ratio becomes (exposure miners/millers ÷ exposure textile workers) 59.2/56465 = 0.001. (For tissue half-lives of 90-110 days or < 10 days, the differences would be even more drastic.) However, the ratio of the estimated exposures ($mpcfy_{Quebec}/mpcfy_{Charleston}$) is 186/3.63 = 50, suggesting that one or other particle count estimate is incorrect.

5.616 In this respect, it might be argued that the exposure estimates for the Charleston cohort represented an under-estimation of exposure, but this suggestion is not supported by the low tremolite content in the lung tissue of the Charleston workers, and is explicitly rejected by Sébastien et al. [7], who state (p. 187):

> "The hypothesis of a systematic underestimation of exposures to asbestos in Charleston, which would have accounted for the difference in risk, must therefore be rejected and other explanations sought."

5.617 Given that contamination of the Charleston chrysotile by mineral oils has now been excluded, one possibility that remains is over-estimation of the exposures for the Quebec chrysotile

[161]Clearly, from the data in Table 2 and the discussion in paras. 5.604 to 5.609, they are not representative.

miners/millers (with under-estimation of risk). If this explanation is unsustainable, it follows that the paradox remains, it remains unexplained, and seems likely to remain so.

5.618 Finally, I draw to the attention of the Panel the following comment by Case and Dufresne [20] in the Abstract for their presentation at the Maastricht meeting:

> "Risk assessment for asbestos exposure is based on lung cancer risk for textile workers, rather than miners/millers."

5.619 In the draft manuscript, Case et al. [19] state only that:

> "... suggestions that the textile worker mortality data [are] suitable for chrysotile risk assessment [for lung cancer] should be re-evaluated ... ."

5.620 Therefore, even if one accepts this proposition for the moment, the claim that the South Carolina cohort can "thereby no longer be used to demonstrate the risks associated with chrysotile fibres" goes beyond the data in this study. For the reasons discussed in this section, I conclude that the data in Sébastien et al. [7] and in Case et al. [19] do not detract from the conclusions drawn by myself and other authorities from the investigations carried out the South Carolina cohort by Dr. Dement and his colleagues [22, 24].

(b) The question of a threshold for the carcinogenicity of chrysotile (lung cancer and mesothelioma

5.621 On this question, I simply reiterate EHC 203:

> "Exposure to chrysotile asbestos poses increased risks for asbestosis, lung cancer and mesothelioma in a dose-dependent manner. No threshold has been identified for carcinogenic risks" [p. 144].

5.622 In the absence of a threshold or an agreed alternative (non-linear) exposure-response model, the linear relationship model is widely employed for risk assessment at low levels of exposure.

5.623 As indicated, the precision or validity of this model is not known at low levels of exposure and, as stated by Dr. de Klerk, the model provides a "conservative estimate". This is the point: in the absence of direct observational data or credible alternative models, the linear model errs - if it does err - on the side of safety, which is appropriate for risk assessment as a prelude to the formulation of occupational health and safety and public health policy. The principle is: if there is doubt, play safe (i.e. first, do no harm; *primum non nocere).*

5.624 In relation to prudent approaches to occupational and public health policy, *The Minerals and Metals Policy of the Government of Canada*[162] states the following (p 7):

> "The precautionary principle is an important factor when the Government needs to make a decision in the face of scientific uncertainties about cause and effect, and when the potential environmental consequences are generally considered to be serious or irreversible. This principle was enunciated clearly as Principle 15 in the 1992 *Rio Declaration on Environment and Development* (the Rio Declaration) of the United Nations Conference on Environment and Development (UNCED), to which Canada is a signatory:
>
> '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.'

[162]NRCAN, The Minerals and Metals Policy of the Government of Canada: *Partnership for Sustainable Development*, Public Works of Canada, 1996.

The principle complements science-based approaches for the management of risks. Its use is premised on the recognition that our scientific understanding of the potential magnitude and consequence of impacts on human health and the environment of the production and uses of some minerals and metals may be incomplete. While there is a need to work toward closing such gaps in our understanding, there is also a requirement, where potential impacts are 'serious or irreversible', to consider a cost-effective precautionary approach."

5.625 Later, on page 12, the same *Minerals and Metals Policy* document states:

"... It is generally accepted that, in some cases, the risks associated with certain products or product uses cannot be properly controlled or managed. Consequently, where such a situation exists, the Government [of Canada] will either discontinue or prohibit the specific product or product use."

5.626 Three additional points are worth iteration:

- Exposure to commercial Canadian chrysotile is not "chrysotile-only", but usually chrysotile + trace tremolite exposure, although evidence indicates that chrysotile when uncontaminated by tremolite also has the capacity for the induction of lung cancer and mesothelioma.

- Risk estimates for lung cancer and mesothelioma for low levels of chrysotile exposure were set out in Tables 12 and 13 (see my response to Question 1(d)).

- As stated in section C.1(f)(viii) and in paragraph 5.95, there are no observational data on the interactive effects of inhaled commercial chrysotile fibres when these are superimposed separately and later upon a pre-existing amphibole ± chrysotile burden within lung tissue (?superimpositional additive or multiplicative carcinogenic effect). In my Report, I emphasized that it has been estimated that up to 15-20 per cent of men in industrialized societies may have sustained occupational exposures to asbestos (chrysotile/amphiboles), and Rödelsperger et al. [23] indicate that fibre concentrations of 100,000-200,000 amphibole f/g dry lung tissue may be expected for about 5 per cent of the population in Germany. Rödelsperger et al. [23] have also identified a dose-response relationship for mesothelioma induction at these low fibre concentrations. We do not know what the effect of subsequent chrysotile fibre inhalation superimposed upon an existing amphibole burden of this order might be, but NICNAS 99 states the following (p. 61):

"... multivariate analysis of cases found a dose-response relationship for lung fibre content of crocidolite, amosite and chrysotile and the development of mesothelioma. Either a multiplicative or additive model could be used to fit the relative risk/dose coefficients for the various asbestos types. A progressive increase in relative risk with increasing fibre content was reported for all fibres ... ."

5.627 Because the risks of both lung cancer and mesothelioma show a dose-response effect related to total cumulative exposure levels, it may be expected that later superimpositional inhalation of chrysotile ± tremolite fibres would aggravate the overall consequences of a pre-existing asbestos burden (i.e. increase the risk further).

(c) The feasibility *in practice* of "controlled use" of chrysotile asbestos

5.628 In para. 5.510, Canada identifies the feasibility in practice of "controlled use" of chrysotile asbestos as "one crucial issue, which seems to override all other issues" (i.e. the question of whether the application of the "controlled use principle" is feasible and credible at all stages in the life cycle of chrysotile asbestos).

5.629 As already indicated (see my reply to Question 5), I agree that this proposition is crucial to the dispute before the WTO. However, for the reasons discussed in my Report, I see no requirement to resile from my perception that - although regulation and control of chrysotile and high-density chrysotile products may be achievable at some points of the life-cycle (e.g. the manufacture of friction and high-density products) - "controlled use" of this type is not feasible in reality or in practice at others (e.g. in building construction and other points of end-use).

5.630 No airborne fibre measurements are available for the overwhelming majority of asbestos-related diseases encountered in my everyday practice, even for exposures throughout the 1970s and in some cases extending into the late 1980s. Among my series of asbestos-associated lung cancers and mesotheliomas, I cannot recollect ever seeing actual airborne dust and fibre measurements at points of end-use (e.g. at building construction sites or shipyards).

5.631 The concentration of total asbestos fibres in lung tissue from one of my cases of asbestos-associated lung cancer was up to 125,000,000 f/g dry lung (up to 108,000,000 amosite + crocidolite fibres), for a worker who had been employed at a major asbestos-cement manufacturing facility for about 2-3 years (lag-time = 28 years) [15]. I also note Dr. de Klerk's comment about demolition of an old asbestos-cement factory in Sydney in the latter half of 1999 (probably the same factory) "where no observable precautions of any kind were being taken"[163] (Dr. de Klerk, response to Question 1(a)).

5.632 Other interventions on high-density asbestos-cement materials that can lead to high fibre concentrations are discussed in my first Report (e.g. Kumagai et al. [25]; my answer to question 1(d); please see also the 1980 report by Rödelsperger et al. [26] on exposure to asbestos-cement dust at building sites, which refers to a daily mean airborne fibre concentration of 0.6 f/ml for fibres > 5µm in length, and "peak concentrations of more than 100 fibres/ml").

5.633 In para. 5.532, the comments from Canada include the statement that chrysotile "can be painted without fibre release" (presumably including building products). However, painting of such products can cover warning notices and disguise the true nature of the product, so that workers who later carry out maintenance or renovation work on the same product - and those who recycle the same material - may be unaware of its true nature. In my own series of mesotheliomas, it is not uncommon to encounter cases for which the patient was unaware or unsure that he (or less often she) had worked in the past with an asbestos-containing product.

5.634 In one recent case, the patient worked (1973-1988) at a factory where tins and pails were produced. In about 1979 she had worked for several months at a conveyor belt that carried the tins and pails into a fan-forced oven, which appears in retrospect to have been lined by asbestos-containing insulation. The patient was present when maintenance work on the oven was carried out, and she recalled hot air continually blowing from the oven into her face as she worked on the conveyor. After diagnosis of her mesothelioma and its treatment in the late 1990s by radical pneuropneumonectomy, an asbestos body and fibre analysis on her lung tissue revealed a count of 1640 asbestos bodies per gram dry lung, and a total asbestos fibre count of 34,120,000 f/g dry lung (30,770,000 chrysotile fibres[164] + 3,350,000 crocidolite fibres). This was the only history of exposure that was obtainable on exhaustive questioning.

[163]The potential for misuse of asbestos-containing materials remains, as shown by some prosecutions (e.g. please see the UK Health & Safety Executive (HSE) press releases E198:98 and E079:99; http://www.hse.gov.uk/press/e98198.htm and http://www.hse.gov.uk/press/e99079.htm), but cases that come before the courts almost certainly represent only a small fraction of the misuses, most passing unnoticed by regulatory agencies.

[164]Please note the high chrysotile count almost a decade after the patient's employment ended.

5.635 A similar history was also obtained in another mesothelioma case seen on referral in 1999, where a radio assembly worker had used asbestos-containing cloths used to clean soldering irons, together with a history of about one fibre-hour of exposure to four asbestos-cement building sheets used for maintenance work on his home; only later did I discover that during his work at the radio factory, he often entered a walk-in fan-forced oven apparently lined by insulation bricks.

5.636 Again, please see the spread of occupations in AMR 99 attached to my Report; a similar spread of occupations is listed by Hodgson et al. [27] in a 1997 report on mesothelioma mortality in Britain[165] - e.g. see Table 1 and Fig 1 in the original reference. In footnote 96 to the comments from Canada, it is stated that:

> "The 'controlled use' approach has been endorsed by the WHO in its 1998 Environmental Health Criteria 203: Chrysotile Asbestos, p. 144. 'Control measures, including engineering controls and work practices, should be used in circumstances where the occupational exposure to chrysotile can occur. Data from industries where control technologies have been applied have demonstrated the feasibility of controlling exposure to levels generally below 0.5 fibres/ml. Personal protective equipment can further reduce individual exposure where engineering controls and work practices prove insufficient'."

5.637 I interpret this passage from EHC 203 differently when it is taken in the context of the preceding paragraphs; apart from the heading, the complete text on page 144 of EHC 203 is:

> a) Exposure to chrysotile asbestos poses increased risks for asbestosis, lung cancer and mesothelioma in a dose-dependent manner. No threshold has been identified for carcinogenic risks.
> b) Where safer substitute materials for chrysotile are available, they should be considered for use.
> c) Some asbestos-containing products pose particular concern and chrysotile use in these circumstances is not recommended. These uses include friable products with high exposure potential. Construction materials are of particular concern for several reasons. The construction industry workforce is large and measures to control asbestos are difficult to institute. In-place building materials may also pose risk to those carrying out alterations, maintenance and demolition. Minerals in place have the potential to deteriorate and create exposures.
> d) Control measures, including engineering controls and work practices, should be used in circumstances where occupational exposure to chrysotile can occur. Data from industries where control technologies have been applied have demonstrated the feasibility of controlling exposure to levels generally below 0.5 fibres/ml. Personal protective equipment can further reduce individual exposure where engineering controls and work practices prove insufficient.[166]
> e) Asbestos exposure and cigarette smoking have been shown to interact to increase greatly the risk of lung cancer. Those who have been exposed to asbestos can substantially reduce their lung cancer risk by avoiding smoking."

5.638 When seen in the context of para. c), I take d) to mean that in those situations where exposure is likely or unavoidable, exposure can be reduced or minimized by certain procedures appropriate to the circumstances (e.g. engineering controls in manufacture/production or best work practices), but EHC 203 has already identified friable products and building products as materials of "particular concern" and their use is "not recommended", in part because of difficulties of control in the construction industry. I do not see paragraph d) as an endorsement of on-going "controlled use".

5.639 A similar sentiment is expressed in NICNAS 99:

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[165]Hodgson, J.T., Peto, J., Jones, J.R., and Matthews, F.E., *Mesothelioma Mortality in Britain: Patterns by Birth Cohort and Occupation,* (1997), 41 Ann. Occup. Hyg., 129-133.

[166]Omitted from my original Report because I did not - and do not - take this to be an endorsement of "controlled use", and also because the figure of up to 0.5 f/ml is up to five times higher than the level of 0.1 f/ml mentioned in Question 5(c) from the WTO Panel.

"Prudent OHS [occupational health and safety] policy and public health policy favours the elimination of chrysotile wherever possible and practicable [p 139] ...
Best practice must be implemented to minimise occupational and public exposure, and to minimise environmental impact, over the remaining period(s) of use [p 140].
A risk reduction strategy using all available and appropriate measures is required to ensure that the risks posed by chrysotile are continually reduced and eliminated wherever possible" [p 140].

5.640 NICNAS 99 also goes on to state (p 140):

"In achieving this it is further recommended that:

a) Specific phase-out periods should be set, with stages (over the shortest possible period of time) to encourage and reflect the availability and suitability of alternatives [to chrysotile].
b) Action is taken in the immediate future to prohibit the replacement of worn non-chrysotile original equipment with chrysotile products, as alternatives are now available.
c) No new uses of chrysotile or chrysotile products should be introduced (i.e., an immediate prohibition on new uses).
d) Occupational health and safety authorities take the lead role in considering this recommendation and specific strategies to implement it as worker health is identified as the major concern."

5.641 As stated in the paper by Jarvholm et al. [28] attached to the Endnote (Section V.C.4) for my report:

"... The first regulation of asbestos [in Sweden] was introduced in the early 1960s and subjects who started their occupational career in the 1960s should have been exposed to lower doses on average, than those who started earlier. On the other hand, by the 1960s asbestos was being used more extensively so the number of people exposed to asbestos may have increased. ... More stringent regulations of asbestos were introduced in the mid-1970s, which led to the sharp decrease in its use. People who have only worked under such conditions were born from 1955 onwards. They have not yet reached a sufficient latency time for possible mesotheliomas to have developed so the number of cases [is] few. However, the first indication is that they may have a decreased risk compared with earlier birth cohorts. A more certain conclusion can probably not be drawn for another ten years. Thus, the preventive measures of the mid-1970s can probably not be evaluated with reasonable precision until around 2005, 30 years later.

The present situation in Sweden, that mortality from mesothelioma due to early use of asbestos is of a similar size to the total number of fatal occupational accidents, is caused by a situation in which at least 90% of the asbestos used was chrysotile. However, we have no information about the type of exposure to asbestos among the cases of mesothelioma - whether they had an exposure to crocidolite or amosite. There is some pressure from the asbestos industry world-wide to change the asbestos regulations to allow the use of chrysotile. To evaluate such an experiment would take at least another 30 years. Even if the major cause of mesothelioma in Sweden was from types of asbestos other than chrysotile, it is difficult to see how the benefits from an increased use of asbestos in Sweden could outweigh the uncertainty of the risks. A similar prudent approach would also be appropriate in other European countries ..."

(d) Are substitute fibres safer than chrysotile?

5.642 In para. 5.539, Canada states:

"Dr. Henderson, for his part, recognises that, as with all fibres, the pathogenicity of substitutes is defined by the "3 Ds" (dimension, dose, durability). He seems also to understand that, due to the (lack of) historical use of substitutes, we cannot fully know the risks of using them. However, he then seems to ignore the importance of these facts."

5.643 My comments on the safety or potential biohazards of substitute fibres were based on the following:

- The dimensions and respirability of substitute fibres. For example, it appears that synthetic fibres can be engineered to be either shorter than the lengths of asbestos fibres that have been associated particularly with carcinogenicity, or to be predominantly non-respirable. In contrast, according to Harrison et al. [29]:

"The intrinsic hazardous properties of chrysotile can never be "engineered out", and the potential for harm will always remain. Prevention of ill-health will thus always rely on the control of exposure, something that history has shown cannot be guaranteed. ... Unlike chrysotile, substitute fibers can often be designed or selected to have particular characteristics."

- Dose: reported airborne fibre concentrations from the manufacture or use of substitute (e.g. synthetic) fibres are low - comparable to or lower than the airborne fibre concentrations produced by the manufacture or subsequent use of chrysotile-containing materials. This being so, my conclusions about the relative safety of chrysotile versus substitute fibres are based primarily on fibre dimensions (discussed above) and biopersistence (discussed below).

- Durability (biopersistence): in para. 5.552, Canada states the following:

"It is well known that biopersistence is a key parameter. Indeed, the human evidence for chrysotile indicates that it is likely to be one of the main reasons why chrysotile is less dangerous than the amphiboles in respect to mesothelioma risk. This is clearly recognised by three of the four experts, as well as by INSERM."

Canada then emphasizes the rapidity of clearance of chrysotile from lung tissue, with reference to a 90-110 day half-life for chrysotile in lung tissue, and an even shorter estimate of < 10 days. Again, I draw attention to the recent study from Finkelstein and Dufresne [5] who estimated a lung tissue half-life of eight years for chrysotile fibres > 10 µm in length in Quebec chrysotile miners and millers. Accordingly, in my survey of the literature, I placed particular emphasis on the biopersistence of substitute fibres in comparison to chrysotile.

- The relative potency of substitute fibres or chrysotile fibres to produce pathological changes (e.g. genotoxicity/mutagenicity and the capacity for tumour induction).

5.644 Warheit et al. [30] claim that p-aramid fibres are biodegradable in the lungs of exposed rats, with faster clearance times than long chrysotile fibres, which showed greater biopersistence.

" ... p-aramid is biodegradable in the lungs of exposed rats; in contrast, the clearance of long chrysotile fibres was slow or insignificant, resulting in a pulmonary retention of long chrysotile asbestos fibres. The dimensional changes of asbestos fibres as well as the pulmonary cell labelling data indicate that chrysotile asbestos fibres may produce greater long-term pulmonary effects when compared to inhaled para-aramid fibrils" [Abstract].

5.645 In 1993, Hesterberg et al. [31] compared the effects of size-separated respirable fractions of fibrous glass (FG) with refractory ceramic fibres (RCF) and chrysotile fibres. They found that:

"Exposure to chrysotile asbestos (10 mg/m^3) and to a lesser extent RCF (30 mg/m3) resulted in pulmonary fibrosis as well as mesothelioma and significant increases in lung tumours. FG [fibreglass designated MMVF10 and MMVD11] exposure was associated with a non-specific inflammatory response (macrophage response) in the lungs that did not appear to progress after 6-12 months of exposure. The cellular changes are reversible and are similar to the effects observed after inhalation of an inert dust. No lung fibrosis was observed in the FG-exposed animals. Further, FG exposure resulted

> in no mesotheliomas and no statistically significant increase in lung tumour incidence when compared to that of the negative control group. These findings, along with previous inhalation studies, suggest that respirable fibrous glass does not represent a significant hazard for fibrotic or neoplastic lung disease in humans" [Abstract].

5.646 In a later (1995) study, Hesterberg et al. [32] found that exposure of rats to crocidolite and chrysotile asbestos and to RCF by inhalation induced pulmonary fibrosis, lung tumours and mesotheliomas (41 per cent of hamsters exposed to RCF developed mesothelioma[167]); fibreglasses MMVF10 and MMVF11, slagwool (MMVF22) and stonewool (MMVF21) did not produce a significant increase in lung tumours or mesotheliomas[168]

5.647 In a further study published in 1998, Hesterberg et al. [33] investigated the biopersistence of synthetic vitreous fibres and amosite in the rat lung, together with refractory ceramic fibres (RCF1A). They found that "the very biopersistent fibres were carcinogenic" (amosite, crocidolite, RCF1 and two relatively durable special application fibreglasses designated MMVF32 and MMVF33), whereas "the more rapidly clearing fibres were not" (including rock [stone] wool designated MMVF21, HT stonewool designated MMVF34, slag wool, and insulation fibreglasses designated MMVF10 and MMVF11).[169]

5.648 An Annex from Canada[170] also includes a 1995 document on p-aramid fibres from the Health & Safety Executive (HSE) in the United Kingdom. In a summary statement (p. 22) the HSE document states that:

> "The balance of evidence suggests that aramid fibres possess a low potential to produce mesothelioma, which is likely to be at least as low as for chrysotile asbestos. While chrysotile is thought to present a hazard with respect to mesothelioma development, current knowledge indicates that the risks for human exposure are low, and would only be detectable following very heavy and prolonged exposure. Thus, if in terms of mesothelioma production, aramid fibres are equally, or less hazardous than chrysotile, it can be concluded that the risks at occupationally relevant levels of exposure would be extremely low."

5.649 The HSE then set an exposure limit of 2.5 f/ml, but in a subsequent document on *Substitutes for Chrysotile (White) Asbestos,* the HSE[171] commented that:

> "There are many long-established alternatives to chrysotile which do not rely on fibre technology. For example, corrugated polyvinylchloride (PVC) and steel sheeting can be used instead of asbestos cement sheets.

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[167]The hamster seems to show a propensity for mesothelioma induction in some circumstances (e.g. SV40 inoculation) but not others; in some studies (Research and Consulting Company) chrysotile did not induce mesothelioma or lung in hamsters but in rats it produced pulmonary fibrosis, lung tumours and mesotheliomas, so that the rat has been advocated as the most appropriate model for assessment of the human risk from fibre inhalation [32].

[168]Hesterberg, T.W., Miller, W.C., Thevenez, Ph. and Anderson, R., *Chronic Inhalation of Man-made Vitreous Fibres: Characterization of Fibres in the Exposure Aerosol and Lungs*, (1995) 39 Ann. Occup. Health, pp. 637-653.

[169]Wilson et al. [34] estimate that fibreglass is 5-10 times less "risky" than chrysotile and they state that "... no one has found any cancer attributable to the manufacture or installation of glass wool fibers ... ." In their estimates of lung cancer risk from chrysotile, they use the unit carcinogenicity factor of 0.01 (K; used before them by the US EPA), and they calculate an absolute excess lung cancer risk of 1.2×10^{-3} for smokers, and 1.4×10^{-4} for non-smokers; for 40 yrs exposure at 1.0 f/ml, these estimates equate to 4.8×10^{-2} (smokers) and 5.6×10^{-3} (non-smokers) - i.e. about 5 per cent and 0.5 per cent respectively, both of which can be considered quite "high". (Wilson, R., Langer, A.M. and Nolan, R.O., *A Risk Assessment for Exposure to Glass Wool*, (1999) 30 Regulatory Toxicology and Pharmacology, pp. 96-109.

[170]Minty, C.A., Meldrum M., Phillips, A.M., and Ogden, T.L., *P-aramid Respirable Fibres Criteria Documents for an Occupational Exposure Limit*, HMSO (1995).

[171]HSE document: http://www.hse.gov.uk/pubns/misc155.htm.

> Several types of non-asbestos fibres can also be substituted for asbestos; they have been developed for use in a wide range of products. The main non-asbestos fibres in current use are polyvinyl alcohol (PVA), aramid and cellulose. A considered scientific view on their safety has recently become available. In July 1998, the UK's Department of Health Committee on Carcinogenicity (CoC) concluded that these three asbestos substitutes (PVA, cellulose and aramid) are safer than chrysotile. This view was endorsed by the European Commission Scientific Committee on Toxicity, Ecotoxicity and the Environment in September 1998."

5.650 More recently, a press release[172] from the UK Health and Safety Commission (HSC/HSE) announced a prohibition on the importation, supply or use of chrysotile in Great Britain, effective from 24 November 1999.

5.651 I also re-emphasize the comments in the reviews quoted in my original Report (answer to Question 6), including the review by Harrison et al. [29] who comment along the following lines:

> "The diameter of PVA [polyvinyl alcohol] fibres, as manufactured, is well above the respirable limit and most of them are not inhalable. ... the fibres are mostly in the range of 10-16 µm diameter. There is evidence that they do not fibrillate (split lengthwise). Many of the particles seen in the atmosphere are non-fibrous. ... Although the published toxicologic information on PVA is relatively sparse, the parent material has been used extensively in surgery and has food contact clearance, presumably based on unpublished studies. Indications of an accumulation of oligomers in the kidney in some circumstance[173] ... mean that the spectrum of molecular weight of material in the fibres as used should be considered, especially if a smaller diameter material were to be produced. The material will degrade only slowly, if at all, in the lungs. ... Thus, substitution of PVA for asbestos fibers in products such as asbestos-cement should result in reduced exposures. This prediction has been confirmed in industrial applications where very low fibre counts have been experienced. Misuse of installed material would not result in significant exposure.
>
> ... On balance, the use of aramid fibers should result in reduced levels of fiber exposure as compared to chrysotile asbestos and the fibrils released will be no more toxic and will be less biopersistent. The predicted reduction in absolute exposure levels has been achieved in industrial practice. Misuse of installed material would not be expected to give significant exposures.
>
> ... On balance, the coarse fiber structure and the long experience in use indicate that substitution of cellulose fiber for chrysotile asbestos should result in reduced occupational exposures to fiber and lower levels of deposition in the lung. The apparent biopersistence of cellulose in the lung would be a possible cause for concern if the potential for limited lung damage is confirmed.
>
> ... We believe that the continued use of chrysotile in asbestos-cement products is not justifiable in the face of available and technically and adequate substitutes. Likewise, there seems to be no justification for the continued residual use of chrysotile in friction materials."

5.652 These comments also coincide with one of the recommendations in NICNAS 99:

> "... Current overseas experience with the phasing out of chrysotile products indicates that a range of alternatives is available to suit the majority of uses. Good OHS practice dictates that use of chrysotile should be restricted to those uses where suitable substitutes are not available, and alternatives should continue to be sought for remaining uses" [p 139].

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[172]HSC press Release C054:99: http://www.hse.gov.uk/press/c99054.htm.
[173]Referred to in the comments from Canada.

(e) Summary

5.653 It is my perception that the conclusions in my Report submitted already to the WTO concur with mainstream thinking and approaches to occupational and public health policy from national and international health authorities; these include, *inter alia:*

- The National Occupational Health & Safety Commission in Australia (WorkSafe Australia). (Please see NICNAS 99.)
- The World Health Organization (EHC 203).
- INSERM (France).
- The National Health & Safety Commission/Health & Safety Executive (HSC/HSE) in Great Britain.
- Medical Research Council (MRC) Institute for Environment and Health at the University of Leicester (UK).
- National health authorities in other European Nations.
- The Collegium Ramazzini.

5.654 This being so, it is my perception that the dispute before the WTO is, to some extent, focused upon inappropriate issues. There has been on-going argument among scientists on the health hazards of chrysotile asbestos *(the chrysotilophiles versus the chrysotilophobes).* Given the extent and complexity of the scientific literature - with contradictory observations on some important issues and with uncertainties related to gaps in observational data - it is almost inconceivable that this controversy can be resolved by the WTO Panel, or, indeed, that it will be resolved in the foreseeable future (partly because no control group free from asbestos exposure can be assembled to ascertain the true spontaneous mesothelioma rate).

5.655 The point to be emphasized is that there exists a substantial body of independent scientific and medical opinion - embodied in national and international health authorities - that chrysotile is carcinogenic with no delineated threshold; that it cannot be controlled at all points of end use; and that existing scientific evidence indicates that safer substitute materials are available.

5.656 To me, this body of opinion is no tendentious artifice designed only to secure a commercial advantage. From my perspective, this is perhaps the crucial issue, from the so-called precautionary principle, given that neither side is likely to concede that the other has proven its case at a high order of scientific probability. In other words, the question is not so much whether there exists a proven health risk or virtually no risk from the continued use of chrysotile, but whether there exists a body of independent and reputable opinion that the possible risks or uncertainties about risk justify a policy of highly restricted use or non-use.

5.657 From this perspective, restriction of chrysotile to only a very few special applications - or its prohibition - is a reasonable and defensible measure designed as a cautious and prudent approach to public and occupational health policy.

5.658 Therefore, I re-affirm the conclusions set out in my original Report (paragraph 5.431) that chrysotile should either:

(a) Be restricted to only a few and well-defined applications[174] so that it is inaccessible to the great majority of workers and is available for use by only small and cohesive specialized worker groups that can be trained effectively in its controlled use (e.g. analogous to nuclear fuels); this means that chrysotile should not be used in building products (e.g. high-density fibro-cement materials such as asbestos-cement sheets) or friction products.

OR

(b) It should be made inaccessible to everyone, by prohibition, unless the alternatives pose equal or greater hazards and equal or greater problems with control.

5.659 In this latter circumstance, the principle is that minimization of exposure is more certain when no new chrysotile-containing products are introduced into the workplace or the general environment, so that the total amount of asbestos in-place will diminish over time; the problem then becomes primarily one of minimization of exposure to existing asbestos products during maintenance, repair, removal, demolition and disposal.

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[174]In the UK HSC Press Release C054:99 announcing implementation of a policy of prohibition of chrysotile from 24 November 1999, the following specific uses are allowable until 2001-2005:

- The use of compressed asbestos fibre (CAF) in gaskets for use with saturated and superheated steam, and with certain flammable, toxic and corrosive chemicals until 1 January 2001;
- The use of CAF in gaskets for use with chlorine until 1 January 2003;
- The use of any sheet which, when in a dry state, has a density greater than 1900 kilograms per cubic metre and is used at temperatures at or above 500°C until 1 January 2003;
- The use of asbestos components in aeroplanes and helicopters where this is crucial for their safe operation until 1 January 2004;
- The use of any product consisting of a mixture of asbestos with a phenol formaldehyde or with a cresylic formaldehyde resin in vanes for rotary vacuum pumps, vanes for rotary compressors, any bearing or its housing or for split-face seals used to prevent water leakage from hydro-electric power generation turbines or from cooling water pumps in power stations until 1 January 2004;
- The use of asbestos in pre-formed joints made from proofed asbestos cloth for sealing the doors of steam boilers until 1 January 2004;

The use of asbestos in personal protective clothing when used in very high temperatures (500°C or more) until 1 January 2005.

VI. SUBMISSIONS FROM NON-GOVERNMENTAL ORGANIZATIONS

6.1 The Panel received four *amicus briefs* from the following non-governmental organizations:

- *Collegium Ramazzini*, dated 7 May 1999
- *Ban Asbestos Network*, dated 22 July 1999
- *Instituto Mexicano de Fibro-Industrias A.C.*, dated 26 July 1999
- *American Federation of Labor and Congress of Industrial Organizations*, dated 28 July 1999

6.2 These *amicus briefs* were transmitted to the parties for their information. In their written rebuttals of 30 June 1999, the EC incorporated by reference the submission of the *Collegium Ramazzini*. In a letter dated 18 August 1999, Canada notified the Panel that, bearing in mind the general nature of the opinions expressed by the non-governmental organizations in those submissions, they would not be useful to the Panel at this advanced stage of the proceedings. Should the Panel nonetheless accept the submissions as *amicus briefs*, Canada believed that the parties should be given the possibility to respond to the factual and legal arguments set out in them. In a letter dated 3 November 1999, the EC informed the Panel that it was incorporating by reference the *amicus brief* submitted by the *American Federation of Labor and Congress of Industrial Organizations*, as that body supported the EC's scientific and legal arguments in this dispute. The EC also proposed to the Panel that it reject the submissions from the *Ban Asbestos Network* and the *Insituto Mexicano de Fibro-Industrias A.C.*, as those documents contained no information of relevance to the dispute. In a letter dated 10 November 1999, Canada again urged the Panel to reject the four *amicus briefs* as it was inappropriate to admit them at this stage in the proceedings. Should the Panel nevertheless consider these submissions, Canada considered that, for the sake of procedural fairness, the parties should have an opportunity to comment on their content.

6.3 In a letter dated 12 November 1999, the Panel informed the parties that, in the light of the EC's decision to incorporate into its own submissions the *amicus briefs* submitted by the *Collegium Ramazzini* and the *American Federation of Labor and Congress of Industrial Organizations*, the Panel would consider these two documents on the same basis as the other documents furnished by the EC in this dispute. It was also on that basis that the Panel submitted those two submissions to the scientific experts for their information. At the second substantive meeting of the Panel with the parties, the Panel gave Canada the opportunity to reply, in writing or orally, to the arguments set forth in these two *amicus briefs*. At that same meeting, the Panel also informed the parties that it had decided not to take into consideration the *amcius briefs* submitted by the *Ban Asbestos Network* and by the *Instituto Mexicano de Fibro-Industrias A.C.*

6.4 On 27 June 2000, the Panel received a written brief from the non-governmental organization *ONE ("Only Nature Endures")* situated in Mumbai, India. The Panel considered that this brief had been submitted at a stage in the procedure when it could no longer be taken into account. It therefore decided not to accept the request of *ONE* and informed the organization accordingly. The Panel transmitted a copy of the documents received from *ONE* to the parties for information and notified them of the decision it had taken. At the same time, it also informed the parties that the same decision would apply to any briefs received from non-governmental organizations between that point and the end of the procedure.

VII. INTERIM REVIEW[1]

A. INTRODUCTION

7.1 The Panel's interim report was given to the parties on 13 June 2000, pursuant to Article 15.2 of the Understanding. On 27 June 2000, Canada and the European Communities sent a request to the Panel in writing asking it to review certain aspects of the interim report. Neither of the parties requested the Panel to hold a further meeting with them. When sending the interim report to the parties, the Panel gave each party an opportunity to transmit in writing its comments on the initial request for review submitted by the other party, if no meeting was requested, provided that the comments were strictly confined to the questions identified by the other party in its initial request for review. The parties submitted their comments on 4 July 2000.[2]

7.2 As a preliminary remark, the Panel notes that the parties requested the Panel to improve upon some of its summaries of their arguments in the findings. The Panel indicates, however, that neither party claimed that the Panel had made any substantive error in its assessment of the facts.[3]

7.3 The Panel also notes that the two Parties have put forward corrections of form and of substance. Wherever appropriate, the Panel accepted the former.[4] The following observations therefore only concern the comments which the Panel considered to be remarks concerning the substance.

B. COMMENTS BY CANADA

7.4 Regarding Canada's comments on substance, the Panel amended footnote 1 to take into account both Canada's remark and the objections of the European Communities.[5]

7.5 Canada's first substantive comment concerning the part of our findings on the application of the Agreement on Technical Barriers to Trade to Decree No. 96-1133[6] relates to the Panel's summary of Canada's arguments in paras. 8.19 and 8.20 of the interim report (paras. 8.20 and 8.21 of the final

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[1] Pursuant to Article 15.3 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (hereinafter the "Understanding"), "The findings of the final panel report shall include a discussion of the arguments made at the interim review stage". The following section entitled "interim review" therefore forms part of our report's findings.

[2] The comments received on 4 July 2000 are dealt with where necessary in the sections on the comments from Canada and the European Communities below.

[3] The Panel notes that, in the letter attached to Canada's comments, the latter indicates that its request for review "is without prejudice to Canada's position on all the aspects of the Panel's Report". In this connection, the Panel considers that, if it had misunderstood or misrepresented some of the factual aspects of the case in its findings, the parties would need the interim review stage in order to make the necessary corrections or clarifications because, unlike errors of law, errors of fact cannot usually be modified on appeal. The parties should take advantage of this last opportunity to rectify the factual assessments of the Panel otherwise the Panel could unnecessarily be at risk of being accused of not having made an objective evaluation of the facts. It might be claimed that the fact that a party does not inform the Panel of a factual error in its findings may be contrary to the obligation in Article 3.10 of the Understanding, which provides *inter alia* that "all Members will engage in these procedures [settlement of disputes] in good faith in an effort to resolve the dispute" (emphasis added).

[4] For example, the Panel kept the words "in good faith" in para. 8.29 because the good faith requirement applies both to the person interpreting the text and the person having drafted it (see Ian Sinclair: The Vienna Convention on the Law of Treaties (1980, p. 119).

[5] Hereinafter the "EC".

[6] Hereinafter the "Decree".

Report).[7] The Panel considers that this summary adequately reflects Canada's arguments in the descriptive part. It did not therefore deem it necessary to replace the text as suggested by Canada. The next comment concerns para. 8.28 (para. 8.29 of the final Report). In response to Canada's remark that the Panel referred to the object and purpose of the WTO Agreement without examining it subsequently, in para. 8.48 of the final Report we have made it clear that we did not find any particularly relevant elements in the preamble to the WTO Agreement relating to the terms we had to interpret. As regards the comment on footnote 37 in the interim report (footnote 41 in the final Report), we did not consider it necessary to delete it because it is not a question of turning to the preparatory work within the meaning of Article 32 of the Vienna Convention on the Law of Treaties (1969), but of a reference to a document showing that the Agreement on Technical Barriers to Trade of the Tokyo Round was already seen as a development of certain rules of the GATT. We have nevertheless edited the footnote in order to make our intention clearer. We have also reworded paras. 8.61 and 8.62 of the final Report and the footnote concerning para. 8.61 in order to make it clear that, in the light of our previous findings, it was not necessary to examine whether the Decree met the five requirements which, in Canada's opinion, are contained in the definition of "technical regulation" in the TBT Agreement. Likewise, we did not wish to give the impression that Canada confirmed the initial view of the Panel that it would be appropriate to analyse the two aspects of the Decree separately. We have also clarified this point. The same applies to para. 8.72 of the final Report. Having reached the conclusion that the legal characterization of the exceptions in the Decree did not affect the legal characterization of the ban, we have simply found that Canada did not make any claims concerning the exceptions and, consequently, we could not reach any findings thereon according to our terms of reference.

7.6 With regard to the section of our findings on application of Article III and/or Article XI of the GATT 1994, we have made our summary of Canada's arguments (para. 8.84 of the final Report) clearer and have revised the rest of the section (paras. 8.87-8.100 of the final Report) in order to respond to the comments concerning paras. 8.85 and 8.95 of the interim report.

7.7 In connection with the discussion on violation of Article III:4 of the GATT 1994, we have also made paras. 8.109, 8.117, 8.121 and 8.145 of the final Report clearer, taking into account Canada's pertinent remarks.

7.8 Concerning application of Article XX(b) of the GATT 1994, we have amended footnote 128 in the interim report (footnote 142 in the final Report) in order to include the EC's arguments, while maintaining the reference to Dr. Henderson's remarks. The Panel has also revised para. 8.187 of the final Report because this was not a reference by Canada but by a Canadian scientist cited by one of the experts consulted pursuant to Article 13 of the Understanding. The Panel did not deem the EC's objection relating to para. 8.187 to be relevant. In addition, while maintaining the order of paras. 8.196 and 8.197 in the final Report, because the EC referred to Article XX of the GATT 1994, the Panel completed the summary of Canada's arguments in para. 8.197 by including the factual elements as well, as was done in the summary of the EC's arguments. The Panel notes that the factual elements mentioned by Canada have already been summarized in para. 8.164 of the final Report, but more concisely.

7.9 With regard to para. 8.233 (para. 8.238 of the final Report), the Panel does not consider that the fall in French imports of asbestos from 1996 onwards (see para. 3.20 above) is proof of protectionist intentions underlying the adoption of the Decree. In this connection, the Panel notes that Canada devotes a long passage (paras. 3.26 and 3.27 above) to showing that the Decree was adopted hastily under the pressure of public opinion. Regarding the industrial and commercial aspects,

[7] The change in the numbering of paragraphs is due to the introduction of a paragraph on the Panel's decision concerning a written submission and a request for a hearing made by a non-governmental organization during the interim review procedure.

Canada's description in para. 3.28 above makes this a secondary element. The French Government's call for research proposals in July 1996, specifically to develop substitute fibres, does not appear to be the consequence of the choice already made for reasons that bear no direct relation to industrial or commercial considerations.

7.10 Lastly, in our considerations on Article XXIII:1(b) of the GATT 1994, we have harmonized our terminology in paras. 8.293, 8.294 and 8.303 of the final Report.

C. COMMENTS BY THE EUROPEAN COMMUNITIES

7.11 Like Canada, the EC have made a number of comments with a view to amending the Panel's summary of their arguments in its findings. As was the case for Canada, we have generally taken these comments into account provided that we were able to identify them in the submissions made to the Panel in the course of the procedure.

7.12 This is the case for para. 8.7 in relation to para. 3.6. Regarding the description of the EC's arguments in para. 8.25 of the final Report, we have taken the relevant parts of paras. 3.264 and 3.265 above, which contain the EC's arguments on these points. We did not accept Canada's comments of 4 July 2000 because they essentially repeated arguments already made and taken into account during the procedure.

7.13 We have made clearer the last sentence of para. 8.32 and the first sentence of para. 8.41 of the final Report. We have also amended the content of footnotes 55 and 58 of the final Report and have revised the text of paras. 8.119, 8.149, 8.162 and 8.185 of the final Report, taking into account Canada's comments of 4 July 2000 and provided that the EC's suggestions were in line with their submissions to the Panel or the terms of the Decree. We have also made the first sentence of para. 8.149 of the final Report clearer. On the other hand, we did not consider it appropriate to replace the words "Canada's position" in para. 8.56 of the final Report by the words "Canada's contextual interpretation", particularly since Canada opposed this in its comments of 4 July 2000. Likewise, we did not consider that the complementary nature of the EC's argument on the transitional nature of the exceptions in the Decree warranted the deletion or amendment of para. 8.65 of the final Report. In this connection, the Panel notes that the EC did not clearly state what they wished the Panel to do with this paragraph.

7.14 The EC also requested the Panel to amend paras. 8.66-8.70 and 9.1(a) of the interim report to take account of the fact that Canada did not include the implementing Decree referred to in Article 2 of the Decree in the terms of reference of the Panel and that, consequently, no finding could be made in this respect. Although we agree with the EC that we cannot reach any *findings* regarding the part of the Decree on exceptions, we consider that this is primarily due to the absence of allegations by Canada regarding these exceptions. In this sense, our assessment is fully in compliance with the practice of the Appellate Body on interpretation of the terms of reference for panels. On the other hand, we do not consider that the fact that the implementing Decree was not specifically mentioned in the Panel's terms of the reference prevents us from taking it into account when evaluating the *legal characterization* of the part of the Decree on exceptions. If this were the case, the legal characterization of a measure could depend on the scope of the terms of reference defined by the complaining party, which is unacceptable from a legal point of view. It thus appears appropriate to us to consider the Decree in the light of the implementing measures it provides. For us, the implementing decree is a fact.[8] In addition, we can infer its existence simply by reading the text of

[8] In this connection, see the approach adopted by the Appellate Body in *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, adopted on 16 January 1998, WT/DS50/AB/R, paras. 65-67. See also the Report of the Panel in *United States – Sections 301-310 of the Trade Act of 1974*, adopted on 20 January 2000, WT/DS152/R, paras. 7.18 and 7.25-7.27.

the Decree. Consequently, we do not consider that we have exceeded our terms of reference by evaluating the legal characterization of one part of the Decree in the light of the facts before us. We are aware that our efforts to define the legal characterization of the exceptions in the Decree might, at first sight and in the absence of claims from Canada, appear to be an *obiter dictum*. Nevertheless, this procedure was necessary for two reasons: (a) it provides positive confirmation of our analysis of the scope of the TBT Agreement; and (b) it permits a comprehensive analysis of the elements of the Decree, fulfilling our obligation to make an objective examination of the facts. We did not therefore deem it necessary to amend the paragraphs in question, except for para. 9.1(a), in order to make the meaning of our conclusions clearer in the light of the comments above.

7.15 In response to the EC's comments and also those of Canada in its communication of 4 July 2000, we have explained in para. 8.273 of the final Report why we considered that the risk of an effective increase in the cost of health measures following application of Article XXIII:1(b) to measures justified under Article XX(b) would be marginal. We have also made the last sentence of para. 8.296 of the final Report clearer.

7.16 Finally, the Panel considered it necessary to add a paragraph concerning the request by a non-governmental organization, received on 27 June 2000, to be allowed to make a written submission and to be heard by the Panel. Moreover, bearing in mind the nature of the comments by the parties, the Panel considered it appropriate to add a footnote to para. 8.35, to revise footnotes 44 and 50, and to amend the first sentence of para. 8.183 of the final Report. The Panel has also clarified its comments in paras. 8.211 and 8.214. Other changes of form have been made in order to take into account the change in the numbering of certain paragraphs. Lastly, the Panel adopted the word "exceptions" to describe the regime applicable under Articles 2 *et seq.* of the Decree, in conformity with the term used in the Decree itself.

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VIII. FINDINGS

A. SUMMARY OF THE FACTS AT THE ORIGIN OF THIS DISPUTE AND CLAIMS BY THE PARTIES

1. Measure at the origin of the dispute

8.1 The measure at the origin of this dispute is Decree No. 96-1133 of 24 December 1996, issued by the Prime Minister of the Government of the French Republic, banning asbestos[1], implemented pursuant to the Labour Code and the Consumer Code[2] (hereinafter the "Decree"). The relevant provisions of the Decree are set out below:[3]

"Article 1

I. For the purpose of protecting workers, and pursuant to Article L. 231-7 of the Labour Code, the manufacture, processing, sale, import, placing on the domestic market and transfer under any title whatsoever of all varieties of asbestos fibres shall be prohibited, regardless of whether these substances have been incorporated into materials, products or devices.

II. For the purpose of protecting consumers, and pursuant to Article L. 221.3 of the Consumer Code, the manufacture, import, domestic marketing, exportation, possession for sale, offer, sale and transfer under any title whatsoever of all varieties of asbestos fibres or any product containing asbestos fibres shall be prohibited.

III. The bans instituted under Articles I and II shall not prevent fulfilment of the obligations arising from legislation on the elimination of wastes.

Article 2

I. On an exceptional and temporary basis, the bans instituted under Article 1 shall not apply to certain existing materials, products or devices containing chrysotile fibre when, to perform an equivalent function, no substitute for that fibre is available which:

- On the one hand, in the present state of scientific knowledge, poses a lesser occupational health risk than chrysotile fibre to workers handling those materials, products or devices;

- on the other, provides all technical guarantees of safety corresponding to the ultimate purpose of the use thereof.

II. The scope of application of paragraph I of this Article shall cover only the materials, products or devices falling within the categories shown in an exhaustive list decreed by the Ministers for Labour, Consumption, the Environment, Industry, Agriculture and Transport. To ascertain the justification for maintaining these exceptions, the list shall be re-examined on an annual basis, after which the Senior Council for the Prevention of Occupational Hazards and the National Commission for Occupational Health and Safety in Agriculture shall be consulted.

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[1] In these findings, the word "asbestos" is used to describe all varieties of asbestos without distinction (see paras. 2.1 and 2.2 above for a description of the product). "The Panel notes that, although the only variety of asbestos referred to by Canada is chrysotile asbestos, Decree No. 96-1133 does not distinguish among the different varieties of asbestos. Only Article 2 on exceptions specifically mentions chrysotile fibres. Consequently, wherever necessary, the Panel will indicate whether it is referring to asbestos in general or chrysotile in particular.

[2] *Official Journal of the French Republic* of 26 December 1996.

[3] The full text of the Decree is attached to this report as Annex I.

Article 3

I. The manufacture, processing, importation and domestic marketing of any of the materials, products or devices falling into one of the categories mentioned on the list envisaged under Article 2 shall be subject to a statement, signed, as appropriate, by the head of the business establishment, the importer or the party responsible for domestic marketing, which should be addressed to the Minister for Labour. This statement shall be filed in January of each year or, as appropriate, three months before the start of a new activity or the alteration of an existing production activity, by means of a form decreed by the Ministers for Labour, Consumption, Industry and Agriculture.

The statement shall be accompanied by all the supporting documents in the possession of the declaring party making it possible, considering the state of scientific and technological progress, to determine that as of the date of signature of the statement, the activity covered by the statement meets the conditions set forth in Article 2.I.

II. Activities that have not been the subject of a full statement submitted within the set time-frame may not benefit from the exception granted under Article 2.

III. The Minister for Labour may at all times convey to the author of the statement such information as may seem to him to establish that the material, product or device in question, although falling into one of the categories on the list mentioned in Article 2, does not meet the conditions laid down in paragraph I of that same Article. After requesting comments from the declaring party, he may serve notice to said party to cease manufacture, processing, importation or domestic marketing and to observe the ban instituted under Article 1. He may make such notification public.

Article 4

The manufacture and processing of the materials, products and devices falling into the categories on the list mentioned in Article 2 of this Decree must conform with the rules laid down under Chapters I and II and Chapter III, Section 1 of the aforementioned Decree dated 7 February 1999.

Labelling and marking shall conform with the requirements of Article L. 231-6 of the Labour Code and the rules established by the aforementioned Decree dated 28 April 1998.[4]

Article 5

Without prejudice to the application of the penalties envisaged under Article L. 263-2 of the Labour Code in the event of violation of the provisions of Article 1.I of this Decree, the act of manufacturing, importing, introducing into the domestic market, exporting, offering, selling, transferring under any title or possessing for sale all varieties of asbestos fibres or any product containing asbestos fibres, in contravention of the provisions of Article 1.II shall be punishable by the fine prescribed for fifth class offences.

Article 6

I. Articles 1, 2, 3 and Article 6.I of the above-mentioned Decree No. 88-466 of 28 April 1998 are hereby repealed.[5]

II. In the first subparagraph of Article 4 of the same Decree, the words: 'bans envisaged in Article 2 above' shall be replaced by the word: 'bans'.

III. In Article 6.II of the same Decree, the words: 'other than those envisaged under Article 2' shall be replaced by the words: 'which are not subject to bans'.

[4] The preambular paragraphs of the Decree have not been included here. The full text of the Decree is attached as Annex I to this Report.

[5] Ibid.

Article 7

Until 31 December 2001 and on a transitional basis, the ban on possession for sale, offering for sale and transfer under any title shall not apply to the used vehicles nor to the agricultural or forestry machinery put into circulation before the effective date of this Decree, and covered by Article R.138 of the Traffic Law. […]"[6]

8.2 The Decree entered into force on 1 January 1997.

2. Main claims by the parties[7]

(a) Main claims by Canada

8.3 Canada claims, firstly that the Decree is a technical regulation covered by the Agreement on Technical Barriers to Trade.[8] As such, it is incompatible with paras. 1, 2, 4 and 8 of Article 2 of the TBT Agreement.

8.4 Secondly, Canada claims that the Decree is incompatible with Articles XI and III:4 of the GATT 1994.

8.5 Lastly, Canada requests that, in the event that the Panel is unable to find a violation of Article XXIII:1(a) of the GATT 1994, it nevertheless finds that the provisions of Article XXIII:1(b) of the GATT 1994 apply.

(b) Main claims by the European Communities

8.6 The European Communities[9] ask the Panel to find that the Decree is not covered by the TBT Agreement and that, in any case, it complies with the relevant provisions of that Agreement.

8.7 With regard to the GATT 1994, the EC request the Panel to confirm that either the Decree does not establish less favourable treatment for imported products than for like domestic products within the meaning of Article III:4 or that the Decree is necessary to protect human health within the meaning of Article XX(b). Lastly, the EC ask the Panel to find that Article XXIII:1(b) of the GATT 1994 does not apply.

8.8 Before going further into the claims by the parties, we must first recall certain decisions taken in the course of the procedure.

B. ISSUES ON WHICH THE PANEL HAD TO TAKE A POSITION DURING THE PROCEDURE

1. Introduction

8.9 In the course of the procedure, the Panel took two decisions which it considers should be reproduced as an integral part of these findings. These were (a) its decision to consult scientific experts on an individual basis taking into account Article 13.1 of the Understanding on Rules and Procedures Governing the Settlement of Disputes; and (b) its decision on whether or not to take into account "*amicus curiae* briefs" received during the procedure.

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[6] Articles 8 and 9 of the Decree have not been reproduced. The full text of the Decree is attached as Annex I to this report.

[7] The full text of the claims by the parties can be found in section III.A above.

[8] Hereinafter the "TBT Agreement".

[9] Hereinafter the "EC".

2. Consultation of experts

8.10 At the first substantive meeting, the Panel informed the parties of its intention to seek the opinion of individual scientific experts except where, in the light of the parties' written rebuttals, it deemed that such a procedure was not necessary. Having consulted the parties and received their comments, the Panel decided to consult experts individually, in accordance with para. 1 and the first sentence of para. 2 of Article 13 of the Understanding.[10] The Panel's decision was reaffirmed on 2 August 1999. The following are the relevant parts of its letter:

> "[…] The Panel carefully examined the arguments put forward by the parties concerning the method of consulting experts, in particular the argument of the European Communities that Article 13.2 of the Understanding requires that, when consulting scientific experts, there should be an expert review group according to the terms of Appendix 4 to the Understanding.
>
> We draw attention to Article 13 of the Understanding which states *inter alia* that "each panel shall have the right to seek information and technical advice from any individual or body which it deems appropriate" and "panels may seek information from any relevant source and may consult experts to obtain their opinion on certain aspects of the matter.
>
> We also note that Article 13.2 provides that panels 'may' request an advisory report in writing from an expert review group, in particular but not exclusively in order to consider a factual issue concerning a scientific matter. We consider that this text allows the establishment of such an expert review group but does not prevent experts being consulted on an individual basis with respect to scientific matters or any 'other technical matter'. In our view, this interpretation of Article 13.2 of the Understanding fully complies with the text of this provision interpreted according to Article 31 of the Vienna Convention on the Law of Treaties and the interpretation of the Appellate Body whereby Article 13 of the Understanding does not prevent a panel from consulting experts individually and leaves the panel free to determine whether it is necessary or appropriate to establish an expert review group.[11]
>
> The Panel also took account of the argument of the European Communities that, if the measure in question should be considered as coming under the TBT Agreement, which it contests in any case, Article 14.2 of the Agreement would mean that a technical expert group would have to be consulted for any scientific or technical question, as well as the position of the European Communities that this provision, pursuant to Article 1.2 of the Understanding, would prevail over the provisions in Article 13 of the Understanding.
>
> Article 14.2 of the TBT Agreement is one of the provisions mentioned in Appendix 2 to the Understanding and which, according to Article 1.2 of the Understanding, prevails over the latter if there is any difference between the two. We note, however, that it is only 'if there is any difference' between the rules and procedures in the Understanding and a special or additional rule or procedure covered by Appendix 2 to the Understanding that the latter would prevail. As the Appellate Body has already pointed out, it is only when the provisions in the Understanding and the special or additional rules and procedures in Appendix 2 *cannot* be construed as *complementary* that the special or additional rules will prevail over those in the Understanding, in other words, in a situation where the

[10] These comments can be found in paras. 5.2 to 5.16 above.

[11] The letter contains the following note: "See the reports of the Appellate Body in *European Communities – Measures Concerning Meat and Meat Products (Hormones)* (WT/DS26-DS48/AB/R, para. 147 ('… in disputes involving scientific or technical issues, neither Article 11.2 of the *SPS Agreement*, nor Article 13 of the DSU prevents panels from consulting with individual experts. Rather, both the *SPS Agreement* and the DSU leave to the sound discretion of a panel the determination of whether the establishment of an expert review group is necessary or appropriate.') and in *Argentina – Measures Affecting Imports of Footwear, Textiles, Apparel and Other Items* (WT/DS56/AB/R), para. 84 (' … Article 13 of the DSU enables a panel to seek information and technical advice as it deems appropriate in a particular case, and (…) the DSU leaves 'to the sound discretion of a panel the determination of whether the establishment of an expert review group is necessary or appropriate'.").

two provisions would be mutually incompatible.[12] In this particular case, Article 14.2 of the TBT Agreement provides that a panel 'may' establish a technical expert group. Like Article 13.2 of the Understanding, this text allows the *possibility* of establishing an expert group and determines the procedures applicable to it, where applicable. It does not however make the establishment of such a group mandatory and, in our view, this possibility is not incompatible with the overall possibility given in Article 13 of the Understanding of consulting experts individually. The two provisions can be seen as complementary.

In this case, it appeared to us that consultation of experts on an individual basis was the most appropriate method inasmuch as it would be the most appropriate way of allowing the Panel to obtain useful information and opinions on the scientific and technical issues raised by this case. In view of the wide variety of fields of competence involved, in particular, it appeared to us to be preferable to obtain different information and opinions individually rather than requesting a joint report on the various scientific or technical issues raised.

[…]

In the light of the foregoing, we emphasize that our decision to consult experts individually is without prejudice to the question of the applicability of the TBT Agreement to the measure in question, on which the parties disagree."

8.11 The Panel reaffirms the decision and the reasoning in this letter.

3. *Amicus curiae* briefs

8.12 In the course of the procedure, the Panel received written submissions or "*amicus curiae*" briefs from four sources other than Members of the WTO.[13] Referring to the position taken by the Appellate Body in *United States – Import Prohibition of Certain Shrimp and Shrimp Products*[14] on the interpretation of Article 13 of the Understanding concerning *amicus curiae* briefs, the Panel informed the parties accordingly and transmitted the submissions to them. The EC included two of these submissions in their own submission. Having examined each of the *amicus curiae* briefs, the Panel decided to take into account the submissions by the *Collegium Ramazzini* and the *American Federation of Labor and Congress of Industrial Organizations*, as they had been included by the EC in their own submissions on an equal footing. At the second meeting with the parties, Canada was given an opportunity to respond in writing and orally to the arguments in the two *amicus curiae* briefs.

8.13 On the other hand, the Panel decided not to take into account the *amicus curiae* briefs submitted respectively by the *Ban Asbestos Network* and by the *Instituto Mexicano de Fibro-Industrias A.C.* and informed Canada and the EC accordingly at the second meeting with the parties held on 21 January 2000.

8.14 On 27 June 2000, the Panel received a written brief from the non-governmental organization *ONE ("Only Nature Endures")* situated in Mumbai, India. In view of the provisions in the Understanding on the interim review, the Panel considered that this brief had been submitted at a stage in the procedure when it could no longer be taken into account. It therefore decided not to accept the request of *ONE* and informed the organization accordingly. The Panel transmitted a copy of the documents received from *ONE* to the parties for information and notified them of the decision it

[12] The letter contains the following note: "See the Report of the Appellate Body in *Guatemala – Anti-Dumping Investigation Regarding Portland Cement from Mexico* (WT/DS60/AB/R), paras. 65 and 66."

[13] See paras. 6.1-6.3 above.

[14] Adopted on 20 September 1999, WT/DS58/AB/R (hereinafter "*United States – Shrimp*"), paras. 101-109. See also the report of the Appellate Body in *United States – Imposition of Countervailing Duties on Certain Hot-Rolled Lead and Bismuth Carbon Steel Products Originating in the United Kingdom*, adopted on 7 June 2000, WT/DS/138/AB/R, paras. 40-42.

had taken. At the same time, it also informed the parties that the same decision would apply to any briefs received from non-governmental organizations between that point and the end of the procedure.

C. ORDER IN WHICH THE PANEL EXAMINED THE CLAIMS

8.15 The Panel notes that Canada considers that the TBT Agreement is applicable to the Decree because the Decree is a "technical regulation" covered by the Agreement. The EC, on the other hand, consider that the Decree is not a technical regulation, that the TBT Agreement does not apply to it and that it should be considered in the context of the GATT 1994 alone.

8.16 We note that the Marrakesh Agreement Establishing the World Trade Organization[15] constitutes a single treaty instrument that was accepted by the WTO Members as a "single undertaking"[16] within whose framework all the applicable provisions must be given meaning.[17] Both the GATT 1994 and the TBT Agreement form part of Annex 1A to the WTO Agreement and may apply to the measures in question. Consequently, although we do not in principle exclude application of the TBT Agreement and/or the GATT 1994 to the Decree, we have to determine the order in which we should consider this case. According to the Appellate Body in *European Communities – Regime for the Importation, Sale and Distribution of Bananas*[18], when the GATT 1994 and another Agreement in Annex 1A appear *a priori* to apply to the measure in question, the latter should be examined on the basis of the Agreement that deals "specifically, and in detail," with such measures. In this particular case, as the parties do not agree on the legal nature of the measure itself (technical regulation covered by the TBT Agreement or general ban coming under the scope of the GATT 1994 alone), it is difficult at this stage to determine which Agreement, either the GATT 1994 or the TBT Agreement, deals with the measure in question most specifically and in the most detailed manner without undertaking an in-depth examination of the measure in the light of each Agreement.

8.17 In order to decide upon the order in which our consideration should proceed, in the way suggested by the Appellate Body, the hypothesis should be that, if the Decree is a "technical regulation" within the meaning of the TBT Agreement, then the latter would deal with the measure in the most specific and most detailed manner. Consequently, in our view it must first be determined whether the Decree is a technical regulation within the meaning of the TBT Agreement. If this is the case, we shall start considering this case by examining the ways in which the Decree violates the TBT Agreement. If we find that the Decree is not a "technical regulation", we shall then immediately start to consider it in the context of the GATT 1994.

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[15] Hereinafter "the WTO Agreement". Reference will also be made in these findings to the Marrakesh Agreement Establishing the World Trade Organization without its Annexes using the words "Agreement Establishing the WTO". The words "WTO Agreements" refer to the Agreements annexed to the Agreement Establishing the WTO.

[16] See the Report of the Appellate Body in *Brazil – Measures Affecting Desiccated Coconut*, adopted on 20 March 1997, WT/DS22/AB/R (hereinafter "*Brazil – Desiccated Coconut*"), pp. 12 and 13.

[17] See the Reports of the Appellate Body in *Brazil – Desiccated Coconut*, op. cit. p. 16 and 17; *Argentina – Safeguard Measures on Imports of Footwear*, (hereinafter "*Argentina – Safeguards*") adopted on 13 January 2000, WT/DS/121/AB/R, para. 89.

[18] Adopted on 25 September 1997, WT/DS27/AB/R, hereinafter "*European Communities – Bananas*", para. 204.

D. APPLICABILITY OF THE TBT AGREEMENT TO THE DECREE

1. Arguments of the parties and approach adopted by the Panel

(a) Arguments of the parties concerning the applicability of the TBT Agreement to the Decree[19]

8.18 Canada considers that the Decree is a "technical regulation" within the meaning of the definition given in Annex 1 to the TBT Agreement. The EC consider that the Decree does not come under the definition of a technical regulation in the TBT Agreement.

8.19 The following is the definition of "technical regulation" in Annex 1.1 to the TBT Agreement:

> "1. *Technical regulation*
>
> Document which lays down product characteristics or the related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method."

8.20 Canada contends that the Decree considers that all asbestos fibres and all materials, products or devices containing such fibres pose risks for people's health. The Decree is a "technical regulation" in particular because it lays down a characteristic of a product, a process and a production method, as well as administrative provisions applicable to a product.

8.21 Referring to the definition of "technical regulation" in Annex 1 to the TBT Agreement, Canada considers that the ordinary meaning of the word "characteristic" is "that which constitutes a recognizable distinctive feature". The Decree describes a recognizable distinctive feature because it bans asbestos fibre, particularly chrysotile, in the manufacturing and processing of materials, products or devices placed on the French market. The characteristic of these materials, products and devices is the absence of asbestos fibres. The Decree indicates precisely or describes the features of the materials, products or devices in whose manufacture or processing the incorporation of asbestos is prohibited. The Decree refers to the processing of all asbestos fibres, whether or not included in products. By so doing, it imposes restrictions on the processes and production methods for asbestos fibres. Moreover, the Decree stipulates that manufacturing activities are subject to the standards governing exposure to asbestos dust in places of business and this imposes a manufacturing process. It includes administrative provisions and a declaration mechanism applicable to products which, exceptionally, contain chrysotile fibre. Lastly, the Decree also deals with labelling requirements and its principal provisions are binding.

8.22 The EC claim that the Decree cannot be construed as a "technical regulation" within the meaning of the TBT Agreement because the latter does not cover general prohibitions on the use of a product for reasons to do with the protection of human health, which come under the GATT 1994. It follows from the preamble, from the background to the TBT Agreement and from the actual wording of several of its provisions that the fundamental objective of the Agreement is to monitor the adoption and application of the "standards" and "technical regulations" that relate to the detailed characteristics of products or their methods of production (e.g. the minimum resistance level for seat-belts). The definition in Annex 1 means that the TBT Agreement does not apply to the Decree because, according to this definition, a technical regulation is a document which lays down the characteristics or processes or production methods with which a specific/identified product must comply, in particular if it is to be released for free circulation on a given market.

[19] The parties' arguments are set out in detail in Section III above.

8.23 For the EC, any other approach would be equivalent to nullifying the effect of certain provisions of the GATT 1994, for example, Articles I and III, which apply to general prohibitions. The TBT Agreement must be considered as the specific application of the principles of the GATT 1994 to technical regulations. The Decree prohibits asbestos fibres at all stages. It does not specify the characteristics, the processes or production methods for asbestos fibres and asbestos-containing products or the products exempt from the prohibition measure. The EC do not consider that the fact of not containing asbestos serves to characterize products placed on the French market. For the Decree to be able to lay down the "characteristics" of a product, it would have had to identify the product(s) to which the said characteristics relate. The Decree, however, does not designate any product. It lays down the principle of prohibition. As regards the "processes and methods", the EC emphasize that the Decree does not lay down any means or set of rules governing the production of asbestos fibres or products containing them.

8.24 In Canada's view, including a general prohibition within the scope of the TBT Agreement is contrary neither to its object nor its purpose. The distinction made by the EC between prohibitions that apply to all products without distinction and measures aimed particularly at a specific product is not supported by the TBT Agreement. The EC's interpretation is contrary to the principle of effectiveness: it would suffice to give a measure the form of a general prohibition in order to allow it to evade the disciplines of the TBT Agreement. Canada also considers that, in order to determine whether the Decree satisfies the criteria for the definition of a "technical regulation", its provisions on both asbestos and exceptions must be examined.

8.25 For the EC, the fact that the definition of "technical regulation" is narrow is not a matter of chance, but signifies that the authors intended to limit the scope of the Agreement. The object and purpose of the TBT Agreement is to deal with technical regulations and standards, not to resolve market access problems associated with general prohibitions. This does not result in a legal vacuum because the general prohibitions continue to be covered by other provisions, in particular Articles I and III of the GATT 1994. The general prohibition eliminates these products from the market. A technical regulation, on the other hand, means that the products affected by the regulation can still be placed on the market. Even in the case of limited and transitional exceptions, the sole preoccupation of the French authorities has been to protect human health. The Decree does not define either the processes and production methods for the products that may be exempted from the general prohibition adopted. The provisions of the Decree concerning exceptions, therefore, do not fall within the scope of the TBT Agreement either.

8.26 Canada claims that the fact that the Decree qualifies as a "technical regulation" is confirmed by France's notification to the Committee on Technical Barriers to Trade. According to Canada, France thereby recognized the applicability of the TBT Agreement in to the Decree. The EC also recognized the applicability of the TBT Agreement in a document from the European Commission and during the consultations relating to this case.

8.27 According to the EC, the fact that the Decree was notified to the Committee on Technical Barriers to Trade in no way prejudges the applicability of the Agreement. The notification was made in good faith for the sake of transparency. Any other interpretation would create additional obligations for Members and would induce them to discontinue, or at least reduce, notifications.

(b) Approach followed by the Panel

(i) Criteria for the application of the TBT Agreement

8.28 The Panel considers that, for the TBT Agreement to apply to the Decree, the measures imposed under the Decree must come within the definition of "technical regulation" in Annex 1.1 to

the TBT Agreement.[20] On the basis of the arguments put forward by Canada and the EC, it appears that the parties share this view. The Panel will therefore examine this definition.

8.29 According to Article 3.2 of the Understanding, the Panel must clarify the terms of the WTO Agreement in accordance with customary rules of interpretation of public international law, more particularly those set out in Articles 31, 32 and 33 of the 1969 Vienna Convention on the Law of Treaties.[21] The Panel will therefore first consider the ordinary meaning to be given in good faith to the wording of the definition of "technical regulation" in Annex 1 to the TBT Agreement, taken in context and in the light of the object and purpose of the TBT Agreement and the WTO Agreement in general. If necessary, additional ways of interpreting Article 32 will be taken into account. As the WTO Agreement is a treaty with authentic texts in three languages, it is also important to bear in mind the spirit underlying the provisions of Article 33.[22]

(ii) Differentiation among the prohibitions as such and the exceptions

8.30 We note that Canada claims that the exceptions to the ban on asbestos in the Decree confirm that the latter is a technical regulation. The EC state that neither the provisions on exceptions nor the prohibition itself are covered by the TBT Agreement.

8.31 Notwithstanding the fact that the main purpose of the Decree is to ban the use of asbestos in France, we note that the text is essentially composed of a general prohibition on the one hand (Articles 1 and 5) and, on the other, exceptions, including the administrative regime applicable to them (Articles 2-4). It must therefore be determined whether we should examine the prohibitions and exceptions as one single measure or as separate measures that might come under different Agreements.

8.32 We note first of all that it is possible for several components of the same administrative act to be covered by a single Agreement or by different Agreements. While it is the responsibility of the parties to prove the facts they claim[23], it is within the competence and is one of the duties of the Panel to determine the law applicable to the facts, with the help of the parties' arguments.[24] Nothing

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[20] The wording of the definition is given in paragraph 8.18 above.

[21] United Nations Document A/CONF. 39/27 (1969). Hereinafter the "Vienna Convention".

[22] The Panel also notes the importance attached by the Appellate Body to the principle of effectiveness (*ut res magis valeat quam pereat)* concerning the interpretation of the provisions of the WTO Agreement in several cases (see, for example, *United States – Standards for Reformulated and Conventional Gasoline*, adopted on 20 May 1996, WT/DS60/AB/R (hereinafter "*United States – Gasoline"*), op. cit., pp.18 and 23; *Guatemala – Cement*, op. cit., para. 75; *Argentina – Safeguards*, op. cit., para. 88. The Panel also notes in the *Reports of the Commission to the General Assembly, Yearbook of the International Law Commission*, 1966, Volume II, A/CN.4/SER.A/1966/Add.1, p. 219, that the International Law Commission indicates that:

> "[…] in so far as the maxim *ut res magis valeat quam pereat* reflects a true general rule of interpretation, it is embodied in Article [31], paragraph 1, which requires that a treaty shall be interpreted *in good faith* in accordance with the ordinary meaning to be given to its terms in the context of the treaty *and in the light of its object and purpose*. When a treaty is open to two interpretations one of which does and the other does not enable the treaty to have appropriate effects, good faith and the object and purposes of the treaty demand that the former interpretation should be adopted." [Italics in the original.]

[23] See the report of the Appellate Body in *United States – Measures Affecting Imports of Woven Wool Shirts and Blouses from India*, adopted on 23 May 1997, WT/DS33/AB/R (hereinafter "*United States – Shirts and Blouses*"), p. 14 and Section VIII.E.1(b) below.

[24] The Panel is not, however, obliged to base itself solely on the arguments of the parties. See the report of the Appellate Body in *EC Measures Concerning Meat and Meat Products (Hormones), adopted on 13 February 1998, WT/DS26/AB/R, WT/DS48/AB/R (hereinafter "European Communities – Hormones"),* para. 156:

therefore prevents the Panel from examining the Decree as a single and unique measure, if it believes there are legal grounds for this. Likewise, if the Panel considers that certain provisions of the Decree are covered by provisions of the WTO Agreement other than those applicable to the rest of the Decree, nothing prevents it from considering these provisions in the light of those other provisions of the WTO Agreement.[25]

8.33 Consequently, without taking any decision at this stage on the ultimate need for a separate study of the two parts of the Decree – we might in fact reach the conclusion that both parts have the same legal characterization or that one should be considered as supplementing the other – we consider that there should be a separate examination of the provisions specifically concerning the ban on asbestos and the provisions on exceptions in order to make our analysis clearer. We shall therefore first consider the applicability of the definition of "technical regulation" in Annex 1 to the TBT Agreement to the provisions of the Decree on the prohibition. On the basis of these conclusions, we shall then consider the legal nature of the exceptions and any effect they may have on the legal status of the Decree as a whole.

2. Is the Decree a technical regulation within the meaning of the TBT Agreement?

(a) Examination of the part of the Decree prohibiting the marketing of asbestos and asbestos-containing products

(i) Preliminary remarks

8.34 Canada puts forward its arguments in general in relation to chrysotile fibres and products containing chrysotile fibres (mainly chrysotile-cement products). Although Canada claims that chrysotile fibre is simply an input in other products and is of no use *per se*, we consider that it is a product. In our examination of the applicability of the TBT Agreement to the Decree, there is no reason to treat chrysotile fibre differently to products containing chrysotile.

8.35 The Panel notes that the measure at issue in this case is a general ban excluding a given product from the French market as such or when it is incorporated in other products not specified in the Decree. Consequently, the Panel wishes to emphasize that its findings regarding the scope of the concept of technical regulation in the context of the TBT Agreement are linked to the specificities of the measure in question and in no way prejudge the conclusions that any other panel might reach concerning the same provisions of the TBT Agreement in other factual circumstances.[26]

"Panels are inhibited from addressing legal claims falling outside their terms of reference. However, nothing in the DSU limits the faculty of a panel freely to use arguments submitted by any of the parties – or to develop its own legal reasoning – to support its own findings and conclusions on the matter under its consideration. A panel might well be unable to carry out an objective assessment of the matter, as mandated by Article 11 of the DSU, if in its reasoning it had to restrict itself solely to arguments presented by the parties to the dispute."

See also the Report of the Panel in *United States – Sections 301-310 of the Trade Act of 1974*, adopted on 27 January 2000, WT/DS152/R, para. 7.16.

[25] With regard to the provisions which the Panel must take into account when considering the Decree, the Panel is of course limited by the provisions in its terms of reference (see the Report of the Appellate Body in *European Communities – Bananas*, op. cit., para. 141).

[26] This is precisely why our analysis lays greater emphasis on the characteristics of the product than on the process and production methods.

(ii) Analysis

Ordinary meaning of the terms in the definition in Annex 1 to the TBT Agreement

8.36 The Panel notes first of all that the definition of "technical regulation" relates to the characteristics of a product or its processes or production methods. The Panel notes that the definition uses the word *product*. Applying the principle of effectiveness[27], we must assume that there was a specific purpose underlying the use of the word "product" in the definition in Annex 1.1 to the TBT Agreement and that it does not appear by chance.[28]

8.37 An initial explanation might be that the authors wished to indicate that this definition related to products rather than services, for example. However, as the TBT Agreement is in Annex 1A to the WTO Agreement, which deals with trade in goods, specifying that the definition applies to products was not necessary.[29] Moreover, it is possible to define a technical regulation applicable to products without specifically using the word "product". As an example, we note that paragraph 3.5.1 of the ISO Guide/IEC 2:1991 contains a definition of the words "technical regulation" that does not employ the word "product".[30] We therefore consider that the authors when using the word "product" were pursuing another objective.

8.38 Another interpretation would be that the purpose sought by introducing the word "product" was to create a link between the technical characteristics and one or more given products. In other words, the product(s) to which the characteristics refer must be clearly identifiable in the document in question. If, in the document, the characteristics described do not refer to an identifiable *product*, the document does not meet the criteria in Annex 1.1 to the TBT Agreement.[31] We consider that this interpretation is better able to give a proper meaning to the word "product" in the definition of "technical regulation" in Annex 1.1 to the TBT Agreement.

8.39 We therefore conclude that a technical regulation is a regulation which sets out the specific characteristics of one or more identifiable products in comparison with general characteristics that may be shared by several unspecified products.

8.40 In this connection, the Panel notes that the ban introduced by the Decree is generally applicable both to asbestos and products containing it, in other words, a very large number of products which the Decree does not identify by name nor even by function or category.

8.41 The Panel also notes that the EC contend that the Decree does not describe the *characteristics* of a product and that its purpose cannot be to describe the *characteristics* of an *imported* product because placing asbestos and asbestos-containing products on the French market is prohibited. In our

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[27] See footnote 22 above on application of the principle of interpretation *ut res magis valeat quam pereat*.

[28] See the Report of the Appellate Body in *European Communities – Hormones*, op. cit., para. 164.

[29] Although the title of Annex 1A is "Multilateral Agreements on Trade in Goods" (emphasis added), we note that the Agreement on Agriculture uses the word "products", as do the Agreement on Textiles and Clothing and other Agreements in Annex 1A. The scope of Annex 1A therefore covers trade in "products". See also the Report of the Panel in *United States – Restrictions on Imports of Tuna*, unadopted, DS21/R, 3 September 1991, para. 5.11: "… Article III covers only measures affecting products as such".

[30] The definition in para. 3.5.1 of the ISO/IEC Guide General Vocabulary Concerning Standardization and Related Activities reads as follows:

"**3.5.1 technical regulation: regulation** that provides technical **requirements**, either directly or by referring to or incorporating the content of a **standard**, **technical specification** or **code of practice**" (in bold in the original, note omitted)

[31] In relation to the foregoing, we also note that the standard notification forms under the TBT Agreement contain a section to be completed by a description of the product affected by the notification, which in our view seems to confirm the second meaning we have given for the word "product".

view, according to the applicable customary rules of interpretation, it is also necessary to examine the meaning of the word "characteristics". The ordinary meaning of "characteristic" is "that which constitutes the distinctive feature, is typical of a person or thing"[32], "a recognizable distinctive feature".[33] There is thus a link between the characteristics of a product and the product itself. Nevertheless, the "characteristics" must be differentiated from the identification of the product itself. It is indeed possible to describe technical characteristics without specifically identifying the product(s) to which they relate. Likewise, the identification of a product does not suffice to show its characteristics. The Panel notes that the reference to "characteristics" is the special feature of the definition of "technical regulation" in Annex 1.1 to the TBT Agreement. The measure must not only relate to one or more given products, but its *purpose* must be to define the characteristics, i.e. the criteria or elements which the product(s) concerned must satisfy in order to be introduced into the territory of the Member that adopted the measure.

8.42 By adding the word "product" before "characteristics", the authors of Annex 1.1 therefore wished to specify the circumstances in which the TBT Agreement applied. In order purely and simply to ban the import of a product, it is not absolutely necessary to define its characteristics. In the same way, if it is desired to exclude certain raw materials as such, it is not necessary to specify the products in which they can be incorporated. On the other hand, if the *characteristics of a given product* are identified – even those which mean that import is not allowed – at the same time the characteristics of products which can be introduced into the territory of the country applying the measure are identified.

8.43 The Panel therefore concludes that, taking into account the ordinary meaning of the words "characteristics" and "product", the definition of "technical regulation" in Annex 1.1 to the TBT Agreement applies to the measures which define the technical specifications that one or more given products must meet in order to be authorized for marketing in a Member.

8.44 It may, however, be considered, as Canada does, that the prohibitions in the Decree concern a given product: asbestos, because of its specific characteristics. Nevertheless, as far as the ban on asbestos as such is concerned, the Decree does not concern itself with the characteristics of this product, in any event, not specifically. What is banned is not asbestos which possesses certain characteristics but all types of asbestos. As regards asbestos-containing products, the Panel notes Canada's argument that the characteristic of the products authorized for import is the absence of asbestos. We note, however, that the definition in Annex 1.1 to the TBT Agreement refers to the technical characteristics of a given product. In this case, the products whose characteristic would be that they contained asbestos are not identified in the Decree. As we have already found, the identification of a product appears to be one of the criteria in the definition in Annex 1.1.

8.45 Lastly, the Panel notes that the ban applicable to asbestos-containing products is in fact one *aspect of* or *complementary to* the general ban on asbestos. It can therefore only be considered together with the ban on asbestos as such. It is in fact there in order to ensure that asbestos is not imported into France in any form whatsoever. In such a context, not defining the products concerned is not simply a choice of wording but is the result of the logic of the objective sought (a ban on *all forms* of asbestos). To specify each product affected would be pointless.

Object and purpose

8.46 To the extent that Article 31 of the Vienna Convention contains a single rule of interpretation and not a number of alternative rules, the various criteria in the Article should be considered as forming part of a whole. Although the Panel subdivided its analysis for reasons of clarity, this does

[32] Petit Larousse illustré (1986), p. 162.
[33] Le Nouveau Petit Robert (1994), p. 304.

not mean that there has to be a hierarchy among the various elements in the rule of interpretation.[34] In this particular case, we deem it preferable to analyse the context after examining the object and purpose because the latter help to clarify the understanding of the context of "technical regulation" in Annex 1 to the TBT Agreement.

8.47 We note that the object and purpose of a treaty can also be found in its preamble.[35] Applying the practice of the Appellate Body in this respect[36], it is relevant to look not only at the preamble to the WTO Agreement but also at the preamble to the TBT Agreement itself, which provides certain indications.

8.48 In this connection, we note first of all that, although the preamble to the WTO Agreement refers in particular to expanding trade in goods, it does not give sufficiently precise information on the terms which we must interpret. We therefore turn to the preamble to the TBT Agreement. This refers to standards for products and their role in improving efficiency of production.[37] The TBT Agreement thus aims to improve market access by encouraging *inter alia* the use of international standards, while at the same time exercising control over the development and use of standards at the national level. The reference in the preamble to packaging, marking and labelling[38] appears to confirm that the object and purpose of the Agreement relate to the criteria for marketing these products.[39]

8.49 It might be argued that the fact that the TBT Agreement only refers to elements relating to the marketing criteria for a product does not in itself mean that it does not apply to import bans. Strict application of standards can in fact lead to a ban on the import of certain products. The Panel notes, however, that there is no specific reference in the TBT Agreement to the type of measure involved in this particular case (i.e. a pure and simple import ban without any reference to the characteristics of given products), even though a ban is by its very nature the most restrictive market access measure. Consequently, if the Members had agreed that the TBT Agreement also applied to general bans, they would undoubtedly have mentioned it. It would appear that the purpose of the TBT Agreement is to prevent much more complex situations than a straightforward unconditional ban on a product, which is covered by the very strict provisions in Article XI:1 of the GATT 1994. In the Panel's view

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[34] See *Report of the Commission to the General Assembly*, *Yearbook of the International Law Commission*, 1966, Volume II, A/CN.4/SER.A/1966/Add.1, pages 219-220:

> "The Commission, by heading the article "General rule of interpretation" in the singular and by underlining the connexion between paragraphs 1 and 2 [of Article 31] and again between paragraph 3 and the two previous paragraphs, intended to indicate that the application of the means of interpretation in the article would be a single combined operation. […] the Commission desired to emphasize that the process of interpretation is a unity and the provisions of the article form a single, closely integrated rule."

[35] See I. Sinclair: The Vienna Convention on the Law of Treaties (1980), pp. 127 and 130.

[36] See the Report of the Appellate Body in *European Communities – Customs Classification of Certain Computer Equipment*, adopted on 22 June 1998, WT/DS62/AB/R; WT/DS67/AB/R; WT/DS68/AB/R, para. 88.

[37] "*Desiring*, therefore to encourage the development of such international standards and conformity assessment systems;".

[38] "*Desiring*, however to ensure that technical regulations and standards, including packaging, marking and labelling requirements, and procedures for assessment of conformity with technical regulations and standards do not create unnecessary obstacles to international trade;".

[39] Although technically these are additional ways of interpreting Article 32, we note that the *preparatory work* confirms this objective. Document TRE/W/21 of 17 January 1994 notes that the draft Code (Spec(72)3) elaborated in the course of the preparatory work for the Tokyo Round refers to the preparation and adoption of "mandatory standards". The use of the words "mandatory *standards*" (one of the definitions of the word "standard" in English is "a document specifying nationally or internationally agreed properties for manufactured goods, principles for procedure, etc.". The New Shorter Oxford English Dictionary (1993), p. 3028) implies that the purpose of the Agreement was to ensure a product's conformity with the characteristics of other products marketed.

the purpose of adopting the TBT Agreement was to control the development and application of standards - situations in which protectionist aims can be better disguised and for which the existing disciplines within the GATT appeared to be inadequate. A general prohibition by nature does not usually involve any technical specifications. It thus appears that the drafters were concerned at the development and application of technical characteristics for protectionist purposes or leading to protectionist effects, as can be seen from the preamble to the TBT Agreement:

> "*Desiring* however to ensure that technical regulations and standards, including packaging, marking and labelling requirements […] do not create unnecessary obstacles to international trade;". (Emphasis added).

8.50 It would therefore seem that in principle the object and purpose of the TBT Agreement were that it should apply to potentially protectionist aspects of the application of technical regulations and standards which, even if their effect might be purely and simply a ban, could circumvent the GATT disciplines more easily for a number of reasons.

8.51 The Panel nevertheless notes that Canada points out that the imposition of technical characteristics applicable to the import of a product implies a ban on products which do not meet these characteristics. Consequently, any technical regulation is also a general prohibition on products that are not in conformity. The Panel does not disagree. It notes however that, in this particular case, none of the products covered by the Decree can be imported, with the exception of those given a temporary exemption. This is a major difference compared with a technical regulation that defines the characteristics of one or more given products. Even if the number of products that can in fact be imported is very restricted, import remains possible, in theory or in practice.

8.52 This does not mean either that a technical regulation which defines the characteristics of a product negatively does not come under the TBT Agreement. It is always possible to define the characteristics of a product negatively as long as these technical characteristics are specified in such a way as to allow the product to be marketed in the importing countries. As we emphasized in para. 8.40 above, the Decree contains a general prohibition that does not define the characteristics of specific products.

Context

8.53 The Panel notes that the provisions of the TBT Agreement are situated within the broader context of Annex 1A to the WTO Agreement. The EC emphasize in this connection that an interpretation reaffirming the applicability of the TBT Agreement to a general prohibition measure would be equivalent to nullifying the effect of Articles I, III, and XI of the GATT. Canada considers that, if the ban in the Decree is not deemed to be a "technical regulation", there is a risk of circumventing the disciplines of the TBT Agreement by introducing "horizontal" prohibitions instead of technical regulations in the strict sense. We consider that these matters should be examined more specifically in the light of the context of the TBT Agreement because it is by taking into account the content of the obligations in the provisions that form part of the context of the TBT Agreement that we will be able to determine the scope of the definition of "technical regulation" in the TBT Agreement.

8.54 The Panel considers that the concept of circumvention implies that a given attitude makes it possible to avoid an obligation that would otherwise apply. An obligation must be generally applicable before circumvention can occur. Firstly, nothing proves that it is in a Member's interest to try to evade the obligations in the TBT Agreement because its provisions represent a combination of rights and obligations whose balance was carefully negotiated. Nevertheless, assuming that it was in the Member's interest, if the object and purpose of the TBT Agreement are to regulate the marketing conditions, a measure that quite simply banned market access would not come under the Agreement. This does not, however, mean that such measures would not be penalized if they created "unnecessary

obstacles to international trade". To the extent that the GATT 1994 applies, especially Articles I, III or XI whose scope is particularly broad, there would not be any legal vacuum.

8.55 We also note that the criteria on the preparation, adoption or application of technical regulations in Article 2.2 of the TBT Agreement are very similar to those in Article XX of the GATT 1994. The preamble to the TBT Agreement in fact repeats some of the wording of Article XX of the GATT.[40] In the Panel's view the TBT Agreement is a development of the GATT. As mentioned in para. 8.49 above, the TBT Agreement appears to have been adopted in order to strengthen the disciplines applicable to the specific area of manufacturing standards, where they appeared to be insufficient to prevent certain forms of protectionism.[41]

8.56 We also note that the EC claim that Canada's interpretation of the TBT Agreement would be equivalent to nullifying the effect of Articles I and III of the GATT 1994. We note in this connection that the Appellate Body has on many occasions, most recently in the *Argentina – Safeguards* case, recalled that "a treaty interpreter must read all applicable provisions of the treaty in a way that gives meaning to *all* of them, harmoniously".[42] It is therefore important that our interpretation of the provisions of the TBT Agreement in this case should not result "in reducing whole clauses or paragraphs of a treaty to redundancy or inutility".[43] Canada is concerned that a particular interpretation might allow Members to circumvent the obligations imposed by the TBT Agreement. As already indicated above, in our view the main reason for circumventing a provision is to avoid certain obligations. If a general prohibition is not covered by the TBT Agreement, this does not mean that it is not subject to any other provision in the WTO Agreement. At the very least, it will come within the scope of Articles I, and/or III, and/or XI of the GATT 1994 and may have to meet the criteria in Article XX in order to be justified under this Agreement. There may be grounds for Canada's position if it is established that the provisions of the TBT Agreement impose stricter disciplines than those in the GATT 1994 and that excluding general prohibitions from their scope would nullify their effect. The elements before us, however, do not allow us to conclude that this is the case.

8.57 The Panel therefore concludes that, taking into account the terms of the definition considered within their context and in the light of the object and purpose of the TBT Agreement, a measure constitutes a "technical regulation" if:

(a) the measure affects one or more given products;

(b) the measure specifies the technical characteristics of the product(s) which allow them to be marketed in the Member that took the measure[44];

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[40] "*Recognizing* that no country should be prevented from taking measures necessary […] for the protection of human […] life or health […] subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade […]" (identical wording to that in Article XX of the GATT 1994, emphasis added).

[41] We note in this connection that the preparatory work on the Agreement on Technical Barriers to Trade in the Tokyo Round show that the TBT Agreement that should have emerged from the Tokyo Round was already seen as being a development of the existing rules of the GATT, notably Article XX. See for example the extract from document MTN/3E/W/26, October 1974, quoted in paragraph 7 of document TRE/W/21, 17 January 1994.

[42] Op. cit., para. 81 and footnote 72, (underlined in the original).

[43] Report of the Appellate Body in *United States – Gasoline,* op. cit., p. 23.

[44] According to the definition in Annex 1.1 to the TBT Agreement, the criteria for placing a product on the market must concern its characteristics or the related processes or production methods, including the applicable administrative provisions.

(c) compliance is mandatory.

8.58 In the light of the above, we provisionally conclude that the part of the Decree dealing with the general prohibition on marketing asbestos and asbestos-containing products does not constitute a "technical regulation" within the meaning of the definition in Annex 1.1 to the TBT Agreement.

(iii) Additional arguments by Canada

8.59 The Panel notes that Canada puts forward two additional arguments that must be examined before coming to a definite conclusion on this matter. Firstly, in Canada's view, the EC recognized that the TBT Agreement applied by notifying the Decree to the Committee on Technical Barriers to Trade and during the consultations relating to this dispute.

8.60 From a legal point of view, the question seems to be whether there is *estoppel* on the part of the EC because they notified the Decree or because of their statements, including those during the consultations. This would be the case if it was determined that Canada had legitimately relied on the notification of the Decree and was now suffering the negative consequences resulting from a change in the EC's position.[45] In this case, however, it does not appear that Canada was able legitimately to rely on a notification to the Committee on Technical Barriers to Trade or on a statement made during the consultations. We consider that notifications under the TBT Agreement are made for reasons of transparency.[46] It has been recognized that such notifications do not have any recognized legal effects.[47] Furthermore, notification under the TBT Agreement is one of the few ways of notifying this type of measure for a Member who wishes to show transparency in good faith. Lastly we consider that both the notification and the comments made by the EC during the consultations or in another context constitute observations on the legal characterization of the Decree. Claims regarding the legal characterization of a fact by the parties, however, cannot bind the Panel.

8.61 Lastly, we note that Canada asserts that the Decree contains five of the requirements in the definition in Annex 1.1 to the TBT Agreement, namely, it indicates the characteristics of a product,

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[45] See the decision by the International Court of Justice in the *North Sea Continental Shelf* case, Reports of Judgements 1969, p. 26, para. 30. Regarding the procedural aspect of the use of the word "estopppel", see also Daillier & Pellet: Droit International Public (1994), p. 834, citing Guggenheim, Traité de Droit international public, volume II, p. 158.

[46] See the preamble to the Decision on Notification Procedures, adopted by the Trade Negotiations Committee on 15 December 1993.

[47] See the second paragraph in Section I of the Decision on Notification Procedures, adopted by the Committee on Trade Negotiations on 15 December 1993, as annexed to the Final Act embodying the results of the Uruguay Round of multilateral trade negotiations, done at Marrakesh on 15 April 1994.

> "Members recall their undertakings set out in the Understanding Regarding Notification, Consultation, Dispute Settlement and Surveillance adopted on 28 November 1979 (BISD 26S/210). With regard to their undertaking therein to notify, to the maximum extent possible, their adoption of trade measures affecting the operation of the GATT 1994, such notification itself being without prejudice to views on the consistency of measures with or their relevance to rights and obligations under the Multilateral Trade Agreements and, where applicable, the Plurilateral Trade Agreements, Members agree to be guided, as appropriate, by the annexed list of measures. Members therefore agree that the introduction or modification of such measures is subject to the notification requirements of the 1979 Understanding." (Emphasis added)

Paragraph 3 of the Understanding Regarding Notification, Consultation, Dispute Settlement and Surveillance, adopted on 28 November 1979 (BISD 26S/210) provides that:

> "Contracting parties moreover undertake, to the maximum extent possible, to notify the CONTRACTING PARTIES of their adoption of trade measures affecting the operation of the General Agreement, it being understood that such notification would of itself be without prejudice to views on the consistency of measures with or their relevance to rights and obligations under the General Agreement."

the processes and production methods relating to a product, the administrative provisions applicable to a product, and packaging or labelling requirements for a product. Finally, compliance is mandatory.[48] We do not in principle rule out that the Decree may include some or even all the requirements mentioned by Canada. We note, however, that our consideration of the terms of the definition of "technical regulation" in Annex 1.1 in their context and in light of the object and purpose of the TBT Agreement in relation to the part of the Decree prohibiting the marketing of asbestos has led us to conclude that this part of the Decree is not covered by the TBT Agreement. Concerning Canada's arguments, we have found that the part of the Decree prohibiting asbestos and for the production of asbestos-containing products does not define the characteristics of the products whose import is banned. We have also found that this part of the Decree does not cover processes or methods for the production of asbestos or asbestos-containing products. Even if we adopt the approach suggested by Canada for the identification of the five requirements, in our view, the absence of the first two requirements suffices to conclude that the Decree does not meet the criteria for the definition of "technical regulation" in the TBT Agreement. We do not therefore think it necessary to consider whether the three other requirements referred to by Canada are to be found in this part of the Decree.

8.62 We nevertheless note that, in its arguments, Canada does not distinguish, as the Panel does, between the part of the Decree banning asbestos and the part relating to exceptions to the ban. It is thus possible that the elements to which Canada refers are to be found in the part of the Decree on exceptions. If this was the case, this would be even greater justification for our decision to analyse the two aspects of the Decree separately.

8.63 We therefore conclude that the part of the Decree dealing with the general ban on the marketing of asbestos and asbestos-containing products does not constitute a "technical regulation" within the meaning of the definition in Annex 1.1 to the TBT Agreement.

(b) Analysis of exceptions and the effect of the type of exceptions on the findings concerning prohibitions

(*i*) *The exceptions in the Decree constitute technical regulations*

8.64 Bearing in mind the discussion in the preceding section, we point out that the following aspects of a measure are likely to mean that the measure is covered by the definition of "technical regulation" in Annex 1.1 to the TBT Agreement.[49]

(a) The measure affects one or more given products;

(b) the measure specifies the technical characteristics of the product(s) which allow them to be marketed in the Member that took the measure[50];

(c) compliance is mandatory.

8.65 First of all, we note that the EC contend that exceptions are transitional measures limited by their purpose and temporary by nature. Consequently, they should not be covered by the TBT Agreement. We do not consider that the "transitional" nature of a measure suffices to exclude it from the scope of the TBT Agreement. The Agreement does not distinguish between measures according to whether or not they are transitional or temporary.

[48] See Canada's arguments, section III.C.1(a) above, in particular paras. 3.246 and 3.260-3.261.

[49] These criteria are by no means exhaustive.

[50] According to the definition in Annex 1.1 of the TBT Agreement, the criteria for placing a product on the market must concern its characteristics or the related processes or production methods, including the applicable administrative provisions.

8.66 We also note the EC's arguments on the ancillary nature of the exceptions.[51] We have already indicated above that, in theory, there is no reason why two parts of the same text could not have a different legal characterization. We note that, pursuant to the accessory theory (*accessorium sequitur principale),* the legal regime applicable to a good or an action may be related or subject to the regime for a principal good or action.[52] Assuming that this theory applies to a public international law situation, we consider that this particular case does not come within its scope. The measures before us do not relate to application of the ban in the strict sense but to an exception which in practice allows chrysotile asbestos to enter the French market. In such a context, we hesitate to consider the exceptions in the Decree as ancillary to the ban on asbestos.

8.67 We note that the part of the Decree concerning exceptions to the general ban on importing asbestos or asbestos-containing products (Articles 2-4) does not define the products benefiting from such exceptions. Article 2.II, however, covers the identification of the materials, products or devices shown in an exhaustive list drawn up by decree by the Ministers for Labour, Consumption, the Environment, Industry, Agriculture and Transport. We therefore consider that the applicable French regulation (i.e. the Decree as implemented by the above-mentioned Decree) identifies the products benefiting from an exception.

8.68 We also note that Article 2 of the Decree sets out the criteria for marketing the products identified in the Decree and not solely the criteria for excluding products from the market. The second sentence in Article 3.I of the Decree completes these criteria.

8.69 In our view, the marketing criteria in Article 2.I of the Decree relate to the characteristics of one or more given products or processes or production methods relating to them. This is particularly true of the second subparagraph on the technical guarantees of safety appropriate to the use, which has to be read in conjunction with the second paragraph of Article 3.I of the Decree. We also note that Article 2.II and Article 3 in particular cover the administrative provisions applicable to the technical regulations. The second paragraph of Article 4 contains provisions on the labelling and marking of products benefiting from an exception. Lastly, compliance with these provisions is mandatory and there is provision for penalties (see Article 3.III).

8.70 We thus conclude that the part of the Decree concerning exceptions to the ban on asbestos comes within the scope of the definition of technical regulation in Annex 1.1 to the TBT Agreement.

(ii) Effect of the legal characterization of the exceptions on the legal characterization of the prohibitions

8.71 The Panel notes that Canada considers that the regime applicable to exceptions proves that the Decree as a whole is a technical regulation. We are of the opinion that there is no legal reason why certain parts of the Decree should not come under one of the WTO Agreements and other parts under another Agreement. We have already referred above to application of the accessory concept in this particular case. Even assuming that the accessory concept might apply to this particular case, the fact that it is the exceptions to the general ban which come under the TBT Agreement and not the principal element of the Decree (namely the general ban on asbestos) makes it difficult to conclude that the ban must follow the exceptions regime. Consequently, the fact that the exceptions in the

[51] See the reply by the EC to question 2 in the questions by the Panel at the second substantive meeting, paras. 220-221.

[52] See R. Guillien and J. Vincent: Lexique de termes juridiques (1981), p. 3: in civil law "the subsidiary follows the principal in the sense that the principal good transmits its legal characterization to the good attached to it". (WTO translation). See also Black's Law Dictionary (1990), p. 14, regarding the criminal law applicable in certain Members.

Decree are covered by the TBT Agreement in our view should not affect the legal characterization of the general ban and especially the fact of whether or not the ban comes within the scope of the TBT Agreement.

8.72 In any event, as the legal characterization of the exceptions does not affect that of the general ban and even though Canada contests the legality of the Decree as a whole, the Panel should not go further than the question of the legal characterization of the exceptions. The Panel considers that Canada did not make any specific claims concerning the exceptions in the terms of reference drawn up under Article 6.2 of the Understanding. The Panel therefore concludes that it does not have to reach any findings concerning the exceptions.

3. Conclusion

(a) The TBT Agreement does not apply to the part of the Decree relating to the ban on imports of asbestos and asbestos-containing products because that part does not constitute a "technical regulation" within the meaning of Annex 1.1 to the TBT Agreement.

(b) The TBT Agreement applies to the part of the Decree relating to exceptions to the ban on imports of asbestos and asbestos-containing products because that part constitutes a "technical regulation" within the meaning of Annex 1.1 to the TBT Agreement. This legal characterization, however, does not affect the legal characterization of the part of the Decree banning asbestos nor our consideration of the rest of this case because Canada did not make any specific claims regarding the exceptions to the general ban.[53]

8.73 Having concluded that the part of the Decree banning asbestos and asbestos-containing products does not come within the scope of the TBT Agreement, we shall now consider Canada's claims relating to the GATT 1994.

E. APPLICATION OF THE GATT 1994 TO THE DECREE

1. Preliminary questions

(a) The effect of practice within the GATT 1947 and the WTO

8.74 The Panel notes that, in support of their arguments, the parties refer to panel and Appellate Body reports adopted in the WTO. They also refer at length to panel reports under the GATT 1947, some of which were adopted and others not. As certain issues raised by the parties have been dealt with in detail or even exclusively under the GATT 1947, we deem it useful to explain how we intend to take into account the panel reports issued within the framework of the GATT 1947. For this purpose, we shall base ourselves on the approach followed by the Appellate Body in *Japan – Taxes on Alcoholic Beverages.*[54]

8.75 In this particular case, the Appellate Body emphasized that, with regard to the reports adopted by panels under the GATT 1947, Article XVI:1 of the Agreement Establishing the WTO and paragraph 1(b)(iv) of Annex 1A incorporating the GATT 1994 into the WTO Agreement allow the "legal history and experience under the GATT 1947" to be brought into the new WTO. Adopted

[53] For example, Canada did not claim that the WTO Agreement had been violated by the way in which France administered the exceptions. Moreover, the Panel notes that they are exceptional and temporary exemptions. They will disappear as and when reliable and effective substitute products are developed.

[54] Adopted on 1 November 1996, WT/DS8; DS10;DS11/AB/R, hereinafter "*Japan – Alcoholic Beverages*", pp. 14-15.

panel reports "are an important part of the GATT *acquis*".[55] They create legitimate expectations among WTO Members and should thus be taken into account when they are relevant to any dispute.

8.76 Turning to unadopted reports, the Appellate Body stated that *unadopted* panel reports "have no legal status in the GATT or WTO system since they have not been endorsed through decisions by the CONTRACTING PARTIES to GATT or WTO Members". [footnote omitted]. Likewise, "a panel could nevertheless find useful guidance in the reasoning of an unadopted panel report that it considered to be relevant". [footnote omitted].

8.77 Following this approach, we shall duly take into account the relevant adopted panel reports and, to the extent necessary, we shall take into account the reasoning set out in unadopted panel reports when we deem it relevant to the issues raised in our examination.

(b) Burden of proof

8.78 Canada claims violation of Articles III:4 and XI:1 of the GATT 1994. The EC consider that, even if there is a violation of these provisions, the measure is justified pursuant to Article XX(b). We note that the Appellate Body reaffirmed the general rules applicable to the burden of proof in the case of *United States – Shirts and Blouses.*[56]

8.79 Applying these rules, it is our opinion that Canada, as the complaining party, should normally provide sufficient evidence to establish a presumption that there are grounds for each of its claims. If it does so, it will then be up to the EC to adduce sufficient evidence to rebut the presumption. When the EC puts forward a particular method of defence in the affirmative, it is up to them to furnish sufficient evidence, just as Canada must do for its own claims. If both parties furnish evidence that meets these requirements, it is the responsibility of the Panel to assess these elements as a whole. Where the evidence concerning a claim or a particular form of defence is, in general, equally balanced, a finding has to be made against the party on which the burden of proof relating to this claim or this form of defence is incumbent.

8.80 The Panel also notes the extreme factual and scientific complexity of this case, which led to the consultation of experts under Article 13 of the Understanding. It notes that, in the context of the Agreement on the Application of Sanitary and Phytosanitary Measures, where scientific facts and data play a very important role, the Appellate Body has taken a special approach. As it is necessary to examine the application of Articles III:4 and XI:1 of the GATT 1994 before even considering the EC's arguments based on Article XX, we simply take note of this approach and, if necessary, will return to it when examining the issues raised in connection with Article XX.

8.81 Bearing in mind the above, we consider that it is important for each party to state clearly its *arguments and factual evidence* in support of its claims. If not, the Panel will only be able to conclude that the party concerned did not make the prima facie case needed to establish its claim.[57] The Panel considers that it can only reach findings concerning a claim or part of a claim, even when it is clearly defined in the terms of reference set by the DSB, if the party making the claim

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[55] Ibid., page 14.

[56] Op. cit., page 14:

"The burden of proof rests upon the party, whether complaining or defending, who asserts the affirmative of a particular claim or defence. If that party adduces evidence sufficient to raise a presumption that what is claimed is true, the burden then shifts to the other party, who will fail unless it adduces sufficient evidence to rebut the presumption".

[57] Report of the Appellate Body in *Japan – Measures Affecting Agricultural Products,* adopted on 19 March 1999, WT/DS76/AB/R, para. 126.

spontaneously makes the prima facie case needed to establish its claim.[58] Information provided by the experts consulted by the Panel pursuant to Article 13 of the Understanding "to help it to understand and evaluate the evidence submitted and the arguments made by the parties"[59], even where it has been requested by the Panel, can under no circumstances be used by a panel to rule in favour of a party which has not established a prima facie case based on specific legal claims or pleas asserted by it.[60] Put another way, the Panel cannot utilize the information furnished by the experts in order to establish the validity of a claim by one of the parties if that party has not already established a prima facie case.

8.82 On any *legal matter*, notably the interpretation of the Agreements concerned, the Panel will be assisted by the arguments of the parties but will not be bound by them. Pursuant to Article 3:2 of the Understanding, our decision on these matters must be in accordance with the customary rules of interpretation of public international law applicable to the WTO Agreement.

(c) Application of Article III:4 and/or Article XI of the GATT 1994

(i) Question before the Panel[61]

8.83 The Panel notes that the parties have differing views concerning the applicability to the Decree of Article III:4 and Article XI:1 of the GATT 1994.

8.84 Canada considers that the Decree should be examined in the light of these two Articles because it comprises two distinct aspects. On the one hand, it prohibits imports of asbestos in a manner incompatible with Article XI:1. On the other, it includes internal regulations prohibiting the sale and use of asbestos in a manner incompatible with Article III:4. Canada considers that two different aspects of the same measure can be examined in the light of two different articles of the same Agreement. Canada considers that the interpretative Note *Ad Article III* does not apply in this case. If the Panel considers that the Decree cannot be examined under the two Articles, it should be considered as a measure affecting imports and incompatible with Article XI:1. If it cannot be considered as a measure affecting imports, it should be considered as a measure affecting sales and other transactions on the French market and so incompatible with Article III:4.

8.85 The EC assert that either the measure is an internal regulation, in which case it is covered by Article III:4, or it only concerns the import of products, in which case it must be assessed in the light of Article XI:1. The distinction made by Canada fails to take account of the relationship between the two Articles, which means that a single measure that applies both to domestic and imported products must necessarily be covered as a whole by Article III:4 if it is imposed on an imported product at the time or place of importation. Previous practice in the GATT confirms that there can be no cumulative application with Article XI. The practical application of the Decree means that the same measure, namely a general ban on asbestos and asbestos-containing products, applies to all products irrespective of their origin. As one and the same measure is applied to both domestic and imported products – application is at the border for the latter – only Article III:4 is applicable in this case.

(ii) Analysis[62]

8.86 The Panel notes that the relevant provisions of Article III:4 provide the following:

> "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

[58] Ibid., para. 130.
[59] Ibid., paras. 128-129.
[60] Ibid., para. 129.
[61] The arguments of the parties are set out in detail in Section III above.
[62] The arguments of the parties are set out in detail in Section III above.

> national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use."

Note *Ad Article III* in the Notes and Supplementary Provisions in Annex I to the GATT 1994 states the following:

> "Any internal tax or other internal charge, or any law, regulation or requirement of the kind referred to in paragraph 1 which applies to an imported product and to the like domestic product and is collected or enforced in the case of the imported product at the time or point of importation, is nevertheless to be regarded as an internal tax or other internal charge, or a law, regulation or requirement of the kind referred to in paragraph 1, and is accordingly subject to the provisions of Article III."

Article XI:1 of the GATT 1994 states the following:

> "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."

8.87 The Panel notes first of all that the parties agree that Article III:4 applies to that aspect of the Decree which bans in particular the sale, domestic marketing and transfer under any title of all varieties of asbestos fibres and any product containing them. This aspect concerns the "treatment accorded to products […] in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use" within the meaning of Article III:4. Canada, on the other hand, considers that Article XI:1 applies to the ban on imports affecting products from Canada.[63]

8.88 The Panel draws attention to Note *Ad Article III*, which specifically covers a situation in which a law, regulation or requirement applies both to an imported product and to the like domestic product and is enforced in the case of the imported product at the time or point of importation. The latter is in fact the case. Consequently, the Panel considers it proper to commence its analysis by determining whether the Note *Ad Article III* applies to this case. As neither of the parties contests the fact that the measure applicable to the imported product is imposed at the time or point of importation, it is necessary to examine whether the Decree "applies to an imported product and to the like domestic product".

8.89 In Canada's view, interpretative Note *Ad Article III* only applies if the measure is applicable to the imported product and to the domestic product. The explicit import ban does not, however, apply to the domestic product because the domestic product is obviously not imported. Moreover, as France neither produces nor mines asbestos fibres on its territory, the ban on manufacturing, processing, selling and domestic marketing is, in practical terms, equivalent to a ban on importing chrysotile asbestos fibre.

8.90 For the EC, the import ban is merely the logical corollary of the general prohibition on the use of asbestos and asbestos-containing products. Article III:4 must be assessed in the light of the interpretative Note relating to it. When a domestic measure applies to both domestic and imported products, Article III must apply.

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[63] It is only if the Panel rejects Canada's first interpretation that the Decree comes in part under Article III:4 and in part under Article XI.1 that Canada considers that the whole of the Decree should fall under Article XI:1 or, if the Panel also rejects this approach, Article III:4.

8.91 The Panel notes that the word "comme" in the French text of Note *Ad Article III* ["and" in the English text] implies in the first place that the measure applies to the imported product and to the like domestic product.[64] The Panel notes in this connection that the fact that France no longer produces asbestos or asbestos-containing products does not suffice to make the Decree a measure falling under Article XI:1. It is in fact because the Decree prohibits the manufacture and processing of asbestos fibres that there is no longer any French production. The cessation of French production is the consequence of the Decree and not the reverse. Consequently, the Decree is a measure which "applies to an imported product and to the like domestic product" within the meaning of Note *Ad Article III*.

8.92 Secondly, the Panel notes that the words "any law, regulation or requirement […] which applies to an imported product and ["comme" in the French text] to the like domestic product" in the Note *Ad Article III* could also mean that the same regime must apply to the imported product and the domestic product.[65] In this case, under the Decree, the domestic product may not be sold, placed on the domestic market or transferred under any title, possessed for sale, offered or exported. If we follow Canada's reasoning, products from third countries are subject to a different regime because, as they cannot be imported, they cannot be sold, placed on the domestic market, transferred under any title, possessed for sale or offered. Firstly, the regulations applicable to domestic products and foreign products lead to the same result: the halting of the spread of asbestos and asbestos-containing products on French territory. In practice, in one case (domestic products), they cannot be placed on the domestic market because they cannot be transferred under any title. In the other (imported products), the import ban also prevents their marketing.

8.93 For the following reasons, we also consider that the wording of Note *Ad Article III* and practice in the GATT 1947 in this respect do not support Canada's approach that an *identical* measure must be applied to the domestic product and the like imported product if the measure applicable to the imported product is to fall under Article III.

8.94 We note that the relevant part of the English text of Note *Ad Article III* reads as follows: "Any […] law, regulation or requirement […] which applies to an imported product *and* to the like domestic product".[66] The word "and" does not have the same meaning as "in the same way as", which can be another meaning for the word "comme" in the French text. We therefore consider that the word "comme" cannot be interpreted as requiring an identical measure to be applied to imported products and domestic products if Article III is to apply.

8.95 We note that our interpretation is confirmed by practice under the GATT 1947. In *United States – Section 337 of the Tariff Act of 1930*[67], the Panel had to examine measures specifically applicable to imported products suspected of violating an American patent right. In this case, referring to Note *Ad Article III*, the Panel considered that the provisions of Article III:4 did apply to the special procedures prescribed for imported products suspected of violating a patent protected in the United States because these procedures were considered to be "laws, regulations and requirements" affecting the internal sale of the imported products, within the meaning of Article III of the GATT. It should be noted that in this case the procedures examined were not the same as the equivalent procedures applicable to domestic products.[68]

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[64] Le Nouveau Petit Robert, op. cit., p. 411.

[65] "In the same way as", "to the same extent as" are among the alternative meanings for the word "comme" in the French text (Le Nouveau Petit Robert, op. cit., p. 411). [In the English text the word is "and"].

[66] Emphasis added. In the place of "and" and "comme", the Spanish version uses the conjunction "y" ("et" in French).

[67] See the Report of the Panel in *United States – Section 337 of the Tariff Act of 1930*, adopted on 7 November 1989, BISD 36S/345, (hereinafter "*United States – Section 337*").

[68] The Panel gave the grounds for its decision in para. 5.10 as follows:

"The fact that Section 337 is used as a means for the enforcement of United States Patent Law at the border does not provide an escape from the applicability of Article III:4; the interpretative Note to

8.96 Canada also claims that the import ban is not an internal measure imposed at the border, for administrative reasons. We consider that an internal charge applied to a domestic product must also be imposed on an imported product. Nevertheless, if it is deemed appropriate to impose the charge at the border rather than waiting until the imported product is actually marketed, the same logic applies in the case of a regulatory measure prescribing a ban on marketing. Is it not equally preferable from the administrative point of view and in the interests of the importers themselves to prevent the entry of the like product into the country applying the measure rather than waiting until it is placed in a warehouse before banning its sale?

8.97 The Panel also notes that Canada makes reference to paras. 4.24 and 4.26 of the Report of the Panel in *Canada – Import, Distribution and Sale of Certain Alcoholic Drinks by Provincial Marketing Agencies*[69] to support its claim that the Decree should be examined under Article XI:1 of the GATT 1994. We note that in paragraph 4.24 of the Report, the Panel considered that according to the Note *Ad Articles* XI, XII, XIII, XIV and XVIII, restrictions made effective through state-trading operations were "import restrictions" or "export restrictions". It considered that, in the case of enterprises enjoying a monopoly of both importation and distribution in the domestic market, the distinction normally made between restrictions affecting the importation of products and restrictions affecting imported products lost much of its significance since both types of restriction could be made effective through decision by the monopoly. In this case, the Decree did not institute a monopoly on the import or distribution of asbestos and like products, so the Note *Ad Articles* XI, XII, XIII, XIV and XVIII is not relevant to settlement of this matter.

8.98 As regards Canada's reference to paragraph 4.26 of the aforementioned report[70], we consider that it does not substantiate Canada's position in this case either. In this paragraph, the Panel refrains from ruling on a violation of Article III:4. It appears to do so, however, for reasons of legal economy because it simultaneously recognizes that Article III:4 could apply to state-trading transactions. Contrary to Canada's assertion, this paragraph does not confirm the non-applicability of Article III:4 to the part of an internal measure dealing with the treatment of imported products. At the most, it could confirm the application of both provisions. Nevertheless, as explained in the preceding paragraph, the Panel found that Article XI:1 applied, referring to the Note *Ad Articles* XI, XII, XIII, XIV and XVIII. This Note only applies to state-trading transactions. In the present case, however, there is no question of a measure applied in the context of state-trading activities.

8.99 For the foregoing reasons, we consider that Article III:4 of the GATT 1994 applies to the ban on importing asbestos and asbestos-containing products imposed by the Decree. On the basis of the

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Article III states that any law, regulation or requirement affecting the internal sale of products that is enforced in the case of the imported product at the time or point of importation is nevertheless subject to the provisions of Article III. Nor could the applicability of Article III:4 be denied on the ground that most of the procedures in the case before the Panel are applied to persons rather than products, since the factor determining whether persons might be susceptible to Section 337 proceedings or federal district court procedures is the source of the challenged products, that is whether they are of United States origin or imported. For these reasons, the Panel found that the procedures under Section 337 come within the concept of 'laws, regulations and requirements' affecting the internal sale of imported products, as set out in Article III of the General Agreement."

[69] Adopted on 22 March 1998, BISD 35S/37.

[70] "The Panel considered that it was not necessary to decide in this particular case whether the practices complained of were contrary to Article III:4 because it had already found that they were inconsistent with Article XI. However, the Panel saw great force in the argument that Article III:4 was also applicable to state-trading enterprises at least when the monopoly of the importation and monopoly of the distribution in the domestic markets were combined, as was the case of the provincial liquor boards in Canada. This interpretation was confirmed *a contrario* by the wording of Article III:8(a)."

grounds for this conclusion, we do not consider it necessary to examine further Canada's arguments on the exclusive application of Article XI:1.

8.100 Looking at Canada's arguments, it is difficult to see whether Canada is claiming that, even if the import ban falls under Article III:4, it is also covered by Article XI:1. If Canada does in fact make such a claim for the cumulative application of Article III:4 and Article XI:1 to the part of the Decree banning imports, we do not consider that this forms part of the terms of reference given to the Panel by the DSB and, even if that were the case, Canada's arguments do not make a prima facie case in the sense given to this concept by the Appellate Body.[71] Consequently, we do not consider it necessary to examine this point any further.[72]

2. Violation of Article III of the GATT 1994

(a) Arguments of the parties[73]

8.101 According to Canada the likeness of products should be assessed on a case-by-case basis, considering, in particular, the end-use of the product, consumers' tastes and habits, and the properties, nature and quality of the product. To these should be added tariff classification. Precedents under the GATT 1947 and the GATT 1994 do not, however, require that all the criteria be applied when evaluating the likeness of given products. Moreover, "like" does not mean "identical", it is a matter of showing that the products compared share many similar features. For Canada, applying the criteria in the precedents confirms the likeness of polyvinyl alcohol (hereinafter "PVA"), cellulose and glass fibres and chrysotile fibre, on the one hand, and fibro-cement and chrysotile-cement products on the other.

8.102 The EC contend that asbestos and asbestos-containing products, on the one hand, and substitute products, on the other, are not like products within the meaning of Article III:4 of the GATT 1994. Four criteria in particular can be used to assess the likeness of products: (a) their properties, nature and quality; (b) their tariff classification; (c) their end-use; and (d) consumers' tastes and habits. In this case, three criteria are relevant: the properties, nature and quality; the tariff classification and the end-use of the product. In the EC's view Canada is confusing the concept of "like" product in Article III:4 with that of "competitive" or "directly substitutable" product in Article III:2, read in conjunction with the relevant interpretative Note. In this case, although certain fibrous products are indeed "substitutable" for chrysotile asbestos and products containing it, they are nevertheless not "like" products. Asbestos has unique physical characteristics and properties that make it difficult to replace for certain industrial purposes. This is why the Decree envisages exceptions. As asbestos has so many uses, there is no single natural or synthetic product which, alone, could replace it in all the products and materials that contain asbestos.

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[71] See the Reports of the Appellate Body in *United States – Shirts and Blouses,* op. cit. and *Australia – Salmon,* op. cit. See also Section VIII.E.1(b) above.

[72] We note in this connection that the Report of the Panel in *Canada – Import, Distribution and Sale of Certain Alcoholic Drinks by Provincial Marketing Agencies,* adopted on 18 February 1992, BISD 39S/27, in para. 5.28 specifically examines the question of whether minimum prices fell under Article XI:1 or Article III:4 and noted the following:

> "The Panel first examined whether the minimum prices fell under Article XI:1 or Article III:4. The Panel noted that, according to the Note Ad Article III, a regulation is subject to the provisions of Article III if it 'applies to an imported product and to the like domestic product' even if it is 'enforced in case of the imported product at the time or point of importation'. The Panel *found* that, as the minimum prices were applied to both imported and domestic beer, they fell, according to this Note, under Article III."

[73] The arguments of the parties are set out in detail in Section III above.

(b) Issues raised in connection with the arguments of the parties relating to Article III:4 of the GATT 1994

8.103 The Panel considers that the arguments of the parties raise the following issues:

(a) The first issue is the criteria to be applied in order to determine the likeness of the products in question. The Panel notes that the parties do not in fact agree on the scope of the concept of like product under Article III:4. Nevertheless, with regard to the criteria to be taken into consideration when assessing likeness, the parties referred to the criteria contained *inter alia* in the Report of the Working Party on *Border Tax Adjustments*[74] and in the Reports of the Panel and the Appellate Body in *Japan – Taxes on Alcoholic Beverages*.[75] The problem can therefore be summarized as whether the criteria developed in these cases must be applied as such or in a particular way in the context of Article III:4, or whether additional criteria should be taken into consideration. Inasmuch as these are the only criteria developed to date in connection with Article III, we consider it appropriate to commence our analysis by applying them to the facts in this case. If, when applying these criteria, we encounter difficulties specific to Article III:4, we shall deal with them at that stage. Moreover, we note that in the above-mentioned case the Appellate Body specified that each criterion should be assessed on a case-by-case basis.[76] It is thus not a question of systematically determining the criteria applicable in the context of Article III:4 but rather of deciding which are relevant in this case.

(b) The second issue is related to the fact that the parties often refer in general to substitute products for chrysotile, products containing asbestos in general, chrysotile-cement products or fibro-cement products. Taking into account the practice of the Appellate Body regarding determination of the likeness of products and the burden of proof in this connection, we consider that the identification of the products which have to be compared pursuant to Article III:4 is of importance in our findings.[77] We also have to decide how to deal with the fibres as such as compared to products containing the fibres.[78]

8.104 In view of the particular implications of the second question for our findings, it appears to us necessary first to devote a special section of the report to this.

(c) The Panel's approach to product-by-product analysis and certain specific aspects of the burden of proof.

8.105 The Panel notes that the EC have indicated that 90 per cent of imported chrysotile fibre was used for making asbestos-cement products prior to the application of the Decree.[79] The Panel also notes that Canada "focuses" its arguments on chrysotile fibres and substitute fibres for chrysotile, as well as on chrysotile-cement and fibro-cement products. With regard to substitute fibres for

[74] Report of the Working Party on *Border Tax Adjustments*, adopted on 2 December 1970, BISD 18S/97, para. 18.

[75] Op. cit., pp. 22-25.

[76] Ibid., p. 22.

[77] See the Report of the Appellate Body in *Japan – Measures Affecting Agricultural Products*, op. cit., paras. 136-138.

[78] Bearing in mind Canada's reply to question No. 15 by the Panel, paras. 74-76, we conclude that Canada does not raise the issue of the likeness of non-fibrous products, whether substitute products or products containing them, as compared to chrysotile or products containing it.

[79] See the EC's reply to question 30 by the Panel, Annex II, para. 113 below.

chrysotile, Canada points out that there are more than 150 substitute fibres for chrysotile fibre. Nevertheless, Canada indicates that, in view of Article III:4 of the GATT 1994, it considers that the Panel's findings and conclusions should take into account the impact of the Decree in relation to three substitute fibres: PVA, cellulose fibres and glass fibres, as well as the fibro-cement products incorporating these. Canada also indicates that it does not invoke the argument of likeness with respect to non-fibrous substitutes for chrysotile fibres (e.g. PVC or ductile iron), nor to non-fibrous products used as substitutes for chrysotile-cement products.

8.106 The EC indicate that in its request for consultations and its request for the establishment of a panel, Canada never claimed that this dispute concerned high-density cement products containing chrysotile. The Panels terms of reference do not refer to these either. Moreover, the EC point out that Canada only exported chrysotile asbestos as a raw material and not in the form of high-density cement products containing chrysotile.

8.107 Taking into account the rules governing the burden of proof[80], the Panel in the first place considers that it should restrict its examination of the likeness of products in the context of Article III:4 to those products identified by Canada for which the parties provided evidence or made an adequate prima facie case to establish their likeness or their absence of likeness to chrysotile and products containing it.[81]

8.108 We note, that although friction products are mentioned, Canada does not include these in its comparisons relating to Article III:4. We therefore conclude that Canada does not intend the Panel to rule on the likeness of friction products containing chrysotile and other products.[82] We shall therefore not examine these products in our findings relating to the provisions of the GATT 1994.

8.109 Secondly, although Canada appears sometimes to consider that chrysotile fibre is simply an input and not a product *per se*, we note that the Decree refers to "varieties of asbestos fibres, … regardless of whether these substances have been incorporated into materials, products or devices". We also note that the two parties discussed the likeness of asbestos fibres as such, irrespective of the products into which they were incorporated.

8.110 Concerning the EC's argument that neither in the request for consultations nor in the request for the establishment of a panel nor in the Panel's terms of reference is it specified that the dispute concerns high-density cement products containing chrysotile, the Panel wishes to recall that it is not necessary for the request for the establishment of a panel to list all the products concerned in detail. The Panel also considers that the fact that Canada did not export high-density cement products containing chrysotile cannot constitute an obstacle to claims relating to these products.[83]

8.111 In the light of the foregoing, it would appear appropriate to structure our analysis as follows:

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[80] See in particular the reports of the Appellate Body in *Australia – Salmon*, op. cit. and *Japan – Agricultural Products*, op. cit..

[81] We are aware that Canada's claims (see para. 3.1 above) state that the Decree is incompatible with Article III:4 of the GATT 1994 because it "favours the national industry of products like chrysotile cement and chrysotile-cement products …" Moreover, our terms of reference are not confined to PVA, cellulose and glass fibres (see WT/DS135/3). We note, however, that Canada does not ask for findings on other fibres. We therefore limit our findings to the products for which we consider Canada had requested findings, namely, PVA, cellulose and glass fibres.

[82] See Annex II, Canada's reply to question 15 by the Panel, paras. 74 *et seq.*.

[83] See the Report of the Appellate Body in *European Communities – Bananas*, op. cit., para. 136, where it is mentioned that the potential export interest by the United States could not be excluded even though at that time the United States did not export bananas from their territory to the EC. See also the Report of the Panel in *Indonesia – Certain Measures Affecting the Automobile Industry*, adopted on 23 July 1998, WT/DS54, 55, 59, 64/R, para. 14.113.

(a) First of all, to examine whether PVA, cellulose and glass fibres, taken separately (i.e. not incorporated in a product), are products like to chrysotile fibre. Even if they are not a finished product, the fibres themselves are products which are exported and marketed and we believe it is relevant to compare them.

(b) Secondly, with regard to products containing asbestos or substitute fibres, we note that Canada confines its comparison to products combining cement and chrysotile ("chrysotile-cement") or one or the other of the three aforementioned fibres ("fibro-cement"). We shall therefore limit our findings to these categories.

(c) Lastly, we note that, although Canada makes a specific reference to and cites as an example certain products: pipes, tiles, insulating tiles or boards, it does not furnish an exhaustive list of the products actually affected by the measure and its claims are not arranged on a "product-by-product" basis. Canada refers in generic terms to two major categories of product: (a) chrysotile, PVA, cellulose and glass fibres; and (b) products combining chrysotile and cement or other fibres and cement. We also note that the EC does not distinguish between various fibro-cement or chrysotile-cement products. Even though the different products composed of chrysotile-cement or fibro-cement have different uses (water pipes, thermal insulation, roofing, etc.), we do not consider it necessary to identify each product manufactured in chrysotile-cement or fibro-cement because they are all composed of either fibro-cement or chrysotile-cement and the matters discussed by the parties concerning their likeness are essentially related to whether or not they contain chrysotile.

(d) Analysis of likeness

(i) Introductory remarks

8.112 We note that both Canada and the EC refer to the Report of the Working Party on *Border Tax Adjustments*, which, using the terms of the Appellate Body in *Japan – Alcoholic Beverages*, lays down the fundamental principle for interpreting the words "like products" in general in the various provisions of the GATT 1947. This Report states the following:

> " … the interpretation of the term ['like products'] should be examined on a case-by-case basis. This would allow a fair assessment in each case of the different elements that constitute a 'similar' product. Some criteria were suggested for determining, on a case-by-case basis, whether a product is 'similar': the product's end-uses in a given market: consumers' tastes and habits, which change from country to country; the product's properties, nature and quality".[84]

8.113 The Panel and the Appellate Body in *Japan – Alcoholic Beverages* recognized the relevance of this list and added tariff classification in the Harmonized System ("HS"). The Appellate Body also pointed out that the principle elaborated by the Working Party in *Border Tax Adjustments* had been followed in almost all the reports of subsequent panels. We note in this connection that the panel in *United States – Gasoline*, in the context of the GATT 1994, applied this principle when examining likeness in relation to Article III:4.[85]

8.114 Finally we note that in *Japan – Alcoholic Beverages* the Appellate Body reaffirmed that panels must use their best judgement when determining whether, products are in fact like products, and this would always inevitably involve a degree of discretionary judgement. The Appellate Body

[84] Op. cit., para. 18.
[85] Op. cit., paras. 6.8 and 6.9.

also confirmed that, when making an assessment, no single approach would be appropriate to every single case. The circumstances peculiar to each case must be taken into account. The criteria outlined in the report on *Border Tax Adjustments* should be examined, but there could be no precise and absolute definition of like.

8.115 We would add that even though, for reasons of clarity, each criterion has to be examined separately, it is more than likely that they are largely interdependent. In other words, it does not appear appropriate to examine each of the criteria in isolation. Our examination should be based on an assessment of each criterion in its context, that is to say in the light of the other criteria deemed relevant in this case.

8.116 Having defined the approach to be used, we commence our analysis by examining the likeness of fibres.

(ii) Likeness of asbestos fibres and substitute fibres

8.117 We note that, in their arguments, the parties have not always distinguished between fibres as such and products containing such fibres.[86] In this section, therefore, we shall examine the relevant criteria provided that they can be related specifically to the fibres.

Properties, nature and quality of the products

8.118 Canada considers that the nature of chrysotile and substitute fibres is the same because they are all fibres. Even if the length, diameter and width-diameter ratio have an effect on pathogenicity, this does not mean that fibres of different dimensions cannot be like fibres. The dimensional parameters set by the WHO do not constitute the criterion of the nature, quality and properties according to which the likeness of fibrous products is determined. Too much importance should not be attached to the special nature of asbestos fibres claimed by the EC. Even if substitute fibres are more costly than chrysotile fibres and have other uses, chrysotile-cement or fibro-cement manufacturers use them for the same purposes and the likeness of the manufacturing processes for chrysotile-cement and fibro-cement shows the similarities of the properties and the nature of these fibres. In order to offer the same technical guarantees as chrysotile-cement products (one of the conditions for substitutability in the Decree), fibro-cement products must indubitably have the same properties, quality and nature. Similarly, the "lower" pathogenicity of substitute fibres should not preclude the conclusion that they are like asbestos. Products may be considered like despite their differing impact on health. There is no contradiction between distinguishing two types of fibre in scientific terms and according to their pathogenicity, on the one hand, and, on the other, applying the criteria derived from WTO and GATT practice for determining whether products are like. The toxicity of a product is not recognized as a criterion for the evaluation of likeness.

8.119 The EC consider that the properties, nature and quality of products are important when assessing likeness within the meaning of Article III:4. Unlike other criteria, this criterion has always been used by panels in connection with Article III:4. In the light of this criterion, the products are in any case different. Asbestos fibres have a very particular fibrous texture (bundles of fibrils that can easily be separated lengthways and have a very small diameter). The physical and chemical characteristics of substitute fibres are not the same as those of asbestos fibres (for example, their diameter is much bigger and their fibrillation capacity is more limited). No single natural or synthetic substitute product is able to combine, or combines, all the properties of asbestos, bearing in mind the unique nature of the characteristics of asbestos fibres. These characteristics also make asbestos fibres particularly dangerous for health. Since 1977, the WHO has classified asbestos fibres in category 1 of

[86] See, for example, the arguments of the parties on the concept of "like products", Section III.C. 2(b)(i) above.

proven carcinogens. The EC point out that, in contrast, none of the substitute products for chrysotile asbestos is classified as a proven carcinogen for humans. The nature, composition, physical properties and proven effects on human health of chrysotile make it radically different from substitute products. In such a situation, the health risk posed by the product must necessarily be taken into account. A dangerous product should be regarded as being different in nature and quality from a harmless or less dangerous product.

8.120 The Panel considers that, in addition to the factual elements, the parties' arguments raise a first issue, namely, in what context should the criterion of the properties, nature and quality of the fibres be taken into account for the likeness test within the meaning of Article III:4? The parties in fact basically take up the question of the way in which the properties, nature and quality of the fibres should be taken into account by the Panel.

8.121 The Panel notes that no party contests that the structure of chrysotile fibres is unique by nature and in comparison with artificial fibres that can replace chrysotile asbestos. The parties agree that none of the substitute fibres mentioned by Canada in connection with Article III:4 has the same structure, either in terms of its form, its diameter, its length or its potential to release particles that possess certain characteristics.[87] Moreover, they do not have the same chemical composition[88], which means that, in purely physical terms, none of them has the same nature or quality. It could therefore be concluded that they are not like products.

8.122 It should be recalled, nevertheless, that the context for the application of Article III:4 is not a scientific classification exercise. The objective of Article III concerns market access for products.[89] Its purpose is to prevent internal measures from being applied in such a way as to protect domestic production.[90] Article III:4 upholds this objective in respect of laws, regulations and requirements affecting the sale, marketing, purchase, transportation, distribution and use of products on the domestic market. We also note that the criterion includes the concept of the "quality" of a product, which is indicative of a commercial approach, otherwise the word "quality" would no doubt have been used in the plural, in which case it would have been the same as "properties" in the sense of a particular quality of a product.[91] It is thus with a view to market access that the properties, nature and quality of imported and domestic products have to be evaluated.

8.123 Although we share Canada's view that all the products are "fibres" and thus like products, we do not consider that the examination of the physical structure and chemical composition (which in our view relate to the nature of the product) should be taken to the other extreme, even though it has been argued that other panels followed a narrower approach in this respect.[92] If such an approach was adopted, many products would never be like in respect of their nature, even if they had a similar use.

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[87] In this connection, we note the observation by one of the experts consulted by the Panel that the characteristics of some artificial substitute fibres can be altered by industry if necessary (Dr. Henderson, para. 5.383 above).

[88] Regarding the chemical composition of asbestos, see the table provided by the EC in reply to question 29 by the Panel, para. 106.

[89] See the Report of the Panel in *United States – Measures Affecting Alcoholic and Malt Beverages*, adopted on 19 June 1992, BISD 39S/206, para. 5.25.

[90] Ibid., para. 5.71. See also the Report of the Panel in *Italian Discrimination Against Imported Agricultural Machinery*, adopted on 23 October 1958, 7S/60, para. 11, and the Report of the Panel *United States – Section 337 of the Tariff Act of 1930*, adopted on 7 November 1989, 36S/345, para. 5.10.

[91] In this connection, we note that the English text of the Report on *Border Tax Adjustments*, op. cit., para. 18, uses the words "properties" and "quality".

[92] See the EC's arguments in para. 3.44 above concerning the Report of the Panel in *EEC – Measures on Animal Feed Proteins*, adopted on 14 March 1978, BISD 25S/49. The Panel does not consider that the factual elements peculiar to this affair and the conclusions of the Panel (see para. 4.2) make it possible to draw the conclusions suggested by the EC in the present case.

On the other hand, products which bore no relation to each other in terms of their use in everyday life could be considered as like products because of their chemical composition. As mentioned in para. 8.114 above, we note the need to evaluate these criteria on a case-by-case basis, in other words, bearing in mind the factual circumstances. In this particular case, because of its physical and chemical characteristics, asbestos is a unique product. We note, nevertheless, that for many industrial uses other products have the same applications as asbestos. If the chemical and physical characteristics were to be recognized as decisive in this case, we would have to disregard all the other criteria and this does not appear to us to be consistent with the flexibility given to panels by the Appellate Body when examining the principle of likeness.

8.124 As regards properties, we note that no substitute fibre alone combines all the properties and qualities of chrysotile fibre itself. Article 2, paragraph I, second sub-paragraph of the Decree recognizes this by basing the criteria for substitution *inter alia* on "all technical guarantees of safety corresponding to the ultimate purpose of the use thereof". A narrow interpretation of the concept of like product might perhaps lead us to exclude the likeness of products which do not always show the same properties in all circumstances. In the context of market access, it is not necessary for domestic products to possess all the properties of the imported product in order to be a like product. It suffices that, for a given utilization, the properties are the same to the extent that one product can replace the other. If the properties of products always had to be the same, the category of like products would be very small, sometimes even just one product. We note in this connection that the Panel in *Japan – Customs Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages*[93] considered that gin, vodka, whisky, brandy, liqueurs, still wine and sparkling wine should be considered as like products within the meaning of Article III:2 in view of their similar properties and end-uses[94] we consider that this Report upholds our approach. If products whose nature is not exactly the same and whose properties are not always identical, for example wine on the one hand and whisky on the other, can be considered like products, the same approach can be followed pursuant to Article III:4 for chrysotile fibres on the one hand and PVA, cellulose and glass fibres on the other.

8.125 In this case, even if the end-uses of chrysotile fibres on the one hand and PVA, cellulose and glass fibres on the other are only the same for a small number of their respective applications, in some cases the applications are similar. Their properties are then equivalent, if not identical. This is the juncture of interest to us, the moment when the products are used for the same purpose. As we have already mentioned above, the criteria proposed for determining likeness should not be examined in isolation. In this particular case, we consider that the end-use of the products should affect the way in which we examine the properties of the fibres compared, inasmuch as none of the fibres mentioned by Canada always fulfils the same functions.

8.126 We therefore conclude that, taking into account the properties criterion, chrysotile fibres are like PVA, cellulose and glass fibres. With regard to nature and quality, we consider that these criteria should not be applied narrowly in the factual circumstances of the present case. Consequently, the fact that chrysotile fibres do not have the same structure or chemical composition as PVA, cellulose or glass fibres cannot be decisive for the evaluation of the likeness of these products.

8.127 The second question that must be answered in relation to the application of the properties, nature and quality criterion is that of the relevance of the risk of the product raised by the EC.[95]

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[93] Adopted on 10 November 1987, BISD 34S/84, hereinafter "*Japan – Alcoholic Beverages (1987)*".

[94] Ibid., para. 5.6.

[95] We note that the EC draw attention to the risk posed by chrysotile fibres not only in connection with the properties, nature and quality criterion but also in relation to the end-use and the tastes and habits of consumers. In this subsection, however, we examine the criterion of the risk of a product inasmuch as the EC, in its arguments, referred to this criterion mainly in relation to the criterion of the properties, nature and quality of asbestos fibres. The conclusions of our examination, however, will apply to all the circumstances in which

8.128 The Panel has noted the EC's argument that the capacity of chrysotile fibres to break up into extremely fine particles that can penetrate the pulmonary alveoli gave these fibres a property which meant that they were not like because this property was the basis for chrysotile's potential to cause diseases of the lung and the pleura, mainly lung cancers and mesotheliomas.[96]

8.129 We note first of all that the risk of a product for human or animal health has never been used as a factor of comparison by panels entrusted with applying the concept of "likeness" within the meaning of Article III. In addition to the fact that no other panel has probably ever been called upon to examine a question similar to the one before us, in our view the reason is to be found in the *economy* of the GATT 1994. Its primordial role is to ensure that a certain number of disciplines are applied to domestic trade regulations. Article XX of the GATT, however, recognizes that certain interests may take precedence over the rules governing international trade and authorizes the adoption of trade measures aimed at preserving these interests while at the same time observing certain criteria.[97]

8.130 We consider that introducing a criterion on the risk of a product into the analysis of likeness within the meaning of Article III would largely nullify the effect of Article XX(b).[98] The protection of human health and life is specifically covered by this Article. Article III, on the other hand, does not refer to this. The burden of proof would not of course be greatly modified because the EC would still have to prove the risk of the product, applying the principle of *probatio incumbit ejus que dixit.* We nevertheless consider that other aspects that form part of the rights and obligations negotiated by the Members would be affected. Introducing the protection of human health and life into the likeness criteria would allow the Member concerned to avoid the obligations in Article XX, particularly the test of necessity for the measure under paragraph (b) and the control exerted by the introductory clause to Article XX concerning any abuse of Article XX(b) when applying the measure. As the Appellate Body has emphasized on a number of occasions[99], all these provisions in the WTO Agreement must be given meaning. Introducing a risk criterion into the examination of likeness under Article III would be contrary to this basic principle of interpretation.

8.131 Finally, if such a criterion was applied, it would make all the other criteria mentioned by the Working Party on *Border Tax Adjustments*[100] totally redundant because it would become decisive when assessing the likeness of products in every case in which it was invoked, irrespective of the other criteria applied.

8.132 We therefore conclude that, bearing in mind the overall economy of the WTO Agreement, in particular the relationship between Article III and Article XX(b), it is not appropriate to apply the "risk" criterion proposed by the EC, neither in the criterion relating to the properties, nature and quality of the product, nor in the other likeness criteria invoked by the parties.

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the EC refer to the risk of a product in relation to the determination of likeness within the meaning of Article III:4 of the GATT 1994.

[96] Mesothelioma is a form of pleural cancer. See for example the description by Dr. Henderson, para. 5.29 above.

[97] See the report of the Panel in *Canada – Measures on Export of Unprocessed Herring and Salmon*, adopted on 22 March 1988, BISD 35S/98, para. 4.6.

[98] See the discussion on the concept of effectiveness, footnote 22 above.

[99] See in particular *Argentina – Safeguards,* op. cit; *Brazil – Desiccated Coconut,* op. cit.

[100] See para. 8.112 above.

End-use

8.133 Canada considers that, given the nature of chrysotile fibre (a raw mineral resource), special importance must be attached to the criterion of the product's end-use. Chrysotile fibre has no use in its raw form. After incorporation into the cement, chrysotile fibre and PVA, cellulose and glass fibres are used for the manufacture of chrysotile-cement and fibro-cement products respectively. At the end-use stage, these products constitute one single product to be used for the same purpose. According to Canada, applying the end-use criterion suffices to conclude that chrysotile fibres and the aforementioned substitute fibres are like products. If end-use is a key criterion for determining whether two products are directly competitive or substitutable pursuant to Article III:2, it is equally important for likeness. It is the market which determines the end-use of a product.

8.134 According to the EC, the end-uses of these fibres are different and this criterion is not decisive when determining "likeness" within the meaning of Article III:4, which is essentially "technical". Even where products may have some end-uses in common, these uses are not sufficient to classify the products as like products when each of them also has many other end-uses. The criterion of end-use could not, by itself, invalidate the conclusion based on other criteria that these products are not like products within the meaning of Article III:4 of the GATT 1994.

8.135 The Panel notes that Canada limited its arguments to the use of chrysotile in cement products and, at the same time, to the use of PVA, cellulose and glass fibres in cement products.

8.136 We have already found above[101] that the respective properties of chrysotile fibres on the one hand and PVA, cellulose or glass fibres on the other allowed certain identical or at least similar end-uses. We do not therefore deem it necessary to elaborate this further, except to recall that, in our view, the fact that all the end-uses of these fibres are not like uses does not mean that the products are not like products.

Consumers' tastes and habits

8.137 As regards consumers' tastes and habits, Canada is of the view that manufacturers of chrysotile-cement or fibro-cement products are the consumers. The drop in chrysotile asbestos imports in 1996 and 1997 is a result of the Decree and not of a change in consumers' tastes and habits. It is thus inappropriate to consider this criterion. Canada agrees with the practice of panels cited by the EC[102], and asks the Panel not to take into account consumers' tastes and habits when determining the likeness of products in this case.

8.138 In the view of the EC, the consumers' tastes and habits criterion is not a priori relevant because the products concerned are not everyday consumer goods. It might nevertheless be interesting to analyse the consumers' perception of these products. Informed users will not choose asbestos after the competent international organizations have decided that it is a proven carcinogen.

8.139 We note first of all that the parties do not consider it useful or necessary for us to take this criterion into account. In our view, this is not in itself sufficient reason for us not to take it into account. We do not agree either, that, in view of Article III:4, there are reasons for excluding consideration of this criterion a priori.[103] We consider that it is up to the Panel to decide whether one

[101] See para. 8.125 above.

[102] These cases are cited in para. 3.446 above and in the corresponding footnotes.

[103] In the cases cited by the EC – to which Canada also refers – we do not find any legal reasons relating to Article III:4 to justify excluding the criterion of consumers' tastes and habits. In *Measures Affecting Alcoholic and Malt Beverages* (adopted on 19 June 1992, BISD 39S/206), para. 5.73, the panel indeed did not agree that low alcohol beer and high alcohol beer were like products on the basis of consumers' tastes and habits, but it did nevertheless use this criterion. In *EEC – Measures on Animal Feed Proteins* (adopted on

of the criteria applicable to determining the "likeness" of the products concerned is relevant or not.[104] What is important is to ensure that our analysis takes into account all the relevant elements. In this particular case, we note first of all that, when determining the tastes and habits of consumers, it is necessary to place oneself at the time prior to the entry into force of the ban in the Decree. Even if we do place ourselves prior to that date, however, it would be difficult to determine precisely what were the tastes and habits of consumers at that time. The groups of consumers to be taken into account are very varied and their tastes and habits based on an equally wide variety of considerations. Because this criterion would not provide clear results, the Panel considers that it is not relevant to take it into account in the special circumstances of this case.

8.140 We shall therefore refrain from taking a position on the impact of this criterion on the likeness of the products considered.

Tariff classification

8.141 As regards tariff classification, Canada recalls that the 107 six or eight-digit codes for chrysotile-cement products in the Harmonized Commodity Description and Coding System of the Customs Cooperation Council[105] are identical to the 107 codes for fibro-cement products.

8.142 The EC consider that the tariff classifications are different, whether for asbestos fibres and substitute fibres or for products containing asbestos and substitutes for asbestos. For example, in the Harmonized System, asbestos fibres are classified in their own heading.

8.143 We do not consider that the fact that asbestos fibres are classified in their own heading is decisive in this case. PVA, cellulose and glass fibres respectively are also classified in different tariff headings. We note, however, that such a classification reflects the difference in their nature, whether they are mineral or vegetable, artificial or natural. We have already found that this factor did not affect the fact that their properties and end-use are the same under certain circumstances.[106]

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14 March 1978, BISD 25S/49), para. 4.2, the panel did not exclude the applicability of consumers' tastes, noting:

> "[…] in this case, such factors as the number of products and tariff items carrying different duty rates and tariff bindings, the varying protein contents and the different vegetable, animal and synthetic origins of the protein products before the Panel – not all of which were subject to the EEC measures".

In view of the terms used by the panel in this case, it does not seem that the panel in principle rejected the relevance of consumers' tastes and habits. In *United States – Gasoline*, op. cit., even though the panel did not mention the criterion of consumers' tastes and habits in its conclusions in para. 6.9, in para. 6.8 it nonetheless recalled the applicability under Article III:4 of the criteria summarized by the Working Party in *Border Tax Adjustments*, op. cit., which include consumers' tastes and habits. We have not found any reason either to restrict the meaning of the word "consumers" solely to the end-consumers of chrysotile-cement products, i.e. individual consumers.

[104] See the Report of the Appellate Body in *Japan – Alcoholic Beverages*, op. cit., p. 24.

[105] Hereinafter "Harmonized System" or "HS".

[106] Asbestos in its natural state falls in heading 25.24. Polyvinyl alcohol falls in heading 39.05, cellulose in 39.12 and glass fibre in 70.19. We note that in *Japan – Alcoholic Beverages (1987)*, the Panel referred to the "Nomenclature of the Customs Cooperation Council (CCCN) for the classification of goods in customs tariffs". We also note that the Appellate Body in *Japan – Alcoholic Beverages* op. cit. p. 24 reaffirmed that that tariff classification, if sufficiently detailed, was a useful basis for confirming the likeness of products. We note that in this case the parties based themselves on the tariff classification in the Harmonized System, and not on tariff bindings, which the Appellate Body urges should be used with caution. We do not consider however, that the particular circumstances of this case justify that, when determining the likeness or absence of likeness of asbestos, PVA, cellulose and glass fibres, overriding significance should be attached to the fact that the products fall in different tariff headings of the HS.

Conclusion

8.144 Above we concluded that chrysotile fibres, on the one hand, and PVA, cellulose and glass fibres, on the other, are, in certain circumstances, similar in properties, nature and quality. We also concluded that these products have similar end-uses. From this it follows that chrysotile fibres, on the one hand, and PVA, cellulose and glass fibres, on the other, are like products within the meaning of Article III:4 of the GATT 1994.

(iii) Likeness between products containing asbestos and certain other products

8.145 The Panel considers that many of the arguments put forward in relation to asbestos, PVA, cellulose and glass fibres are applicable *mutatis mutandis* to products containing those fibres. Thus, if a fibro-cement product, for example, a tile, is compared with a similar tile of chrysotile-cement, the only difference between the products concerned is the presence of either chrysotile or a substitute fibre in the tile, the product itself being a tile and the other component of the material being in both cases cement. It is the presence of chrysotile or some other fibre that gives the cement product its specific function: mechanical strength, resistance to heat, compression, etc.

8.146 Moreover, we note that, in Canada's opinion, chrysotile-cement and fibro-cement products are both industrial products which cannot be distinguished on the basis of their external appearance. From the standpoint of the tastes and habits of the French consumer, they are interchangeable. According to the EC, informed users would not use products containing asbestos after the international organizations had decided that asbestos was a proven carcinogen.

8.147 Consequently, we consider that in fact the likeness between a chrysotile-cement product and a fibro-cement product depends on two factors: (a) the nature of the product itself and (b) the presence of chrysotile fibres or of PVA, cellulose or glass fibres in the product.

8.148 Using the criteria adopted by the Panel and the Appellate Body in *Japan – Alcoholic Beverages*, we note, first of all, that the HS tariff classification (heading 68.11) is the same for articles of asbestos-cement, of cellulose fibro-cement or the like. This heading covers hardened articles consisting essentially of an intimate mixture of fibres (for example, asbestos, cellulose or other vegetable fibres, synthetic polymer or glass fibres) and cement or other hydraulic binders, the fibres acting as strengthening agents. Other products may fall into different tariff headings. However, many of the products mentioned by Canada appear to fall within this subdivision.[107]

8.149 We consider, moreover, that one of the EC's main arguments against the likeness between fibro-cement and chrysotile-cement products with respect to their properties, nature and quality and their end-use is based on the risk associated with the chrysotile which they contain. To the extent that in paragraph 8.132 we concluded that the "risk" criterion cannot be included among the criteria

[107] In fact, the HS Explanatory Notes describe the products that fall within heading 68.11 ("Articles of asbestos-cement, of cellulose fibro-cement or the like") as follows:

> "This heading covers hardened articles consisting essentially of an intimate mixture of fibres (for example, asbestos, cellulose or other vegetable fibres, synthetic polymer, glass or metallic fibres) and cement or other hydraulic binders, the fibres acting as strengthening agents. […]
>
> The heading includes sheets of all sizes and thicknesses, obtained as described above, and also articles made by cutting these sheets or by pressing, moulding or bending them before they have set, e.g., roofing, facing or partition sheets and tiles; sheets for making furniture; window sills; sign-plates, letters and numbers; barrier bars; corrugated sheets; reservoirs, troughs, basins, sinks; tubing joints; packing washers and joints; panels imitating carving; ridge tiles, gutters, window frames; flower-pots; ventilation or other tubing, cable conduits; chimney cowls, etc.
>
> All these articles may be coloured in the mass, varnished, printed, enamelled, decorated, drilled, filed, planed, smoothed, polished or otherwise worked; they may also be reinforced with metal, etc."

applicable to the determination of likeness under Article III:4, we do not consider it necessary to discuss the applicability of this criterion with respect to chrysotile-cement products. The same applies with respect to consumers' tastes and habits.

8.150 We therefore conclude that chrysotile-fibre products and fibro-cement products are like products within the meaning of Article III:4 of the GATT 1994.

(e) Less favourable treatment of Canadian products[108]

8.151 With respect to the existence of less favourable treatment, Canada argues that the Decree alters the conditions of competition between, on the one hand, substitute fibres and products containing them of French origin and, on the other hand, chrysotile fibre and products containing it from Canada. The Decree does not afford chrysotile fibre imported from Canada and products containing it effective equality of opportunities for imported products in respect of the application of laws, regulations and requirements affecting the internal sale, offering for sale, purchase, transportation, distribution or use of products. Not only does the ban apply only to asbestos fibre and products containing it but it is applicable only if there are products like to chrysotile fibre or to the products containing it. Thus, the Decree imposes less favourable treatment in all cases where like products exist. Accordingly, the Decree constitutes *de jure* discrimination between chrysotile fibres and products containing them, on the one hand, and like products (PVA, cellulose or glass fibres and fibro-cement products containing them), on the other.

8.152 Canada also alleges de facto discrimination. The French PVA fibres industry is in better shape than ever. Moreover, it is not because France has imported a marginal additional quantity of Canadian cellulose fibres that the French domestic industry has not benefited from the ban. The Decree does indeed impose a choice on the French consumer who is now prevented from using chrysotile fibre or products containing it.

8.153 The EC maintain that the contested measure accords with the fundamental purpose of Article III, which is to prevent protectionism, and is not discriminatory, neither *de jure* nor de facto, inasmuch as it guarantees effective equality of opportunities for domestic and imported products. The context in which the Decree was adopted and its provisions show that the intention of the French authorities was in no way to protect domestic substitute products but to protect human health against the risks associated with asbestos. They also show that the Decree makes no distinction between imported and domestic products, whether it be a question of substitute or asbestos products, and that neither its object nor its effect is to protect domestic production. The Decree does not create any de facto discrimination, since in France most substitute products are imported from various third countries. Moreover, France has a negative trade balance in substitute products. The ban on the use of asbestos on public health grounds has required a painful changeover, in human and financial terms, including the loss of external outlets for French industry. Finally, the Decree is "neutral" in respect of the choices that businesses can make concerning replacement products.

8.154 We note that with regard to the establishment of the existence of less favourable treatment, it is first necessary to determine, as we have done, whether there is a likeness between the imported and the domestic products. Above, both with regard to chrysotile fibres, on the one hand, and PVA, cellulose and glass fibres, on the other[109], and with regard to products made of chrysotile-cement, on the one hand, and fibro-cement, on the other, we concluded that they were "like" within the meaning of Article III:4. With respect to the treatment of these products as compared with the like domestic

[108] The arguments of the parties are set out in detail in Section III above.

[109] We note, incidentally, that Canada has not made any allegation concerning the less favourable treatment of Canadian chrysotile fibres as compared with domestic chrysotile fibres. Accordingly, we shall not make any finding in this respect.

products, we note, first of all, that France does produce substitutes for chrysotile fibres and chrysotile-cement products. We next note that the terms of the Decree in themselves establish less favourable treatment for asbestos and products containing asbestos as compared with substitute fibres and products containing substitute fibres. Thus, paragraphs I and II of Article 1 of the Decree read as follows:

> "I. For the purpose of protecting workers, and pursuant to Article L. 231-7 of the Labour Code, the manufacture, processing, sale, import, placing on the domestic market and transfer under any title whatsoever of all varieties of asbestos fibres shall be prohibited, regardless of whether these substances have been incorporated into materials, products or devices.
>
> II. For the purpose of protecting consumers, and pursuant to Article L. 221.3 of the Consumer Code, the manufacture, import, domestic marketing, exportation, possession for sale, offer, sale and transfer under any title whatsoever of all varieties of asbestos fibres or any product containing asbestos fibres shall be prohibited."

8.155 Inasmuch as the Decree does not place an identical ban on PVA, cellulose or glass fibre and fibro-cement products containing PVA, cellulose or glass fibres, we must conclude that *de jure* it treats imported chrysotile fibres and chrysotile-cement products less favourably than domestic PVA, cellulose or glass fibre and fibro-cement products.

8.156 Having established *de jure* discrimination on the basis of the Decree and, moreover, the European Communities not having submitted any evidence that might lead us to believe that the Decree is applied in such a way as not to introduce less favourable treatment for chrysotile fibres and chrysotile-cement products as compared with PVA, cellulose and glass fibres and fibro-cement products containing PVA, cellulose or glass fibres[110], we do not consider it necessary to determine whether there is any *de facto* discrimination between these products.

8.157 For these reasons, we conclude that the Decree applies to chrysotile and chrysotile-cement products a treatment less favourable than that which it applies to PVA, cellulose and glass fibres and products containing them, within the meaning of Article III:4.

(f) Conclusion

8.158 On the basis of the above, we find that the provisions of the Decree relating to the prohibiting of the marketing of chrysotile fibres and chrysotile-cement products violate Article III:4 of the GATT 1994.

3. Violation of Article XI of the GATT 1994

8.159 In the light of our observations on the applicability of Article III:4 of the GATT 1994 to the border measures imposed on chrysotile fibres and chrysotile-cement products and considering our findings with regard to the violation of Article III:4 by the Decree, we conclude that it is not necessary to examine the Canadian argument concerning the violation of Article XI:1 of the GATT 1994.

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[110] See the Report of the Panel in *United States – Sections 301-310 of the Trade Act of 1974*, op. cit., para. 7.27.

4. Applicability of Article XX of the GATT 1994

(a) Arguments of the parties[111]

8.160 The European Communities contend that the Decree falls under the exception provided in Article XX of the GATT 1994. Thus, the Decree is necessary to achieve the French Government's public health goals under Article XX(b) and is not applied in such a manner as to constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or a disguised restriction on international trade, within the meaning of the introductory clause of Article XX.

8.161 Canada notes that, in accordance with panel and Appellate Body practice, Article XX permits a limited and conditional exception from the obligations set out in the other Articles of the GATT and must be interpreted narrowly. Although the European Communities assert that they have the right to establish the level of protection they desire, in so doing they must comply with their obligations. In this connection, the Appellate Body has condemned abuse of rights under Article XX. Moreover, it is up to the European Communities to demonstrate that the Decree falls under Article XX(b).

8.162 The European Communities argue that asbestos fibres and products containing them are a proven hazard for human health. The risks linked to the use of these fibres are recognized both by scientists and international organizations. By prohibiting the marketing and use of asbestos and asbestos-containing products, the Decree seeks to halt the spread of these risks, in particular for people occasionally and often unwittingly exposed to asbestos, and thereby reduce the number of deaths among the French population. It is the only measure capable of preventing the spread of the risks due to asbestos exposure. According to the EC, the review in the light of Article XX cannot be allowed to undermine the health protection goal set by the Member concerned. Its sole purpose must be to assess whether the trade measure adopted is necessary to attain that goal. This test concerns the trade measure and not the level of protection set by the Member.

8.163 Canada considers that the only exposures that could be affected by the Decree are exposures to chrysotile encapsulated in high-density products. In order to determine whether there is an equally effective alternative that is less restrictive for international trade and that is capable of protecting human life or health just as effectively, the health risk can and must be examined. Otherwise any country could cite the risk – real or not – in support of a prohibition measure.

8.164 Canada is of the opinion that the current uses of chrysotile do not constitute a detectable risk to human health. According to Canada, the European Communities do not explain that the exposures of secondary users are essentially to friable materials, very often containing amphiboles, which are no longer marketed and have been in place for a long time. Contrary to what the EC appear to believe, controlled use substantially reduces exposure. As a result of pre-fabrication, pre-machining, the use of fittings and compliance with work standards, workers are not subjected to high levels of exposure, as the EC claim.

8.165 Canada considers that, inasmuch as the only risk associated with asbestos is that of the past use of amphiboles and the use of friable materials, the Decree, which prohibits the contemporary uses of chrysotile, is not "necessary" to protect human life or health from the risks associated with past uses of asbestos. A ban is not "necessary" because high-density chrysotile products do not pose any detectable risk. On the other hand, controlled use indisputably constitutes an alternative to a total ban that is significantly less restrictive for international trade.

[111] The arguments of the parties are set out in detail in Section III above.

(b) Approach adopted by the Panel and burden of proof

(i) Introductory remarks concerning the approach adopted by the Panel

8.166 At this stage, the Panel wishes to point out that, inasmuch as Article XX provides for a certain number of exceptions to the rules of the GATT 1994, it is necessary and sufficient to examine the applicability of these exceptions solely with regard to measures[112] and in relation to products for which a violation of another provision of the GATT has been identified. In the present case we have found that the Decree violates Article III:4 of the GATT 1994 as regards the treatment accorded to imported chrysotile asbestos fibres as compared with PVA, cellulose and glass fibres. We have also found a violation of Article III:4 with respect to the treatment of chrysotile-cement products as compared with fibro-cement products containing PVA, cellulose or glass fibres.

8.167 In accordance with the approach noted by the Panel in *United States – Gasoline*[113] and the Appellate Body in *United States – Import Prohibition of Certain Shrimp and Shrimp Products*[114], we will first examine whether the measure falls within the scope of paragraph (b) of Article XX, the provision expressly invoked by the European Communities.[115] If we decide that it does, we will consider whether, in its application, the Decree satisfies the conditions of the introductory clause of Article XX.

8.168 First of all, as regards Article XX(b), we find that the provisions of this paragraph relevant to the present case require that, subject to fulfilment of the conditions of the introductory clause of Article XX, nothing in the GATT 1994 shall be construed to prevent the adoption or enforcement by any Member of measures

> "(b) necessary to protect human … life or health"

8.169 The Panel notes that in *United States – Gasoline*, the Panel stipulated that with respect to Article XX(b), the party invoking that provision must prove:

> (a) That the policy in respect of the measures for which Article XX is invoked falls within the range of policies designed to protect human life or health; and
>
> (b) the inconsistent measures for which the exception is invoked are necessary to fulfil the policy objective.[116]

8.170 As regards subparagraph (a), we consider that, inasmuch as they include the notion of "protection", the words "policies designed to protect human life or health" imply the existence of a *health risk.* We must therefore determine, on the basis of the relevant rules of evidence, whether

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[112] See the Report of the Appellate Body in *United States – Gasoline*, op. cit., pp. 14-15 and 17-18. In the present case, it is the part of the Decree relating to the prohibiting of the placement on the French market of chrysotile asbestos and products containing it that has been found contrary to Article III:4 of the GATT 1994 (see paras. 8.155 and 8.158 above). It is this same "measure" that we shall examine in the light of Article XX(b).

[113] Op. cit., para. 6.20.

[114] Adopted 6 November 1998, WT/DS58/AB/R, paras. 118-122.

[115] In this connection, we note that it is not for the Panel to examine on its own initiative the exceptions for which Article XX provides unless they have been invoked (see Report of the Panel in *United States – Restrictions on Imports of Tuna*, DS21/R (unadopted), 3 September 1991, BISD 39S/155, para. 5.27, citing the Report of the Panel in *EEC – Regulation on Imports of Parts and Components*, adopted 16 May 1990, 37S/132, para. 5.11). However, it is only necessary to determine that the measure in question satisfies the conditions of one of the paragraphs of Article XX and the introductory clause of the same article for that measure to be justified under Article XX of the GATT 1994.

[116] Report of the Panel in *United States – Gasoline*, para. 6.20.

chrysotile-asbestos, in the various forms we have considered so far, poses a risk to human life or health.

8.171 This said, we note that the panel in *United States – Gasoline* also made clear that it did not have to examine the necessity of the policy goal.[117] In other words, we do not have to assess the choice made by France to protect its population against certain risks, nor the level of protection of public health that France wishes to achieve. We must simply determine if the French policy of prohibiting the use of chrysotile-asbestos falls within the range of policies designed to protect human life or health.

8.172 As regards the criterion of the *necessity* of the measure (subparagraph (b) of paragraph 8.169), we note that previous panels that had to assess the "necessity" of a measure under Article XX(b) appear to have done so solely in relation to the existence of other measures consistent or less inconsistent with the GATT in the light of the health objective pursued. Thus, in *Thailand – Cigarettes*, the Panel ruled that:

> "The import restrictions imposed by Thailand could be considered to be "necessary" in terms of Article XX(b) only if there were no alternative measure consistent with the General Agreement, or less inconsistent with it, which Thailand could reasonably be expected to employ to achieve its health policy objectives".[118]

8.173 In this particular case, the public health objectives pursued by Thailand were confirmed by a WHO expert and accepted by the parties to the dispute. In the present case, Canada does not deny that France's goal, namely to protect the health of workers and consumers, is a public health objective, but it disputes the existence of a public health problem in relation to chrysotile. Thus, Canada denies that chrysotile fibre poses a public health risk in its applications because once in place chrysotile-cement does not release any fibres and because it is possible to work with chrysotile-cement products in a safe or controlled fashion.

8.174 For the Panel, the assessment of the necessity of a measure could be focused on the existence of other measures consistent or less inconsistent with the GATT 1994 if, as in previous cases, the parties were agreed on the *existence and extent of the health problem associated with chrysotile*. In this respect, we note that Canada does not dispute that chrysotile fibres in themselves pose health risks. However, Canada does not consider that any risk is posed by chrysotile enclosed in a matrix of high-density cement.

8.175 Consequently, inasmuch as the parties disagree on the extent of the health risk posed by chrysotile-cement products, we consider that our examination of the existence of a general health objective in the light of subparagraph (a) of paragraph 8.169 should include the question of the existence of a health problem in relation (i) to chrysotile fibres as such and (ii) to chrysotile-cement products.[119]

8.176 This being so, we shall have to take expressly into account the extent of the health problem in assessing the necessity of the measure. Thus, if we were to conclude that the health hazard

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[117] Ibid., para. 6.22. See also the Report of the Panel in *United States – Section 337*, op. cit., para. 5.26 and the Report of the Panel in *Thailand – Restrictions on Importation of and Internal Taxes on Cigarettes*, adopted on 7 November 1990, BISD 37S/200 (hereinafter "*Thailand – Cigarettes")*, para. 74.

[118] Op. cit., para. 75.

[119] Our approach does not affect the possibility of each Member determining what level of risk it wishes to assure. Guaranteeing a very low risk of exposure when the health risks are high might require strict measures, but when the health risk is low a very low level of exposure might be obtainable with less severe measures. This comment is made in full awareness of the fact that particularly serious risks can sometimes be neutralized by very simple means.

represented by chrysotile or chrysotile-cement was less than the EC allege, less vigorous measures might then be justified.[120]

(ii) Burden of proof

General considerations

8.177 With regard to the burden of proof, we refer, first of all, to our previous remarks concerning those cases in which a party invokes a defence.[121] We consider that the reasoning of the Appellate Body in *United States – Shirts and Blouses from India*[122] is applicable to Article XX, inasmuch as the invocation of that Article constitutes a "defence" in the sense in which that word is used in the above-mentioned report. It is therefore for the European Communities to submit in respect of this defence a prima facie case showing that the measure is justified. Of course, as the Appellate Body pointed out in *United States – Gasoline*, the burden on the European Communities could vary according to what has to be proved. It will then be for Canada to rebut that prima facie case, if established.

8.178 If we mention this working rule at this stage, it is because it could play a part in our assessment of the evidence submitted by the parties. Thus, the fact that a party invokes Article XX does not mean that it does not need to supply the evidence necessary to support its allegation. Similarly, it does not release the complaining party from having to supply sufficient arguments and evidence in response to the claims of the defending party. Moreover, we are of the opinion that it is not for the party invoking Article XX to prove that the arguments put forward in rebuttal by the complaining party are incorrect until the latter has backed them up with sufficient evidence.[123]

Considerations specific to the burden of proof as regards the scientific aspects

8.179 As pointed out above, three essential elements must be considered by the Panel when examining the justification of a measure in the light of Article XX(b): (a) the existence of a risk for human health; (b) the level of protection which the Member concerned wishes to achieve; and (c) the existence of other measures consistent or less inconsistent with the GATT 1994 and enabling the same objective of protecting public health to be obtained. The Panel considers that its examination of the scientific data should be exclusively concerned with points (a) and (c), inasmuch as it has long been established that Members are free to set the level of protection of their choice for their populations.[124]

8.180 The Panel has therefore had to determine how it should assess the existence of a health risk in relation to chrysotile and, more particularly, chrysotile-cement and the necessity of the measures in question. The Panel has examined the practice in relation to Article XX of the GATT 1994, but also in the context of other WTO Agreements in which scientific studies are invoked, mainly the

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[120] In this case, the justification for less severe measures would not be the existence of less inconsistent measures that meet the objectives originally set by the EC, but the fact that the risk was actually lower than the EC had estimated.

[121] See Section VIII.E.1(b) above.

[122] Op. cit., pp. 15-16:

"We acknowledge that several GATT 1947 and WTO panels have required such proof of a party invoking a defence such as those found in Article XX[122] or Article XI:2(c)(i)[122], to a claim of violation of a GATT obligation, such as those found in Articles I:1, II:1, III or XI:1. Articles XX and XI:2(c)(i) are limited exceptions from obligations under certain other provisions of the GATT 1994, not positive rules establishing obligations in themselves. They are in the nature of affirmative defences. It is only reasonable that the burden of establishing such a defence should rest on the party asserting it."

[123] See Report of the Appellate Body in *European Communities – Hormones*, op. cit., para. 104.

[124] See para. 8.171 above. See also the Report of the Appellate Body in *United States – Gasoline*, op. cit., p. 33.

Agreement on Sanitary and Phytosanitary Measures.[125] The Panel noted that the SPS Agreement contains more detailed provisions than Article XX with respect to the scientific justification of a sanitary or phytosanitary measure[126] and that these provisions have been the subject of clarifications by panels and by the Appellate Body.[127] However, it also noted that in the first dispute settlement proceedings initiated under the WTO Agreement concerning Article XX of the GATT 1994, the Appellate Body had not sought to extend the principles of the SPS Agreement to the examination of the measures for which Article XX(b) had been invoked or even to base itself on them, although the SPS Agreement was already in force.[128] The Panel preferred to confine itself to the provisions of the GATT 1994 and to the criteria defined by the practice relating to the application of Article XX.

8.181 In this context, in relation to the scientific information submitted by the parties and the experts, the Panel feels bound to point out that it is not its function to settle a scientific debate, not being composed of experts in the field of the possible human health risks posed by asbestos. Consequently, the Panel does not intend to set itself up as an arbiter of the opinions expressed by the scientific community.

8.182 Its role, taking into account the burden of proof, is to determine whether there is sufficient scientific evidence to conclude that there exists a risk for human life or health and that the measures taken by France are necessary in relation to the objectives pursued. The Panel therefore considers that it should base its conclusions with respect to the existence of a public health risk on the scientific evidence put forward by the parties and the comments of the experts consulted within the context of the present case. The opinions expressed by the experts we have consulted will help us to understand and evaluate the evidence submitted and the arguments advanced by the parties.[129] The same approach will be adopted with respect to the necessity of the measure concerned.

8.183 In proceeding with this exercise, the Panel will have to make a pragmatic assessment of the scientific situation and the measures available, as would the decision-makers responsible for the adoption of a health policy.[130] In this connection, it notes that the determination of the existence of other measures consistent or less inconsistent with the GATT largely depends on a scientific assessment of the risk.[131] In any event, this determination cannot be interpreted as restricting the freedom of Members to take certain measures rather than others under Article XX(b), in the absence of a measure that would be consistent or less inconsistent with the GATT 1994.

(c) Application of Article XX(b) of the GATT 1994 to the Decree

(i) "Protection of human life and health"

8.184 In accordance with the approach defined by the Panel in *United States – Gasoline*, we must first establish whether the policy in respect of the measure for which the provisions of Article XX(b) were invoked falls within the range of policies designed to protect human life or health. As we have

[125] Hereinafter the "SPS Agreement".

[126] See, in particular, Articles 2.2, 3 and 5 of the SPS Agreement.

[127] See, in particular, the Reports of the Panels and Appellate Body in *European Communities – Hormones*, op. cit.

[128] In *European Communities – Hormones*, op. cit., para. 115, the Appellate Body itself expressed its reluctance to adopt within the context of the SPS Agreement a standard of review not clearly rooted in the text of the SPS Agreement, for fear of disturbing the balance between the rights and obligations negotiated.

[129] Report of the Appellate Body in *Japan – Agricultural Products*, op. cit., para. 129. At this point, we recall that the experts were selected in consultation with the parties and that the latter did not challenge the appointment of any of them, although they reserved the right to comment on their statements. With respect to the various stages in the selection and consultation of the experts, see Section V.A and B.

[130] See Report of the Panel in *United States – Gasoline*, op. cit., para. 6.20.

[131] See paras. 8.173-176.

already pointed out, the use of the word "protection" implies the existence of a risk. Accordingly, we must begin by identifying a risk for public health. In the light of the comments of the panel in *United States – Gasoline* and our own remarks in paragraph 8.182, we must also take into account the fact that it is a public health policy that we have to assess.

8.185 First of all, we note that the EC argue that in prohibiting the placing on the market and use of asbestos and products containing it, the Decree seeks to halt the spread of the risks due to asbestos, particularly for those exposed occasionally and very often unwittingly to asbestos when working on asbestos-containing products. France considers that it can thereby reduce the number of deaths due to exposure to asbestos fibres among the French population, whether by asbestosis, lung cancer or mesothelioma.[132]

8.186 In principle, a policy that seeks to reduce exposure to a risk should fall within the range of policies designed to protect human life or health, insofar as a risk exists. According to the EC, the international scientific community appears to be generally of the opinion that chrysotile fibres as such are carcinogens. In this connection, we note the EC's argument that, since 1977, the International Agency for Research on Cancer (IARC) has classified chrysotile among the proven carcinogens.

8.187 Canada does not dispute that chrysotile asbestos causes lung cancer. However, Canada argues that the mechanism that could give rise to an increased risk of lung cancer has not yet been fully explained and that the link with chrysotile might only be indirect.[133] This risk depends on the intensity and duration of the exposure. On the other hand, according to Canada, there is a great deal of scientific evidence to support the thesis according to which chrysotile does not cause mesotheliomas.[134] In particular, the mesotheliomas linked to asbestos could be the result of exposure to low-density products containing amphiboles. It has not been established that, in their uses, chrysotile fibres pose the same risk as amphiboles, whose chemical composition, in particular, is different.

8.188 First of all, we note that the carcinogenicity of chrysotile fibres has been acknowledged for some time by international bodies.[135] This carcinogenicity was confirmed by the experts consulted by the Panel, with respect to both lung cancers and mesotheliomas[136], even though the experts appear to acknowledge that chrysotile is less likely to cause mesotheliomas than amphiboles.[137] We also note that the experts confirmed that the types of cancer concerned had a mortality rate of close to 100 per cent.[138] We therefore consider that we have sufficient evidence that there is in fact a serious carcinogenic risk associated with the inhalation of chrysotile fibres. Moreover, in the light of the comments made by one of the experts[139], the doubts expressed by Canada with respect to the direct effects of chrysotile on mesotheliomas and lung cancers are not sufficient to conclude that an official

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[132] With regard to the group of pathologies that asbestos can cause, see Dr. Henderson, para. 5.28.

[133] See Annex II, Canadian reply to the EC's question No. 4, para. 180.

[134] See Annex II, Canadian replies to the EC's questions nos. 1-4, paras. 175-181.

[135] Since 1977 by the IARC (see *List of Agents Carcinogenic to Humans, Overall Evaluations of Carcinogenicity to Humans*, Monographs of the International Agency for Research on Cancer, Volumes 1-63), see also WHO, *IPCS Environmental Health Criteria (203) on Chrysotile*, Geneva (1998), cited in para. 5.584 above. On the development of knowledge of the risks associated with asbestos, see Dr. Henderson, para. 5.595.

[136] See, in particular, Dr. Henderson, paras. 5.29 to 5.34; 5.142 to 5.165; Dr. Infante, paras. 5.267, 5.290-5.298; Dr. de Klerk, para. 5.288.

[137] See, for example, the ratios suggested by Dr. Henderson, paras. 5.103, 5.141, 5.415, 5.589 and his remarks, paras. 5.265-5.266; see also Dr. de Klerk, para. 5.264; Dr. Infante, paras. 5.267-5.268 and Annex VI, para. 19 of the transcript of the meeting with experts.

[138] Dr. Henderson, meeting with experts, Annex VI, para. 182.

[139] See the comments made by Dr. Henderson, paras. 5.153-5.157 concerning the link between fibrosis and lung cancer.

responsible for public health policy would find that there was not enough evidence of the existence of a public health risk.

8.189 We note, however, that Canada makes a distinction between chrysotile fibres and chrysotile encapsulated in a cement matrix. In fact, Canada challenges the Decree insofar as it prohibits, *inter alia*, the use of chrysotile-cement products. In this connection, we note that the experts consulted by the Panel agreed that the risks of fibres being dispersed due to the degradation of chrysotile-cement were limited. However, the experts acknowledged that working with non-friable products containing chrysotile might result in the dispersion of large quantities of fibres and that those fibres pose a definite health risk.[140] The experts also noted that even though the risk might be lower than for production or processing workers, it concerned a much larger group.[141]

8.190 In this respect, the Panel notes that the European Communities have stated that the Decree is intended, in particular, to protect categories of workers or consumers downstream of the asbestos mining or processing stage, whatever the frequency and level of their exposure. Canada considers that below a certain exposure threshold there is no detectable health risk. Accordingly, Canada believes that people only occasionally exposed are not running a detectable risk.

8.191 The data submitted to the Panel by the EC show that the use of tools not specifically designed to prevent the release of fibres[142], which cannot be excluded, especially in the case of DIY enthusiasts[143] or professionals who work only occasionally in an environment where asbestos is present, can result in an exposure in excess of the statutory limits under ISO 7337[144], which are themselves higher than those of the WHO (0.2 fibre/ml) or those applied by France before the ban (0.1 fibre/ml).[145] The Panel also notes the position of the experts consulted on this point. All agree that building workers now count among those most exposed to chrysotile fibres and hence to the risk of mesothelioma[146], but they also mention cases of mesothelioma in patients who had been only

[140] See the replies of the experts to the Panel's question 1.(b), paras. 5.196-5.209.

[141] See Dr. Henderson, paras. 5.176, 5.183; Dr. de Klerk, para. 5.185.

[142] In reply to a question by Canada (see Annex II, para. 167) the EC indicated that the question of the exposure associated with working intermittently with material such as chrysotile-cement had been analysed in the report of the *Institut national de la science et de la recherche medicale* (INSERM) entitled *Rapport sur les effets sur la santé des principaux types d'exposition à l'amiante* (Report of the health effects of the main types of exposure to asbestos, INSERM joint report, 1997, pp. 193-214. The EC appended to their first written submission to the Panel exposure values measured during such working (see *Note de présentation des orientations du Conseil supérieur de prévention des risques professionnels*, 3 July 1995). They also give the example of a roofing worker using a grinder in the open air to repair corrugated roof sheeting made of asbestos-cement and exposed to a peak level of 41f/ml. In this connection, the Panel also notes the reference by Dr. Henderson, in para. 5.199 above, to a study by Kamugai S, Nakachi S, Kurumatani N. *et al. Estimation of Asbestos Exposure Among Workers Repairing Asbestos Cement Pipes Used for Conduits*, Sangkyo Igaku 1993; 35.

[143] By "DIY enthusiast" (bricoleur) the Panel means someone who does small repair and renovation jobs (Le Nouveau Petit Robert (1994), p. 261) without engaging in these activities in a professional capacity.

[144] See International Organization for Standardization, ISO 7337 (1984).

[145] See Decree 96-98 of 7 February 1996. The European Communities, in para. 3.134, note, for example, that in the case of a handsaw application of the ISO standard leaves the worker exposed to a level 30 times in excess of the maximum limit of 0.1 f/ml. In this connection, the Panel notes that the experts agree that at least some of the fibres released during operations on products containing chrysotile present the same carcinogenicity as chrysotile fibres not incorporated in cement (see Dr. de Klerk, para. 5.220; Dr. Henderson, paras. 5.221-5.224; Dr. Infante, paras. 5.225–5.226).

[146] See *Full Public Report: Chrysotile Asbestos – Priority Existing Chemical No. 9*, National Industrial Chemicals Notification and Assessment Scheme (NICNAS), National Occupation Health and Safety Commission (NOHSC), Australia 1999 (hereinafter "NICNAS 99"), cited by Dr. Henderson, which shows that exposure is spreading. Originally confined to workers in the traditional industries, exposure to asbestos now extends to products and the domestic and external environment (see para. 5.179). Similar observations have

incidentally exposed, without any relation to their occupational activity.[147] The scientists consulted by the Panel also considered that the existence of a threshold below which exposure does not present any risks had not been established for any of the diseases attributable to chrysotile, except perhaps for asbestosis.[148]

8.192 The Panel took note of Canada's argument according to which there has been no study specifically concerned with the occupational sectors to which the EC refer.[149] It also notes that Canada disputes the relevance of the data of the studies of Charleston textile factory workers (United States)[150] as compared with the Canadian studies of Quebec asbestos sector miners and workers, which are said to show the limited impact of chrysotile on public health.[151] However, the scientific experts consulted stressed the relevance and quality of the Charleston study. On the other hand, doubts were expressed with regard to the reliability of certain exposure data in the studies carried out in occupational and non-occupational environments in Quebec and invoked by Canada.[152] Canada also refers to a study concerned with car brake maintenance.[153] We note that the scientists consulted drew attention to the limits of this study and produced statistical data which, on the contrary, confirmed the impact of chrysotile on mechanics exposed to that material in a car brake maintenance context.[154]

8.193 The Panel therefore considers that the evidence before it tends to show that handling chrysotile-cement products constitutes a risk to health rather than the opposite. Accordingly, a decision-maker responsible for taking public health measures might reasonably conclude that the presence of chrysotile-cement products posed a risk because of the risks involved in working with those products.

8.194 Accordingly, the Panel concludes that the EC has made a prima facie case for the existence of a health risk in connection with the use of chrysotile, in particular as regards lung cancer and

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been made in the United Kingdom with regard to the patterns of exposure and the resultant diseases (para. 5.180).

[147] See the example of the fireman and the lecturer whose exposure was not connected with their occupations, given by Dr. Henderson, para. 250 of the transcript of the meeting with experts.

[148] See Dr. Henderson, para. 5.312. Concerning the opinion of the experts with regard to the absence of a threshold, see paras. 5.306 et seq. and, more particularly, Dr. Infante, para. 5.315.

[149] The absence of a study on the impact of chrysotile on building workers was confirmed by the scientists consulted by the Panel (see Dr. Infante, para. 137; Dr. Henderson, para. 140; Dr. Musk, para. 202 of the transcript of the meeting with experts, Annex VI). Concerning Canada's arguments and the comments of the experts, see the discussion of the relevance of the study of Charleston textile factory workers (hereinafter "Charleston study", see footnote 150) as compared with the study of Quebec asbestos mine and mill workers (hereinafter "Quebec workers study", see footnote 151), paras. 135–153 of the transcript of the meeting with experts, Annex VI.

[150] See, in particular, Dement J.M., Brown D.P., Okun A., *Follow-up Study of Chrysotile Asbestos Textile Workers: Cohort Mortality and Case-Control Analyses*, Am J Ind Med 1994; 26; Dement J. M., Brown D.P., *Lung Cancer Mortality among Asbestos Textile Workers: A Review and Update*, Ann Occup Hyg 1994; 38.

[151] See, in particular, McDonald A.D., Case B.W., Churg A., *et al.*, *Mesothelioma in Quebec Chrysotile Miners and Millers: Epidemiology and Aetiology*, Ann Occup Hyg 1997, 41. With respect to non-occupational situations, see Camus M., Siemiatycki J., Meek B., *Nonoccupational Exposure to Chrysotile Asbestos and the Risk of Lung Cancer*, New England Journal of Medicine 1998, 338.

[152] See the comments of Dr. Infante on the Quebec workers study by McDonald et al, para. 19 of the transcript of the meeting with experts, Annex VI, and those of Dr. Henderson, paras. 5.118 and 5.158–5.162 above.

[153] See Woitowitz H.J., Rödelsperger K., *Mesothelioma among Car Mechanics?* Ann Occup Hyg, 1994.

[154] See Dr. Henderson, paras. 59, 89 and 101 of the transcript of the meeting with experts, Annex VI. We note that Canada has not formulated a specific request with regard to friction products, such as car brakes, for example.

mesothelioma in the occupational sectors downstream of production and processing and for the public in general in relation to chrysotile-cement products. This prima facie case has not been rebutted by Canada. Moreover, the Panel considers that the comments by the experts confirm the health risk associated with exposure to chrysotile in its various uses. The Panel therefore considers that the EC have shown that the policy of prohibiting chrysotile asbestos implemented by the Decree falls within the range of policies designed to protect human life or health. On the other hand, Canada has not succeeded in rebutting the presumption established on the basis of the evidence submitted by the EC and confirmed by the experts. The Panel concludes therefore that the French policy of prohibiting chrysotile asbestos falls within the range of policies designed to protect human life or health, within the meaning of Article XX(b) of the GATT 1994.

8.195 Accordingly, the Panel will now turn to the question of whether the measure is "necessary" within the meaning of Article XX(b).

(ii) "Necessary"

The ban on chrysotile asbestos in its various forms

8.196 According to the European Communities, the danger of inhaling asbestos at levels above 0.1 fibre/ml concerns not only the asbestos mining and processing sectors but, more especially, secondary (textile, building and automobile industry, for example), para-occupational (servicing, maintenance) and domestic (DIY) workers whom Canada mentions only in part or not at all. Even in production and processing, which in principle are easier to monitor, there are limits to the controlled or safe use of asbestos, which does not halt the spread of the risks. So-called "controlled" or "safe" use is *a fortiori* completely ineffective in cases of occasional exposure to asbestos. The 1997 INSERM report[155] indicates that the risk occurs mainly among those who work with materials containing asbestos. The encapsulation of asbestos in a matrix cannot be guaranteed to make asbestos-cement products harmless, inasmuch as any subsequent working of the product will release large numbers of carcinogenic fibres in the form of dust. Controlled use is impossible to implement where hundreds of thousands of people are involved in sectors as unregulated in terms of health as the building industry. The 1984 ISO standard is inadequate in relation to the French health objective. The EC also note that, once asbestos is on the market, there is no reasonable way of controlling its use and, in particular, of controlling the everyday operations that many people are likely to perform. Moreover, the numerous, particularly legal obstacles which confront the victims of current exposure seeking redress in the courts constitute an additional social justification for resorting to a total ban.

8.197 With regard to the test of necessity, Canada takes the same approach as in connection with Article 2.2 TBT[156], considering that in many respects the test of necessity is similar in the two provisions. According to Canada, the measure must not be an excessive or over-reaching means to achieve a legitimate end. The two factors to be considered are, on the one hand, the risks that the absence of a technical regulation would create and, on the other, the existence of a less trade-restrictive alternative measure that would make it possible to fulfil the stated objective. As far as the second test is concerned, Canada notes that the controlled use of asbestos fibres allows fulfilment of the French objective of protecting human health while authorizing certain safe or controlled uses of chrysotile and products containing it. As controlled use is a less trade-restrictive alternative based on scientific data and having international support, a total ban on asbestos is not necessary. Canada is of the opinion that, today, high-density non-friable products do not pose a detectable risk. The risks which existed in the past and in certain cases still exist today are associated with past uses, very often

[155] INSERM: *Rapport sur les effets sur la santé des principaux types d'exposition à l'amiante*, INSERM joint report, 1997. This report was submitted by the European Communities as one of the underpinnings of the measure adopted by France.

[156] See Canada's arguments, paras. 3.279 *et seq* above.

of amphiboles in friable materials. In Canada's view, the EC are trying to mislead the Panel by invoking the risks of the asbestos mining and processing industry, even though they have already recognized that controlled use is effective here in eliminating the risk. The EC also show bad faith in citing the risks for building maintenance workers and mechanics. The EC do not explain that these exposures are essentially to friable materials very often containing amphiboles with a high pathogenic potential. Controlled use is effective and can be accepted by professionals. According to the data of the *United States Occupational Safety & Health Administration* (OSHA), the institution of control measures lowers the average exposures of workers handling asbestos-cement pipes to 0.00253 f/ml and those of workers handling asbestos-cement sheets to 0.00727 f/ml. The average exposure of mechanics handling friction products is 0.00294 f/ml. Moreover, the use of pre-machined parts and fittings has been a big success. It reduces field activities and, at the same time, exposure rates.

8.198 We note that in *Thailand – Cigarettes* the Panel defined the test of necessity applicable under Article XX(b):

> "The import restrictions imposed by Thailand could be considered to be 'necessary' in terms of Article XX(b) only if there were no alternative measure consistent with the General Agreement, or less inconsistent with it, which Thailand could reasonably be expected to employ to achieve its health policy objectives."[157]

8.199 This test has been applied in other disputes[158], in order to apply the test defined in *Thailand – Cigarettes*, we must (a) establish *the scope* of the health policy objectives pursued by France and (b) consider the existence of measures consistent, or less inconsistent, with the GATT 1994.

8.200 First of all, we note that the risk due to chrysotile is important to the extent that, as confirmed in the previous section, it can generate lung cancers and mesotheliomas which are still difficult to cure or even incurable.[159] The populations potentially at risk in France are very numerous, since products containing chrysotile, in particular, chrysotile-cement, have many applications in industrial, commercial and residential buildings. The fields of activity concerned include building workers (several hundred thousand) and DIY enthusiasts[160] These are areas in which health controls are difficult to apply, as the comments of the experts have shown.[161]

8.201 The experts also confirmed that the intensive use of asbestos (in France, mainly chrysotile) over several decades has resulted in the risks of exposure being displaced from the mining and processing industry towards other sectors further downstream and, indeed, the general public.[162] In this context, the Panel finds that the European Communities have shown that a risk exists for a very broad sector of the French population.

8.202 The Panel notes that the exposure of these groups is generally lower. However, the experts confirm the position of the European Communities according to which it has not been possible to identify any threshold below which exposure to chrysotile would have no effect.[163] The experts are also agreed that the linear relationship model, which does not identify any minimum exposure

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[157] BISD 37S/200, para. 75.

[158] See, for example, the Report of the Panel in *United States – Section 337*, op. cit., para. 5.26, and the Report of the Panel in *United States – Gasoline*, op. cit., para. 6.24.

[159] See Dr. Henderson, para. 5.29 and the transcript of the meeting with experts, Annex VI, end of para. 182.

[160] See Dr. Infante, para. 5.183; Dr. de Klerk, para. 5.185.

[161] See Dr. Infante for the United States (para. 161 of the transcript of the meeting with experts); Dr. de Klerk and Dr. Henderson for Australia (paras. 222 and 225, respectively, of the transcript of the meeting with experts).

[162] See Dr. Henderson, paras. 5.174–5.181; Dr. Infante, paras. 5.182-5.183, 5.190.

[163] See Dr. Henderson, para. 5.312; Dr. Infante, paras. 5.313-5.315.

threshold, is appropriate for assessing the existence of a risk.[164] We find therefore that no minimum threshold of level of exposure or duration of exposure has been identified with regard to the risk of pathologies associated with chrysotile, except for asbestosis. Consequently, the possibility remains that low exposure over a fairly long period of time could lead to lung cancer or mesothelioma. Similarly, high-level exposure over a short period could also result in lung cancer or mesothelioma. These two possibilities were confirmed by the experts.[165] The Panel therefore concludes that even though some trades or the French population in general are only intermittently exposed to low levels of asbestos, a decision-maker responsible for public health policy might reasonably conclude that there was nevertheless a real risk for these categories.

8.203 In the light of the above, the Panel concludes that, in addition to the risk presented by low-density friable products, there is an undeniable public health risk in relation to the chrysotile contained in high-density chrysotile-cement products. This risk exists even at low or intermittent exposure levels and can affect a broad section of the population.

8.204 We also note that France's objective is to halt the spread of this risk which, considering the risk identified and its extent, could in principle justify strict measures. However, it is necessary to consider whether there is not, as Canada alleges, a measure that would be consistent, or less inconsistent, with the GATT 1994 and would allow the objective pursued by France to be achieved. Canada refers to the possibility of controlled use which consists in taking precautionary measures to restrict the release of fibres (use of special tools, high-density products and special methods of handling asbestos products) and protect the airways and in adopting methods of decontaminating equipment and work clothing. This controlled or safe use would be based on international standards.

8.205 We note that, according to the EC, controlled use does not work in certain occupational sectors such as those connected with building.[166] Moreover, if the international standards suggested by Canada (in particular, ISO 7337) were applied, the exposure rate would still be higher than the level of risk that France considers acceptable.[167] The EC also stress that the consistent or less inconsistent measures must be "technically and economically feasible."[168]

8.206 We note that the EC do not dispute that controlled use could constitute a measure consistent, or less inconsistent, with the GATT 1994. They nevertheless consider that it would not allow the public health objectives pursued by France to be achieved. Insofar as Canada refers solely to controlled or safe use as an alternative to outright prohibition, we will focus our attention on this possibility.[169] However, before continuing with our analysis of whether measures consistent, or less inconsistent, with the GATT are available in the present case, we consider it pertinent, in the light of the contradictory arguments put forward by the parties, to return to the question of the applicability of the feasibility test suggested by the EC.

8.207 We note that in *United States – Section 337*, the Panel stated that:

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[164] See Dr. de Klerk, para. 5.317; Dr. Henderson, para. 5.318; Dr. Infante, paras. 5.321-5.323; Dr. Musk, para. 5.324.

[165] See, for example, Dr. Infante, para. 5.304.

[166] See, in particular, Annex II, reply by the EC to Canada's question No. 6, para. 168

[167] See Annex II, reply by the EC to Canada's question No. 5, para. 167.

[168] The European Communities refer to Article 5.6 of the Agreement on the Application of Sanitary and Phytosanitary Measures. They consider that the principle incorporated in that provision should also be applied in the context of Article XX.

[169] In this respect, we note that the experts likewise did not mention any alternatives other than controlled use. Moreover, in the light of the approach defined by the Appellate Body in *Australia – Salmon*, op. cit. (see Section VIII E.1.(b) above), we consider that we do not need to ascertain whether other measures were possible.

> "A contracting party cannot justify a measure inconsistent with another GATT provision as 'necessary' in terms of Articles XX(d) if an alternative measure *which it could reasonably be expected to employ* and which is not inconsistent with other GATT provisions is available to it. By the same token, in cases where a measure consistent with other GATT provisions *is not reasonably available*, a contracting party is bound to use, *among the measures reasonably available to it*, that which entails the least degree of inconsistency with other GATT provisions."[170]

We therefore find that in order to determine whether a measure is necessary it is important to assess whether consistent or less inconsistent measures are *reasonably* available. The term "reasonably" has not been defined as such by the panels that have referred to it in the context of Article XX. It suggests, however, that the availability of a measure should not be examined theoretically or in absolute terms. Nevertheless, in the light of the reasoning of these panels, we find the word "reasonably" should not be interpreted loosely either. The fact that, administratively, one measure may be easier to implement than another does not mean that the other measure is not reasonably available.[171] We consider that the existence of a reasonably available measure must be assessed in the light of the economic and administrative realities facing the Member concerned but also by taking into account the fact that the State must provide itself with the means of implementing its policies. Thus, the Panel considers that it is legitimate to expect a country such as France with advanced labour legislation and specialized administrative services to deploy administrative resources proportionate to its public health objectives and to be prepared to incur the necessary expenditure.

8.208 After clarifying this point, we will now proceed to examine whether controlled use (a) is sufficiently effective in the light of France's health policy objectives and (b) whether it constitutes a reasonably available measure.

8.209 In relation to the first of these considerations, we note, first of all, that although controlled use is applied in some countries, such as the United States or Canada, and has also been applied by France, in general in certain sectors its efficacity still remains to be demonstrated. This is confirmed by a number of studies[172], as well as by the comments of the experts.[173] Thus, even though it seems possible to apply controlled use successfully upstream (mining and manufacturing) or downstream (removal and destruction) of product use, it would seem to be much less easy to apply it in the building sector, which is one of the areas more particularly targeted by the measures contained in the Decree. The Panel therefore concludes that, in view of the difficulties of application of controlled use, an official in charge of public health policy might reasonably consider that controlled use did not provide protection that was adequate in relation to the policy objectives.

8.210 Moreover, Canada refers to the existence of international standards for the protection of workers in contact with chrysotile.[174] First of all, we find that the international standards cover only the precautions to be taken if a worker has to handle asbestos. They contain neither a guarantee of free access for asbestos nor an incentive to use asbestos. On the contrary, the international conventions suggest that, as far as possible, asbestos should be replaced by less hazardous materials.[175] Next, we note that the levels of protection obtained by following international standards, whether it be the ISO standard or the WHO Convention, are lower than those established by France, including those applicable before the introduction of the Decree. Considering the high level of risk

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[170] Op. cit., para. 5.26.

[171] See *United States – Gasoline*, op. cit., paras. 6.26 to 6.28.

[172] See Peto *et al: Continuing Increase in Mesothelioma Mortality in Britain, The Lancet*, volume 345, 535-539 (1995). See also Dr. Henderson, citing EHC 203, paras. 5.365-5.368; Dr. Infante, paras. 5.351-5.352 and 5.369.

[173] See the comments of the experts on controlled use and its feasibility, paras. 5.335-5.373.

[174] See, for example, ISO 7337.

[175] See International Labour Organization, Geneva, Convention Concerning Safety in the Use of Asbestos (hereinafter "Convention 162", adopted on 24 June 1986).

identified, France's objective – which the Panel cannot question -[176] justifies the adoption of exposure ceilings lower than those for which the international conventions provide. We therefore find that controlled use based on international standards would not seem to make it possible to achieve the level of protection sought by France.

8.211 The Panel is aware that in some sectors controlled or safe use could be envisaged with greater certainty that it would prove effective. However, as confirmed by the experts[177], the circumstances of use must be controllable. These circumstances are extremely varied and we note that the safety measures that would make possible results at least equivalent to the exposure level (0.1 f/ml) applied by France before the ban (restrictions on the number of workers and working areas and total containment of the product) exceed the requirements of the international standards and considerably limit the number of industrial sectors that could apply them.[178] Even in these cases, according to one of the experts, the level of exposure is still high enough for there to be a significant residual risk of developing asbestos-related diseases.[179] According to another, it is not possible to guarantee that fibre concentrations will never exceed 0.1 f/ml.[180] In addition, we note that for the application of controlled use to satisfy France's public health objectives, mined or processed products should never be handled by anyone outside the mining and processing industries. If these products were subsequently to be handled by unprotected persons, the fact that they could be mined and processed and then destroyed using controlled use techniques would not be sufficient to meet those objectives. We therefore find that a decision-maker responsible for establishing a health policy might have reasonable doubts about the possibility of ensuring the achievement of France's health policy objectives by relying on controlled use, even in sectors which might lend themselves more readily to these practices.[181]

8.212 *A fortiori* and for the following reasons, we consider that controlled use is not a reasonably available alternative in all the other sectors in which workers may be exposed to chrysotile.

8.213 The Panel notes that Canada's arguments under Article III:4 are limited to chrysotile and chrysotile-cement products. In fact, chrysotile-cement is mainly used in the building sector. As the experts have confirmed, because of the mobility of the workers and their sometimes inadequate training, as well as the large number of sites and therefore of people liable to exposure, it is very difficult to impose on the building sector sophisticated occupational safety practices of the type that can be applied in sectors with smaller numbers of workers concentrated in well-defined areas.[182]

8.214 Moreover, while controlled use may seem difficult to apply in the building sector, it is even less feasible in the case of DIY enthusiasts or undeclared workers operating outside any proper framework or system of controls. France's objective is to halt the spread of the risks associated with chrysotile. At least as far as DIY enthusiasts are concerned, controlled use is not a reasonably available option. In this context, the fact that controlled use might be reasonably available in other

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[176] See *United States – Gasoline*, op. cit., para. 6.22. The Panel also notes that XX(b) does not impose the same constraints as Article 3.3 of the SPS Agreement on Members wishing to apply measures that involve a level of protection higher than that which would be obtained with measures based on the relevant international standards.

[177] Dr. Henderson, paras. 5.336-5.341.

[178] Ibid., paras. 5.337-5.339.

[179] Dr. Infante, para. 5.343 referring to an opinion given by the United States Occupational Safety and Health Administration (OSHA). See also Dr. Infante, paras. 5.358-5.362.

[180] Dr. Henderson, paras. 5.355-5.357.

[181] In any event, in the light of the opinion of one of the experts (Dr. Henderson, para 5.658 and footnote), the sectors in which effective controlled use is feasible appear to be extremely few and concern applications for which, at this stage, there are no chrysotile substitutes, an area in which the Decree provides for exceptions to the prohibition on the use of chrysotile.

[182] We note that the experts' comments relate to countries with a level of economic development equivalent to that of France and with similar administrative resources.

sectors is irrelevant. Here, we are concerned with a product that could be installed in people's homes, not one limited to a restricted use in areas in which only professionals would be required to work. Insofar as, once the products have been installed, it is impossible to guarantee that they will not be handled by someone who will not follow controlled use practices, it seems to us that a decision-maker responsible for adopting a health policy might well conclude that there was still a flaw in the health protection system if only controlled use measures were applied.[183]

8.215 Canada also points out that, even though their use might not be limited to occupational activities, some products will never be handled by unqualified people. The Panel notes, however, that, as it found in paragraphs 8.200-8.202 above, exposure to asbestos fibres is not restricted exclusively to workers or DIY enthusiasts. Others present while the work is going on, in some cases even spouses, could be directly or indirectly affected.[184] As one of the experts has shown, exposure to asbestos may be the result of pure chance.[185]

8.216 Moreover, the Panel notes that products containing chrysotile may remain in place for very long periods of time. Thus, every time they are handled, the handler could be exposed. The continued marketing of products containing chrysotile asbestos multiplies the situations in which workers are routinely exposed and exposes them to concentrations of asbestos which have already been related to pathologies in humans.[186] In other words, even if the exposure rates are very low, the multiplication of sources of exposure may lead to concentrations already found to have caused disease.

8.217 We therefore conclude that the European Communities have shown that controlled use is neither effective nor reasonably available, at least in the building sector and for DIY enthusiasts. Accordingly, controlled use does not constitute a reasonable alternative to the banning of chrysotile asbestos that might be chosen by a decision-maker responsible for developing public health measures, bearing in mind the objectives pursued by France.

Recourse to substitute fibres and products

8.218 Canada argues that France is creating a false sense of security by requiring chrysotile, whose effects are well known, to be replaced by products whose effects on health are uncertain.

8.219 The European Communities argue that the Decree does not recommend the indiscriminate use of substitute products. It leaves it to businesses to replace asbestos by whichever product they choose. In view of the procedure laid down in Article 2 of the Decree, the replacement of asbestos fibres by substitute fibres is the result of a reasonable and justified process.

8.220 The Panel notes, first of all, that the risk posed by chrysotile is recognized internationally[187], which in itself may justify the taking of measures to restrict its use. On the other hand, we find that the substitute fibres examined in the context of this case (PVA, cellulose and glass) are not classified by the WHO at the same level of risk as chrysotile. Moreover, the experts consulted by the Panel who commented in detail on the risks associated with the substitute fibres examined in the context of this case (PVA, cellulose and glass) and other fibres, (in particular aramid and ceramic) confirmed that

[183] See the experts' comments on this subject: Dr. de Klerk, para. 5.335; Dr. Henderson, para. 5.341; Dr. Infante, para 5.343.

[184] See the studies cited by Dr. Infante, para. 5.304.

[185] See the examples of the lecturer and the fireman mentioned by Dr. Henderson during the meeting with experts, para. 250, Annex VI.

[186] See Dr. Infante, para. 5.315.

[187] See IARC classification, op. cit.

these fibres did not present the same risk to health as chrysotile.[188] In particular, animal studies do not show the fibres in question to be carcinogenic.[189]

8.221 Canada's approach seems to be based on the fact that chrysotile can be used safely. As we have already concluded, this does not appear to be a reasonably available possibility, at least as far as building workers and DIY enthusiasts are concerned. If we were to follow Canada's reasoning, then substitute fibres could not be used until a degree of certainty equivalent to that which exists with respect to chrysotile had been established. In the opinion of the Panel, to make the adoption of health measures concerning a definite risk depend upon establishing with certainty a risk already assessed as being lower than that created by chrysotile would have the effect of preventing any possibility of legislating in the field of public health. In fact, it would mean waiting until scientific certainty, which is often difficult to achieve, had been established over the whole of a particular field before public health measures could be implemented.

Conclusion

8.222 In the light of France's public health objectives as presented by the European Communities, the Panel concludes that the EC has made a prima facie case for the non-existence of a reasonably available alternative to the banning of chrysotile and chrysotile-cement products and recourse to substitute products. Canada has not rebutted the presumption established by the EC. We also consider that the EC's position is confirmed by the comments of the experts consulted in the course of this proceeding.

8.223 At this stage, we conclude that the Decree satisfies the conditions of Article XX(b) of the GATT 1994.

(d) Application of the introductory clause (chapeau) of Article XX of the GATT 1994 to the application of the Decree

(i) "Means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail"

8.224 With regard to the introductory clause of Article XX, the EC point out that it applies to the manner in which the measure is applied. In the present case there is nothing to support the contention that France acted "in bad faith" or in an "unreasonable", "improper" or "abusive" manner in exercising its right under Article XX(b). The ban is not a means of imposing arbitrary or unjustifiable discrimination between countries where the same conditions prevail. It covers products originating in any country, including France, where the same conditions prevail. The European Communities consider that, as the Decree does not meet the definition of discrimination laid down by the Appellate Body, it cannot be applied in such a manner as to constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail.

8.225 Canada claims that it has already shown, in respect of Article III:4, that the initial Decree was discriminatory. The Decree is also arbitrary and unjustified because it is not motivated by the objective of protecting human life or health but rather by the desire to reassure a panicked population.

8.226 The Panel notes that under the first of the alternatives mentioned in the introductory clause of Article XX it is required to examine whether the *application* of the Decree constitutes a means of

[188] See Dr. de Klerk, paras. 5.375-5.377; Dr. Henderson, para. 5.385; Dr. Infante, para. 5.388.
[189] See Dr. Musk, para. 5.390.

arbitrary or unjustifiable discrimination between countries where the same conditions prevail.[190] The Panel considers that, within the context of this alternative, its first step should be to determine whether the measure is "discriminatory" in its application.[191] If the application of the measure is found to be discriminatory, it still remains to be seen whether it is *arbitrary* and/or *unjustifiable* between countries where the same conditions prevail. It is in this context, and not in the stage of the existence of discrimination – which is an objective fact, that we shall determine whether the measures falling within the particular exceptions of Article XX(b) – in this case the initial Decree as applied – have been applied reasonably, with due regard to both the legal duties of the party claiming the exception and the legal rights of the other parties concerned.[192]

8.227 The Panel also notes that, in *United States – Gasoline*, the Appellate Body stated that the word "discrimination" in the introductory clause of Article XX covers both discrimination between products from different supplier countries and discrimination between domestic and imported products. Finally, in the same case, the Appellate Body ruled that "the provisions of the chapeau [of Article XX] cannot logically refer to the same standard(s) by which a violation of a substantive rule has been determined to have occurred."[193] In other words, we cannot conclude that discrimination exists on the basis of the violation of Article III:4 identified above. This means that the less favourable treatment of asbestos as compared with substitute fibres identified by Canada is not relevant for establishing the existence of discrimination under Article XX. The question is therefore confined to the suppliers of asbestos, whether domestic or foreign. However, we understand that another form of discrimination, for example between supplier countries, not invoked by Canada as its principal argument, could be taken into consideration under the introductory clause of Article XX. It is on this dual basis that we shall examine whether the measure is being applied in a "discriminatory" manner.

8.228 The Panel notes that the European Communities consider the Decree to concern products originating in any country, including France, where the same conditions prevail. The text of the Decree as such appears to confirm this. Only the product in question is mentioned, without any reference to its origin. Even Articles 2 and 3, which concern the establishment and administration of exceptions, do not contain any expressly discriminatory provision. It should be borne in mind, however, that the introductory clause of Article XX concerns the application of the measure. It would therefore be possible for Canadian exports of chrysotile or products containing it to receive less favourable treatment than imports from other countries or French production with respect to the way in which the exceptions are administered by the French authorities. For example, the minister responsible might use the powers of notice under Article 3:III of the Decree to discriminate against an operator qualifying for an exception who imports chrysotile fibres from Canada. However, we note that Canada has not argued that this was or had been the case. Canada merely recalls that it has demonstrated the existence of discrimination under Article III:4. For the reasons set out above, we consider that this demonstration is not relevant in terms of the introductory clause of Article XX.

8.229 We therefore conclude that, although this is a heavier task than that involved in showing that an exception falling within one of the paragraphs of Article XX encompasses the measure at issue, the

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[190] See the Reports of the Appellate Body in *United States – Gasoline*, op. cit., p. 25, and *United States – Shrimp*, op. cit., para. 115.

[191] The Panel considers that what is prohibited by the introductory clause to Article XX is a particular form of discrimination (that which is arbitrary or unjustifiable between countries where the same conditions prevail) and not all forms of discrimination. If the measure is not discriminatory in general in its application, then *a fortiori* it cannot constitute arbitrary or unjustifiable discrimination between countries where the same conditions prevail. See also the Report of the Panel in *United States – Imports of Certain Automotive Spring Assemblies*, adopted on 26 May 1983, BISD 30S/107 (hereinafter "*United States – Automotive Springs*"), para. 55.

[192] Report of the Appellate Body in *United States – Gasoline*, op. cit., p. 22.

[193] Ibid.

EC have made a prima facie case for their argument that the Decree does not constitute, in its application, arbitrary or unjustifiable discrimination. We do not consider that Canada has rebutted the presumption established by the prima facie case made by the EC, according to which the Decree does not introduce discrimination.

8.230 In accordance with our approach, since discrimination has not been established in relation to the application of the Decree, there is no need to consider the question of its arbitrariness or unjustifiability.

(ii) "Disguised restriction on international trade"

8.231 According to the EC, the Decree does not constitute a "disguised restriction on international trade". The EC consider that the fact that the Decree is not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination is proof enough that it is not being applied in a manner which constitutes a disguised restriction on international trade. In particular, the EC point out that the restriction was published, that many other Members of the WTO also apply restrictions on these products and that the restriction takes international standards as a base. Any other approach would imply that all legislation on asbestos and asbestos-containing products, in so far as it imposes restrictions, amounts to a "disguised restriction on international trade".

8.232 Canada considers that the Decree is a "disguised restriction on international trade". The Appellate Body has excluded a narrow reading of the term "disguised restriction". The fact that the measure was published does not prevent it from being a disguised restriction on international trade. The Decree is contrary to the introductory clause of Article XX in the sense that, under the cover of a public health decision, it favours the French national industry of substitute products for chrysotile and products containing it.

8.233 The Panel notes, first of all, that the actual scope of the words "disguised restriction on international trade" has not been clearly defined. Under the GATT 1947, panels seem mainly to have considered that a disguised restriction on international trade was a restriction that had not been taken in the form of a trade measure or had not been announced beforehand[194] or formed the subject of a publication, or even had not been the subject of an investigation.[195]

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[194] The Report of the Panel in *United States – Prohibition of Imports of Tuna and Tuna Products from Canada*, adopted on 22 February 1982, BISD 29S/91 (hereinafter "*United States – Tuna (1982)*"), states, in para. 4.8:

> "[The Panel] furthermore felt that the United States action should not be considered to be a disguised restriction on international trade, noting that the United States prohibition of imports of tuna and tuna products from Canada had been taken as a trade measure and publicly announced as such. The Panel therefore considered it appropriate to examine further the United States import prohibition of tuna and tuna produce from Canada in the light of the list of specific types of measures contained in Article XX and notably in Article XX(g)."

[195] The Report of the Panel in *United States – Automotive Springs*, op. cit., states in para. 56:

> "The Panel then considered whether or not the exclusion order was "applied in a manner which would constitute … a disguised restriction on international trade". The Panel noted that the preamble of Article XX made it clear that it was the application of the measure and not the measure itself that needed to be examined. Notice of the exclusion order was published in the Federal Register and the order was enforced by the United States customs at the border. The Panel also noted that the ITC proceedings in this particular case were directed against the importation of automotive spring assemblies produced in violation of a valid United States patent and that, before an exclusion order could be issued under Section 337, both the validity of the patent and its infringement by a foreign manufacturer had to be clearly established. Furthermore, the exclusion order would not prohibit the importation of automotive spring assemblies produced by any producer outside the United States who had a licence from Kuhlman Corporation to produce these goods. Consequently, the Panel found that

8.234 In *United States – Gasoline*, the Appellate Body considered "that concealed or unannounced restriction … in international trade does not exhaust the meaning of 'disguised restriction'." This seems to imply that a measure that was not published would not satisfy the requirements of the second proposition of the introductory clause of Article XX. We note that the Decree was published in the Official Journal of the French Republic on 26 December 1996 and entered into force on 1 January 1997. We also note that it applies unequivocally to international trade, since as far as asbestos is concerned both importation and exportation are prohibited. In this sense, the criteria developed in *United States – Tuna (1982)* and in *United States – Automotive Springs* have already been satisfied.

8.235 However, the remark made by the Appellate Body in *United States – Gasoline* also implies that the expression "disguised restriction on international trade" covers other requirements. In the same case, the Appellate Body mentions that "'disguised restriction' includes disguised *discrimination* in international trade". This appears to signify that the word "restriction" should not be given a narrow meaning. In paragraph 8.229 above, we found that the Decree did not constitute discrimination within the meaning of the first condition of the introductory clause of Article XX. We consider that our conclusion can also be used for determining whether the Decree constitutes a disguised restriction. In this respect, we note that in the above-mentioned case the Appellate Body considered that:

> "'disguised restriction', whatever else it covers, may properly be read as embracing restrictions amounting to arbitrary or unjustifiable discrimination in international trade taken under the guise of a measure formally within the terms of an exception listed in Article XX. Put in a somewhat different manner, the kinds of considerations pertinent in deciding whether the application of a particular measure amounts to 'arbitrary or unjustifiable discrimination', may also be taken into account in determining the presence of a 'disguised restriction' on international trade. The fundamental theme is to be found in the purpose and object of avoiding abuse or illegitimate use of the exceptions to substantive rules available in Article XX."[196]

8.236 Referring also to the remark made by the Appellate Body in the same case according to which "the provisions of the chapeau [of Article XX] cannot logically refer to the same standard(s) by which a violation of the substantive rule has been determined to have occurred", we consider that the key to understanding what is covered by "disguised restriction on international trade" is not so much the word "restriction", inasmuch as, in essence, any measure falling within Article XX is a restriction on international trade, but the word "disguised". In accordance with the approach defined in Article 31 of the Vienna Convention, we note that, as ordinarily understood, the verb "to disguise" implies an *intention*. Thus, "to disguise" (*déguiser*) means, in particular, "conceal beneath deceptive appearances, counterfeit", "alter so as to deceive", "misrepresent", "dissimulate".[197] Accordingly, a restriction which formally meets the requirements of Article XX(b) will constitute an abuse if such compliance is in fact only a disguise to conceal the pursuit of trade-restrictive objectives. However, as the Appellate Body acknowledged in *Japan – Alcoholic Beverages*, the aim of a measure may not be easily ascertained.[198] Nevertheless, we note that, in the same case, the Appellate Body suggested that the protective application of a measure can most often be discerned from its design, architecture and revealing structure.[199]

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the exclusion order had not been applied in a manner which constituted a disguised restriction on international trade."

[196] *United States – Gasoline*, op. cit., p. 25.

[197] Petit Larousse Illustré (1986), p. 292; Le Nouveau Petit Robert (1994), p. 572.

[198] Op. cit., p. 31.

[199] Ibid. Although this approach was developed in relation to Article III:4 of the GATT 1994, we see no reason why it should not be applicable in other circumstances where it is necessary to determine whether a measure is being applied for protective purposes.

8.237 It is on this basis that we shall analyse Canada's argument according to which the Decree favours the French domestic industry producing substitutes for chrysotile and chrysotile-containing products.[200] We have already found that the Decree was necessary to achieve a public health objective and did not, in its application, constitute arbitrary or unjustifiable discrimination. We recall that in *United States – Gasoline*, the Appellate Body considered that the kinds of considerations pertinent in deciding whether the application of a particular measure amounts to "arbitrary or unjustifiable discrimination" may also be taken into account in determining the presence of a "disguised restriction" on international trade. Since we have not identified discrimination, we consider it is unnecessary to determine whether we are faced with discrimination that might constitute a disguised restriction on international trade.

8.238 As far as the design, architecture and revealing structure of the Decree are concerned, we find nothing that might lead us to conclude that the Decree has protectionist objectives. Canada implicitly admits as much when it asserts that the Decree is a response of the French authorities to panicked public opinion and other health scares implicating officials and members of the government.[201] If this was the case, it seems difficult to reconcile the Decree being adopted in great haste with the idea that it was the result of a premeditated intention to protect French industry.

8.239 Admittedly, there is always the possibility that measures such as those contained in the Decree might have the effect of favouring the domestic substitute product manufacturers. This is a natural consequence of prohibiting a given product and in itself cannot justify the conclusion that the measure has a protectionist aim, as long as it remains within certain limits. In fact, the information made available to the Panel does not suggest that the import ban has benefited the French substitute fibre industry, to the detriment of third country producers, to such an extent as to lead to the conclusion that the Decree has been so applied as to constitute a disguised restriction on international trade.[202]

8.240 Consequently, we conclude that the Decree satisfies the conditions of the introductory clause of Article XX.

5. Conclusion

8.241 In the light of the above, the Panel concludes that the provisions of the Decree which violate Article III:4 of the GATT 1994 are justified under Article XX(b).

F. ALLEGATION OF NULLIFICATION OR IMPAIRMENT OF A BENEFIT UNDER ARTICLE XXIII:1(b) OF THE GATT 1994

1. Arguments of the parties[203]

8.242 Having determined that the Decree was justified in the light of Article XX(b) of the GATT 1994 and consistent in its application with the introductory provisions of that Article, we must now examine Canada's allegations and arguments based on Article XXIII:(b) of the GATT 1994.

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[200] In this respect, we consider the EC to have satisfied the burden of proof as regards the introductory clause of Article XX. We shall therefore treat Canada's argument as an attempt to rebut the presumption established in favour of the EC.

[201] See Canada's arguments, para. 3.27. Canada refers to a study entitled *L'amiante dans l'environnement, ses conséquences et son avenir*, Office parlementaire d'évaluation des choix scientifiques et technologiques, National Assembly No. 329/Senate No. 41, p. 57.

[202] See, in particular, the reply of the European Communities to the Panel's question No. 30, paras. 113-115, Annex II.

[203] The arguments of the parties are set out in detail in Section III above.

8.243 The main arguments of the parties with regard to the existence of non-violation nullification or impairment of a benefit (hereinafter "non-violation nullification") can be summarized as follows.

8.244 Canada considers that, in accordance with panel practice under the GATT 1947, as confirmed in *Japan – Measures Affecting Consumer Photographic Film and Paper*[204], three conditions must be met for a case of non-violation nullification: (i) the negotiation of a tariff concession; (ii) the subsequent adoption of a governmental measure that unfavourably disrupts conditions of competition between the imported product for which the concessions were granted and the like or directly competitive domestic products; and (iii) the fact that the adoption of the measure in question could not reasonably have been foreseen at the time of the tariff concession negotiations.

8.245 Canada considers that these three conditions are present in this case. Asbestos and many asbestos-containing products are subject to tariff concessions by France and the European Communities starting in 1947 and 1960-1961, respectively, as well as during the Uruguay Round negotiations. By establishing a total ban, the Decree disrupted the competitive relationship in the French market between, on the one hand, chrysotile asbestos fibre and products containing it and, on the other, like and competitive French products, thus creating a monopoly for substitute fibres. Finally, at the time the tariff concessions concerning asbestos were negotiated, Canada could not reasonably have foreseen that France was going to abandon its policy of controlled use and compromise the value of its commitments by implementing a total ban on chrysotile and any possible use thereof by means of a measure as excessive as the Decree. Furthermore, this measure was inconsistent with the type of regulatory intervention then in place and still in effect today concerning products equally harmful, if not more harmful, than chrysotile. Canada's expectations were that this type of measure would not be adopted unless there were exceptional circumstances, but there had been no new scientific developments that had changed anything in terms of managing the risks or the effects associated with chrysotile. Finally, Canada argues that it could not reasonably have expected that chrysotile would be banned in favour of substitute products without those products having been subjected to a rigorous process of examination to prove that their use satisfied the public health objectives invoked by France.

8.246 By way of a preliminary remark, the European Communities point out that in the context of a non-violation allegation the burden of proof is especially onerous as a result of, in particular, Article XXVI:1(a) of the Understanding. They also note that in *Japan – Film*, the Panel stated that Article XXIII:1(b) of the GATT 1994 should be approached with caution and that non-violation nullification or impairment of benefits should be treated as an exceptional concept.[205] The European Communities also claim that the rules on non-violation nullification or impairment apply only if the measure in question does not fall under other provisions of the GATT and that, while there may be "legitimate expectations" in connection with a purely commercial measure, there can be no such expectations with respect to a measure taken to protect human health and which can therefore be justified with regard to Article XX:(b) of the GATT 1994.

8.247 The European Communities maintain that Canada fails to demonstrate how the French measure could not reasonably have been anticipated. In substance, according to the European Communities, since 1977, chrysotile has been classified as a category I carcinogenic product by the WHO. Thus, when the tariff negotiations took place, Canada knew that there was a danger that the product under negotiation could at any time be prohibited by Members of the WTO, particularly if non-hazardous or less hazardous substitutes could be used. In 1986, ILO Convention 162 on asbestos stated that national legislation should provide wherever possible for the replacement of asbestos or of certain types of asbestos or products containing asbestos by other materials or products or the use of

[204] Adopted on 22 April 1998, WT/SD44/R, hereinafter "*Japan – Film*".
[205] Ibid., para. 10.36.

alternative technology, scientifically evaluated by the competent authority as harmless or less harmful. Since 1990, the European Communities, under Directive 90/394/EEC, has provided for the replacement of asbestos. This Directive recommends the principle of replacing a dangerous substance or process with a non-dangerous or less dangerous substance or process, where one exists. In 1983, WTO Members began to ban the use of asbestos, including chrysotile. Among EC Members, Austria banned chrysotile in 1990, followed by Finland and Italy in 1992, and Germany in 1993. Canada might have expected France to follow suit.

8.248 Furthermore, the European Communities assert that there are no provisions in the GATT or the TBT Agreement requiring consistency in the application of health measures against substances that pose a carcinogenic risk for human health. Accepting Canada's argument that it could not legitimately have anticipated the ban imposed by the Decree because France did not simultaneously ban other potentially dangerous substances (such as lead and copper) would be equivalent to preventing Members entirely from taking measures to protect human health on their territory.

8.249 Moreover, according to the European Communities, Canada cannot claim a legitimate expectation of "improved" market access with respect to a product which entails risks for human health when, as the facts show, the tendency is for exports to the industrialized countries to fall. Canada must give detailed reasons as to why it could legitimately have expected that France would not adopt measures restricting or eliminating the use of any asbestos product after the Uruguay Round negotiations, given the growing scientific evidence that all types of asbestos and asbestos-containing products are carcinogenic to humans.

8.250 The European Communities then argue that Canada fails to demonstrate how the Decree upsets the competitive relationship between asbestos and fibrous or non-fibrous substitute products. It has not established a "clear correlation" between the two. The issue is not whether equality of competitive conditions exists but whether the relative conditions of competition which existed between domestic and foreign products as a consequence of the relevant tariff concessions have been upset. The EC consider that the products for which the competitive conditions must be examined are those covered by the tariff concession. If a tariff concession is granted for asbestos, the competitive conditions to be examined are those concerning Canadian asbestos and French asbestos. It is irrelevant to compare chrysotile with French substitute products because such products cannot be considered in terms of the same relevant tariff concession.

8.251 Canada rejects the EC's claim that an examination of the impact of the Decree's effect on competitive conditions must be limited to Canadian asbestos and French asbestos. This approach is contradicted by two panel reports which have clearly established that Article XXIII:1(b) can be invoked in the case of a measure which upsets the competitive relationship between two non-identical products.[206]

2. Analysis by the Panel

(a) Preliminary issues

(i) Questions before the Panel

8.252 Article XXIII:1(b) of the GATT 1994 (Nullification or impairment) reads as follows:

[206] Canada refers to the Report of the Working Party on *Australian Subsidy on Ammonium Sulphate*, adopted on 3 April 1950, II/188 and to the Report of the Panel on Complaints in *Treatment by Germany of Imports of Sardines*, (hereinafter "*Germany – Sardines*"), adopted on 31 October 1952, BISD 1S/53.

> "1. If any contracting party should consider that any benefit accruing to it directly or indirectly under this Agreement is being nullified or impaired or that the attainment of any objective of the Agreement is being impeded as the result of
>
> […]
>
> (b) the application by another contracting party of any measure, whether or not it conflicts with the provisions of this Agreement,
>
> […]
>
> the contracting party may, with a view to the satisfactory adjustment of the matter, make written representations or proposals to the other contracting party or parties which it considers to be concerned. Any contracting party thus approached shall give sympathetic consideration to the representations or proposals made to it."

8.253 The Panel notes, first of all, that the EC have put forward two arguments which, if well-founded, should lead us to conclude that Article XXIII:1(b) does not apply to the facts in this case. If we find that these arguments are not pertinent, we shall examine the substance of the Canadian complaint.

8.254 The EC's two arguments which could determine the applicability of Article XXIII:1(b) are as follows:

8.255 Firstly, the EC claim that the rules on non-violation nullification apply only if the measure in question does not fall under other provisions of the GATT 1994. Article XXIII:1(b) is applicable only if the Panel reaches the conclusion that the Decree is consistent with Article III of the GATT 1994. Otherwise there cannot be "non-violation". In the light of the introductory clause of Article XX of the GATT 1994, the European Communities conclude that if the French measure is considered "necessary" for the protection of human health by the Panel and hence if specific rules have been applied in this respect, the provisions of Article XXIII:1(b) of the GATT are inapplicable.

8.256 Canada replies that the cases *Uruguay – Recourse to Article XXIII*[207] and *United States – Trade Measures Affecting Nicaragua*[208] do not support the EC's interpretation. Moreover, inasmuch as Article 26:1(b) of the Understanding provides for the granting of compensation rather than the withdrawal of a measure, recourse in non-violation affects neither the adoption nor the application of the contested measure.

8.257 The EC's second argument is that while it is possible to have legitimate expectations in connection with a purely commercial measure, it is not possible to claim legitimate expectations with respect to a measure that is taken to protect human health and can therefore be justified, particularly in the light of Article XX(b) of the GATT 1994. The protection of human health is a fundamental duty and cannot be compromised or restricted by the concept of non-violation.

8.258 For Canada, the distinction made by the EC between measures of a purely commercial nature and measures which have health-protection related aspects has no basis either in the texts of the WTO Agreement or in case-law. A legitimate expectation does not in any way concern a particular measure adopted by a Member, but rather the opportunities for competition agreed during multilateral trade negotiations on a given product. The Community reasoning is also wrong because it does not concur with the preparatory work on the GATT 1947, which shows that the objective of Article XXIII:1(b) is to prevent abuse of the provisions of the General Agreement.

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[207] Adopted on 16 November 1962, BISD 11S/95.
[208] L/6053 (1986), unadopted.

8.259 The EC consider that Canada has taken a selective look at the preparatory documents. As the Appellate Body pointed out in the *United States – Shrimp* case, the conditions laid down in the chapeau of Article XX(b) are meant precisely to address situations in which a Member applies in bad faith and in an abusive manner the exceptions laid down in Article XX. There cannot be two sets of provisions which address the same problem twice.

(ii) The EC's argument according to which the rules on non-violation nullification apply only if the measure in question does not fall under other provisions of the GATT.

8.260 The EC seem to believe that the fact that a measure is "justified" on the basis of Article XX creates a legal situation different, on the one hand, from the situation in which the measure violates a provision of the GATT 1994 and, on the other, from the situation in which the measure does not fall under the provisions of the GATT 1994. In support of their position, the EC cite a passage from the Panel Report in *Japan – Film* which mentions that Article XXIII:1(b) provides "the means to redress government actions not otherwise regulated by GATT rules … ". The Communities also refer to the introductory clause of Article XX which states that "nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures" necessary to protect human life or health.

8.261 The Panel recalls, first of all, that both the preamble to Article 26.1 of the Understanding and Article XXIII:1(b) use the words "measure, *whether or not it conflicts with the provisions* [of the particular agreement]" (emphasis added). To begin with, it should be noted that the wording of Article XXIII:1(b) shows unequivocally that this provision applies both in situations in which a measure conflicts and in situations in which it does not conflict with the provisions of the GATT 1994. Above, we found that the treatment accorded by the Decree to chrysotile asbestos fibres violated Article III:4 of the GATT 1994 as such, in as much as these products were like the substitute fibres mentioned by the parties and the treatment of products containing chrysotile asbestos and products containing the substitute fibres mentioned by the parties was discriminatory. Accordingly, the Decree *conflicts* with the provisions of Article III:4, in the sense in which that word is used in Article XXIII:1(b).[209] However, we note that the introductory clause of Article XX states that "nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures" necessary to protect human life or health, which might suggest that a provision consistent with the requirements of Article XX no longer conflicts with Article III:4, because Article III:4 cannot be construed as preventing this kind of measure. However, whether a measure *justified* on the basis of Article XX of the GATT 1994 is considered still to be in conflict with Article III:4 or is considered no longer to conflict with Article III:4 because justified under Article XX, under the terms of Article XXIII:1(b) the latter continues to be applicable to it.

8.262 We also note, firstly, that the introductory clause to Article XX, to which the EC refer, concerns the *adoption or enforcement* of measures necessary to protect health. The application of Article XXIII:1(b) does not prevent either the adoption or the enforcement of the Decree concerned. Article 26:1(b) stipulates that even where a measure has been found to nullify or impair benefits under, or impede the attainment of objectives, of the GATT 1994 without violation thereof, there is no obligation to withdraw the measure. Accordingly, there is no contradiction between the invocation of Article XX and the application of Article XXIII:1(b). However, that Article must be applied in such a way as to protect the balance of rights and duties negotiated.[210] Accordingly, we do not consider that

[209] This remark is made without prejudice to Canada's allegations based on Article XXIII:1(a) (see Section VIII.A.2(a) above).

[210] See the Report of the Panel in *EEC – Payments and Subsidies Paid to Processors and Producers of Oilseeds and Related Animal-feed Proteins*, adopted on 25 January 1990, BISD 37S/86 (hereinafter "*EEC – Oilseeds*", para.148, where the Panel considered that:

the text of Article XXIII:1(b) or that of Article XX or, finally, that of Article 26.1 of the Understanding supports the EC's interpretation.

8.263 Secondly, we do not consider that the passage from the *Japan – Film* report cited by the EC supports its interpretation either. Admittedly, the words used by the panel, taken in isolation, might at first glance appear to confirm the EC's position, insofar as it refers to "government actions not otherwise *regulated* by GATT rules" (emphasis added). The use of the word "regulated" could signify that the field of application of Article XXIII:1(b) covered only situations in which no provision of the GATT was *applicable*. First of all, it is our opinion that the fact that a measure does not violate Article III:4 does not necessarily mean that the latter is not applicable to it. Article III:4 applies to any law, regulation or requirement affecting the internal sale, offering for sale, purchase, transportation, distribution or use of imported products and like products of national origin. Consequently, even if the EC's interpretation were correct, it would not apply in the present case insofar as Article III:4 continues to be applicable to the Decree. Next, it should be noted that the panel in *Japan – Film* refers, in the footnote at the end of the sentence cited by the EEC [211], to the *EEC – Oilseeds* report which states, in particular, that:

> "the Panel noted that these provisions, as conceived by the drafters and applied by the CONTRACTING PARTIES, serve mainly to protect the balance of tariff concessions. [footnote omitted] The idea underlying them is that the improved competitive opportunities that can legitimately be expected from a tariff concession can be frustrated not only by measures proscribed by the General Agreement but also by measures consistent with that Agreement".[212]

8.264 We consider that a "measure which is not otherwise regulated by GATT rules", that is to say to which the GATT does not apply, is, *a fortiori*, "not in conflict" with the GATT within the meaning of Article XXIII:1(b) or "consistent" within the meaning of the *EEC – Oilseeds* report. Consequently, we find that the passage in the *Japan – Film* report cited by the EC, far from supporting their position, confirms the opinion according to which Article XXIII:1(b) applies to a measure whether it is consistent with the GATT because the GATT does not apply to it or is justified by Article XX.[213]

8.265 For these reasons, we do not allow the EC's first argument.

> "… the recognition of the legitimacy of an expectation relating to the use of production subsidies therefore in no way prevents a contracting party from using production subsidies consistently with the General Agreement, it merely delineates the scope of the protection of a negotiated balance of concessions."

We also note that the Appellate Body in *United States – Gasoline*, op. cit., p. 25, stated, with regard to the application of Article XX, that "the measures falling within the particular exceptions must be applied reasonably, with due regard both to the legal duties of the Party claiming the exception and the legal rights of the other Parties concerned".

[211] See *Japan – Film*, para. 10.50, footnote 1214.

[212] *EEC – Oilseeds*, op. cit., para. 144.

[213] In this connection, we note that in the context of the examination of a United States measure granted a waiver under Article XXV of the GATT 1947, the Panel in *United States – Restrictions on the Importation of Sugar and Sugar-containing Products applied under the 1955 Waiver and under the Headnote to the Schedule of Tariff Concessions*, adopted on 7 November 1990, BISD 37S/228, noted, in para.5.21, that:

> "… Article XXIII:1(b) applies whether or not the measure at issue conflicts with the General Agreement and that therefore, the question of whether a measure inconsistent with Article XI:1 remains inconsistent with the General Agreement even if covered by a waiver cannot, by itself, determine whether it nullifies or impairs benefits accruing under the General Agreement within the meaning of that provision".

(iii) The EC's argument according to which there cannot be a "legitimate expectation" in the case of a measure that concerns the protection of human health.

8.266 With regard to the EC's second argument, we note, first of all, that neither the text of Article XXIII:1(b) of the GATT 1994 nor that of Article 26:1 of the Understanding expressly incorporates the separation suggested by the EC between measures of a purely commercial nature and measures designed to protect human health. Although these articles require the existence of a *measure* – which neither of the Parties disputes - they do not distinguish between different *types* of measures. We have also found, on the basis of Article XX, that the application of the latter does not *a priori* exclude the application of Article XXIII:1(b).[214] We therefore find that the terms and the context of Article XXIII:1(b) do not support the interpretation proposed by the EC.

8.267 Canada cites the preparatory work on the GATT 1947. On the basis of Article 32 of the Vienna Convention, we consider that it is not necessary to have recourse to the preparatory work unless, in particular, the interpretation based on the criteria of Article 31 leaves the meaning of the terms ambiguous or obscure or leads to a manifestly absurd or unreasonable result. Such is not the case. However, recourse to the preparatory work also makes it possible to confirm the meaning resulting from the application of Article 31.

8.268 In this respect, we note that the EC consider that Canada's reading of the preparatory work is selective. According to them, the potential problems of abuse and bad faith to which Canada alludes are adequately covered by the chapeau of Article XX. For the EC, there cannot be two sets of provisions which address the same problem twice.

8.269 Although it is not necessary to take a position on the content of the preparatory work, we consider that the EC's argument tends to confuse two aspects: the first is abuse resulting from the application of a measure falling within one of the paragraphs of Article XX. If a measure necessary to protect human health is applied in a manner that conflicts with the provisions of the introductory clause of Article XX, the measure will still be in conflict with the provisions of the GATT whose violation Article XX is supposed to justify. This aspect is very different from the situation in which a measure is perfectly justified in itself in relation to the GATT (as in the case of a measure which satisfies all the conditions of Article XX), but which, viewed in a given context, could give rise to a situation of nullification or impairment of a benefit under a tariff concession.

8.270 It remains, however, for us to discuss the EC's argument to the effect that the fundamental duty to protect human health cannot be compromised or restricted by the concept of non-violation nullification. We must begin by acknowledging that all the cases examined by panels so far have concerned situations in which the measure adopted following the negotiation of a concession was purely commercial in nature, generally a subsidy, a tariff preference or a measure relating to product distribution.[215] Accordingly, we have no precedents to guide us. However, a preliminary remark,

[214] In this respect, we note that panel practice cannot be regarded as falling within Article 31.3(a) or (b) of the Vienna Convention (see Article 3.2 of the Understanding, Article IX: 2 of the Agreement Establishing the WTO and the Report of the Appellate Body in *Japan – Alcoholic Beverages*, op. cit., pp.13-5). Moreover, the GATT 1947 and WTO panels have never discussed the situation with respect to a measure designed to protect public health. All previous cases have concerned situations in which a measure of a purely commercial nature was adopted pursuant to the negotiation of a concession.

[215] Apart from *Japan – Film*, op. cit., the cases in which working parties or panels have examined the substance of complaints formulated under Article XXIII:1(b) are as follows: Working Party Report in *Australian Subsidy on Ammonium Sulphate*, adopted on 3 April 1950, BISD II/188, Panel Report in *Germany – Sardines*, op. cit.; *Uruguay – Recourse*, adopted on 16 November 1962, BISD 11S/95; Working Party Report in *European Communities – Tariff Treatment on Imports of Citrus Products from Certain Countries in the Mediterranean Region ("EC – Citrus Products")*, GATT document L/5576, dated 7 February 1985 (unadopted); Panel Report in *EEC Production Aids Granted on Canned Peaches, Canned Pears, Canned Fruit Cocktail and*

similar to that made in paragraph 8.262 above, is called for. A finding based on Article XXIII:1(b) of the GATT 1994 and Article 26.1 of the Understanding never results in an obligation not to apply or to withdraw the measure in question. The Member concerned can only be asked to make "a mutually satisfactory adjustment". Article 26:1(b) also specifies that compensation may be part of a mutually satisfactory adjustment as final settlement of the dispute.[216] The Member adopting a public health protection measure is totally free to continue to apply the measure concerned as it stands while offering in exchange compensation for the benefits nullified or impaired.[217]

8.271 The Panel also considers, as did the panel in *Japan – Film*[218], that non-violation should be approached with caution and treated as an exceptional instrument of dispute settlement. It appears that Members which have negotiated a set of rights and obligations would only exceptionally expect to be challenged for actions not in contravention of those rights or obligations.

8.272 Moreover, the Panel is of the opinion that even if the justification of a measure by Article XX does not, in principle, make it impossible to invoke Article XXIII:1(b) in relation to the application of the measure justified, the situation of a measure falling under Article XX with respect to Article XXIII:1(b) cannot be quite the same as that of a measure consistent with another provision of the GATT 1994. This is because Article XX, which is headed "General Exceptions", is intended, in particular, to ensure the protection of public health or, as stated by the Appellate Body in *United States – Gasoline*, to "permit important State interests – including the protection of human health … to find expression".[219] The Panel considers that in accepting the WTO Agreement Members also accept *a priori*, through the introduction of these general exceptions, that Members will be able, at some point, to have recourse to these exceptions.[220] Moreover, Members have attached to the use of these exceptions a certain number of conditions contained either in paragraphs (a) to (j) or in the introductory clause of Article XX. These conditions have generally been narrowly interpreted.[221] The result is that

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Dried Grapes ("EEC – Canned Fruit"), GATT document L/5778, dated 20 February 1985 (unadopted); *Japan – Semi-Conductors*, report adopted on 4 May 1988, BISD 35S/116; *EEC – Oilseeds*, report adopted on 25 January 1990, BISD 37S/86; *United States – Agricultural Waiver*, adopted on 7 November 1990, BISD 37S/228.

[216] See Report of the Appellate Body in *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, adopted on 16 January 1998, WT/DS/50/AB/R (hereinafter "*India – Patents (United States)*", end of para. 41.

[217] See Report of the Panel in *EEC – Oilseeds*, op. cit., paras. 147-148.

[218] Op. cit., para. 10.36. Referring to the Report of the Panel in *EEC – Oilseeds*, footnote 1205, the Panel in *Japan – Film* noted the following:

> "In *EEC – Oilseeds*, the United States stated that it concurred in the proposition that non-violation nullification or impairment should remain an exceptional concept. Although this concept had been in the text of Article XXIII of the General Agreement from the outset, a cautious approach should continue to be taken in applying the concept. *EEC – Oilseeds*, BISD 37S/86, 118, para. 114. The EEC in that case stated that recourse to the "non-violation" concept under Article XXIII:1(b) should remain exceptional, since otherwise the trading world would be plunged into a state of precariousness and uncertainty. Ibid., para. 113."

[219] See the Report of the Appellate Body in *United States – Gasoline*, op. cit., p. 30. See also the Report of the Panel *Canada – Measures affecting exports of unprocessed herring and salmon*, op. cit., para. 4.6 and the Report of the Appellate Body in *United States – Gasoline*, op. cit., p. 18.

[220] In *Thailand – Cigarettes*, op. cit., para. 73, the panel considered that Article XX "clearly allowed contracting parties to give priority to human health over trade liberalization".

[221] See, in particular, *United States – Article 337*, op. cit., para. 5.9; *Canada – Foreign Investment Review Act*, adopted on 7 February 1984, BISD 30S/140, para. 5.20, and *United States – Prohibition of Imports of Tuna*, op. cit., para. 5.22.

(a) both the intended objective of these exceptions (pursuit of interests recognized *a priori* as being of greater importance than Members' commercial interests, since they can outweigh the latter) and

(b) the specific conditions that must be satisfied by Members invoking these exceptions

mean that, while recognizing that Article XXIII:1(b) applies to measures that fall under Article XX, we are justified in treating recourse to Article XIII:1(b) as particularly exceptional in relation to measures justified by Article XX(b).

8.273 All this leads the Panel to consider that, in practice, even if in a particular case a mutually satisfactory adjustment may be made under Article XXIII:1(b), in general, the risk of an effective increase in the cost of measures necessary to protect public health because of the applicability of Article XXIII:1(b) to measures justified under Article XX can only be very marginal. In fact, considering the criteria mentioned in the previous paragraph, very few measures of this kind could give rise to the application of Article XXIII:1(b).

8.274 For these reasons we do not subscribe to the interpretation proposed by the European Communities. Accordingly, we will continue our examination of the measure in the light of Article XIII:1(b) of the GATT 1994.

(b) Examination of the substantial aspects of Canada's arguments under Article XXIII:1(b) of the GATT 1994

(i) Burden of proof

8.275 The Panel has already discussed the question of the burden of proof in general in Section VIII.E.1(b) above. However, it is important, in the light of the arguments of the parties, to clarify the application of the burden of proof in the context of non-violation nullification or impairment of a benefit.

8.276 Where the application of Article XXIII:1(b) is concerned, Article 26.1(a) of the Understanding and panel practice in the context of the WTO Agreement and the GATT 1947 confirm that this is an exceptional course of action requiring the complaining party to carry the burden of presenting a detailed justification in support of its complaint. Thus, Article 26.1(a) stipulates that:

> "Where the provisions of paragraph 1(b) of Article XXIII of the GATT 1994 are applicable to a covered agreement, a panel or the Appellate Body may only make rulings and recommendations where a party to the dispute considers that any benefit accruing to it directly or indirectly under the relevant covered agreement is being nullified or impaired or the attainment of any objective of that Agreement is being impeded as a result of the application by a Member of any measure, whether or not it conflicts with the provisions of that Agreement. Where and to the extent that such party considers and the panel or the Appellate Body determines that a case concerns a measure that does not conflict with the provisions of a covered agreement to which the provisions of paragraph 1(b) of Article XXIII of the GATT 1994 are applicable, the procedures in this Understanding shall apply, subject to the following:
>
> (a) the complaining party shall present a detailed justification in support of any complaint relating to a measure which does not conflict with the relevant covered agreement;"

8.277 In *Japan – Film*, the Panel specified how the burden of proof should be applied in this context:

> "Consistent with the explicit terms of the DSU and established WTO/GATT jurisprudence, and recalling the Appellate Body ruling that 'precisely how much and precisely what kind of evidence will be required to establish … a presumption [that what is claimed is true] will necessarily vary from …

> provision to provision', we thus consider that the United States, with respect to its claim of non-violation nullification or impairment under Article XXIII:1(b), bears the burden of providing a detailed justification for its claim in order to establish a presumption that what is claimed is true. It will be for Japan to rebut any such presumption."[222]

8.278 We conclude that, with respect to its claims of non-violation, Canada bears the primary burden of presenting a detailed justification for its claims.[223]

8.279 Canada maintains that, when a complainant proves that it enjoys a tariff concession and the respondent subsequently adopts a measure that affects the value of this concession, the complainant benefits from the presumption that it could not reasonably anticipate that this concession would be nullified or otherwise impaired by this measure. In such circumstances, it is up to the respondent to prove that the complainant should have anticipated the possibility of such a measure being adopted. Canada refers to the Appellate Body report in *India – Patent (United States)*[224] and to the Panel report in *Japan – Film*.[225]

8.280 We do not consider that Canada has correctly interpreted the Panel report in *Japan – Film*. First of all, the presumption to which the Panel refers is that, if it is shown that a measure has been introduced after the conclusion of the tariff negotiations in question, then the complainant should not be considered as having anticipated that measure, which is only one of the tests applied by the Panel. Moreover, if the interpretation of the burden of proof suggested by Canada were followed, the obligation to present a detailed justification for which Article 26.1(a) provides might in certain cases be evaded. Accordingly, we do not follow the interpretation proposed by Canada but the rule laid down in *Japan – Film.*

8.281 Furthermore, in the light of our reasoning in paragraph 8.272 above, we consider that the special situation of measures justified under Article XX, insofar as they concern non-commercial interests whose importance has been recognized *a priori* by Members, requires special treatment. By creating the right to invoke exceptions in certain circumstances, Members have recognized *a priori* the possibility that the benefits they derive from certain concessions may eventually be nullified or impaired at some future time for reasons recognized as being of overriding importance. This situation is different from that in which a Member takes a measure of a commercial or economic nature such as, for example, a subsidy or a decision organizing a sector of its economy, from which it expects a purely economic benefit. In this latter case, the measure remains within the field of international trade. Moreover, the nature and importance of certain measures falling under Article XX can also justify their being taken at any time, which militates in favour of a stricter treatment of actions brought against them on the basis of Article XXIII:1(b).

8.282 Consequently, the Panel concludes that because of the importance conferred on them *a priori* by the GATT 1994, as compared with the rules governing international trade, situations that fall under Article XX justify a stricter burden of proof being applied in this context to the party invoking Article XXIII:1(b), particularly with regard to the existence of legitimate expectations and whether or not the initial Decree could be reasonably anticipated.

(ii) Examination of the conditions

8.283 As recalled by the Panel in *Japan – Film*, the text of Article XXIII:1(b) establishes three elements whose existence a complainant must prove in order to be able legitimately to invoke that provision, namely: (1) the application of a measure by a Member of the WTO; (2) the existence of a

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[222] *Japan – Film*, op. cit., para. 10.32.
[223] Previous Panels have not defined the precise scope of the concept of detailed justification.
[224] Op. cit., para. 41.
[225] Op. cit., para. 10.79.

benefit accruing under the applicable agreement; and (3) the nullification or impairment of a benefit as a result of the application of the measure.

8.284 The existence of a *measure* is not in dispute. In this particular case, the measure in question is Decree No. 96-1133 of 24 December 1996 which, moreover, forms the subject of a violation complaint on the part of Canada and which we have examined in this respect in previous sections. We also note that, apart from stressing that its objective is to protect human health, the European Communities do not claim that the nature of the measure (an import and marketing ban) is such that it is not covered by the definition of the term "measure" in Article XXIII:1(b). We therefore conclude that a "measure" exists.

8.285 With regard to the existence of a *benefit*, we note that the Panel in *Japan – Film* recalled that, with only one exception, in all the previous cases in which Article XXIII:1(b) was invoked the benefit claimed consisted in the legitimate expectation of improved market access opportunities resulting from the relevant tariff concessions. We first need to know what benefit Canada could legitimately have expected from the Community concessions on chrysotile asbestos. We note, however, that previous panels approached the question differently, insofar as they appear to have assumed the existence of a benefit in the form of improved market access opportunities and then considered whether a party could have had a *legitimate expectation* of a given benefit.

8.286 In the present context, there would be a certain logic in making a distinction between the concept of legitimate expectation of a benefit and that of the reasonable foreseeability of a measure.[226] In fact, it could be argued that, in the circumstances, Canada's expectations with regard to the benefits it could derive from the concession could not be as high as for a product that posed no known risk to health. In such a context, in which it might be argued that, at best, Canada could anticipate a gradual decline in its chrysotile exports, an "upsetting of the competitive relationship" as a result of the measure in question would seem to be more difficult to establish. The situation is not one in which more or less promising prospects of market access disappear, as in the previous cases considered, but of a market in decline, as confirmed by the trend in the amounts produced and the number of countries which, in the last 25 years, have restricted or banned the use of chrysotile[227] and by the increasing reliance on substitute products. In these circumstances, the Decree could not be considered to have *upset* the competitive relationship between chrysotile and products containing it, on the one hand, and substitute fibres and products containing them on the other.

8.287 However, as this element would be difficult to quantify and in the light of our reasoning in paragraphs 8.272 and 8.282 above, we consider it more appropriate to discuss the circumstances which led France to adopt a measure justified under Article XX in the context of the examination of the question of whether Canada could reasonably have anticipated the French measure. These elements seem to relate more particularly to the measure at issue. We will therefore now proceed to examine the criteria developed by previous panels.

8.288 According to the criteria developed in previous cases, (a) the Decree must have had the effect of upsetting the competitive relationship between Canadian asbestos and products containing it, on the one hand, and substitute fibres and products containing them, on the other, and (b) the Canadian

[226] See the approach followed in the Report of the Panel in *EEC – Canned Fruit*, op. cit., paras. 51 and 52. See also the Report of the Panel in *EEC Oilseeds*, op. cit., para. 144.

[227] See para. 3.22 in which the European Communities point out that world production of asbestos reached a peak of 5.2 million tonnes, since when production has steadily declined, falling to 1.92 million tonnes in 1997. With regard to the countries that have restricted or banned the use of asbestos, see the description given by the European Communities in paras. 3.31 *et seq.* above.

Government must not have been able reasonably to anticipate the Decree when it was negotiating the various tariff concessions covering the products concerned.[228]

8.289 At this stage, the Panel finds it appropriate to consider that in view of the type of measure in question the "upsetting of the competitive relationship" can be assumed. By its very nature, an import ban constitutes a denial of any opportunity for competition, whatever the import volume that existed before the introduction of the ban. We will therefore concentrate on the question of whether the measure could reasonably have been anticipated by the Canadian Government at the time that it was negotiating the various tariff concessions covering the products concerned.

8.290 With regard to the tariff concessions to be taken into account in assessing the "predictability" of the measure, the Panel notes that Canada refers expressly to the concessions made by France in 1947, by the European Economic Community in 1962 and by the European Communities at the end of the Uruguay Round.[229] Canada notes, in particular, that the concessions included in the 1962 Protocol have been renewed until now. The European Communities do not dispute the information submitted by Canada, but recall that the Panel in *Japan – Film* pointed out that the establishment of a case based on expectations from rounds concluded 18 or 30 years ago might be difficult. The EC consider that Canada should provide detailed explanations of why it could legitimately have expected that France would not adopt measures restricting the use of any asbestos product after the Uruguay Round negotiations, given the growing scientific evidence that all types of asbestos were carcinogenic to humans.

8.291 With regard to the factors to be taken into account determining whether the measure in question could reasonably have been anticipated, previous panels found that a number of elements were not relevant. We consider it necessary to assess their applicability in relation to the circumstances of the present case.

(a) First of all, we note that the reports in *Japan – Film* and *EEC – Oilseeds* concluded that a specific measure could not be considered foreseeable solely because it was consistent with or a continuation of a past general government policy. However, we note that, in contrast to the two cases mentioned above, France had already developed a specific policy in response to the health problems created by asbestos before the adoption of the Decree. This factor must certainly be taken into account in our analysis.[230]

(b) The Panel in *Japan – Film*, also concluded that it would not be appropriate to charge the United States with having reasonably anticipated all GATT-consistent measures. Consequently, we do not consider that Canada reasonably anticipated all GATT-consistent measures, or even possible measures justifiable under Article XX.

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[228] The Panel does not consider that the EC's argument based on a comparison between products corresponding to the same tariff line are relevant. The concept of competition is not limited to products that fall in the same tariff heading and was established in the earliest cases based on Article XXIII:1(b). See, in particular, the Report of the Working Party on *Australian Subsidy on Ammonium Sulphate*, adopted on 3 April 1950, II/188, para. 12, the Report of the Panel on Complaints in the case *Germany – Sardines*, op. cit., para. 16, and the Report of the Panel in *Japan – Film*, op. cit., para. 10.73.

[229] The concessions concerned do not seem to have been affected by the enlargement of the European Communities to include Austria, Finland and Sweden in 1996.

[230] In our opinion, there is a difference between, on the one hand, an import ban following upon a series of national measures gradually reinforcing, since 1977, the measures taken to protect public health against the effects of asbestos and, on the other, the relationship which the EC tried to establish in *EEC – Oilseeds* between the existence in 1962 of oil-seeds subsidies in certain member States of the European Communities and the development of a subsidy programme insulating oil-seed producers from competition from imports (see para. 149 of the panel report).

(c) Finally, insofar as the Decree postdates the most recent tariff negotiations, we could apply the presumption applied by the Panel in *Japan – Film*, according to which normally Canada should not be considered to have anticipated a measure introduced after the tariff concession had been negotiated. However, we do not consider such a presumption to be consistent with the standard of proof that we found to be applicable in paragraph 8.272 above in the case of an allegation of non-violation nullification concerning measures falling under Article XX of the GATT 1994.

Moreover, the circumstances of the present case seem to us to be different from the situation envisaged in *Japan – Film*. In that case, the measures in question concerned the organization of the Japanese domestic market. They were therefore economic measures of a kind that a third country might find surprising and, accordingly, difficult to anticipate. Here, it is a question of measures to protect public health under Article XX(b), that is to say, measures whose adoption is expressly envisaged by the GATT 1994. We therefore consider that the presumption applied in *Japan – Film* is not applicable to the present case.

8.292 Canada mentions, first of all, the concessions made by France in 1947 and by the EEC in 1962. However, we consider that in view of the time that elapsed between those concessions and the adoption of the Decree (between 50 and 35 years), Canada could not assume that, over such a long period, there would not be advances in medical knowledge with the risk that one day a product would be banned on health grounds. For this reason, too, we also consider that the presumption applied in *Japan – Film* cannot be applied to the concessions granted in 1947 and 1962. Any other interpretation would extend the scope of the concept of non-violation nullification well beyond that envisaged by the Panel in *Japan – Film*. On the contrary, it is for Canada to present detailed evidence showing why it could legitimately expect the 1947 and 1962 concessions not to be affected and could not reasonably anticipate that France might adopt measures restricting the use of all asbestos products 50 and 35 years, respectively, after the negotiation of the concessions concerned. In the present case, the burden of proof must be all the heavier inasmuch as the intervening period has been so long. Indeed, it is very difficult to anticipate what a Member will do in 50 years time. It would therefore be easy for a Member to establish that he could not reasonably anticipate the adoption of a measure if the burden of proof were not made heavier.

8.293 In the present case, we do not consider that Canada has provided a detailed explanation of why it could reasonably expect France not to adopt measures restricting the use of any asbestos product 50 and 35 years respectively, after the concessions concerned.

8.294 We therefore now turn to the question of whether, at the conclusion of the Uruguay Round, Canada could reasonably have expected France (a) not to adopt a measure restricting the use of asbestos and (b) not to do so by introducing a total ban.

8.295 As we have found (in paragraph 8.28), the presumption applied by the Panel in *Japan – Film* cannot be applied to the present case.[231] Unlike Canada, which claims that no recent scientific development could have made the measure foreseeable, we consider that there is evidence to show that regulations restricting the use of asbestos could have been anticipated. First of all, the hazardous nature of chrysotile has long been known. Thus, since 1977, chrysotile has been classified by the WHO as a category I carcinogen. In 1986, ILO Convention 162 required national legislators to make provision, whenever possible, for the replacement of asbestos or of certain types of asbestos or of products containing asbestos by other materials or products or the use of alternative technology,

[231] Even if it were applicable, we consider that the EC rebutted this presumption by their references to the systems established at international and Community level concerning the use of asbestos.

scientifically evaluated by the competent authority as harmless or less harmful. In 1990, the European Communities issued Directive 90/394/EEC providing for the replacement of asbestos. This Directive advocates the principle that a dangerous agent or procedure should be replaced by a harmless or less harmful agent or procedure insofar as one exists.

8.296 Moreover, in the light of the information submitted by the parties and the experts, we consider that the study of the diseases associated with the inhalation of asbestos is a field of science in which any possible conclusion would appear to be based on the observation of pathological cases day by day. In the Panel's opinion, the numerous constraints under which the scientists must work, such as the need to limit themselves to a given number of individuals, the establishment of the history of exposure and the period over which the health effects of asbestos develop, make the impact of these studies largely relative. It is the accumulation of data that gradually establishes scientific certainty. This impression is confirmed by the experts consulted by the Panel whose opinions are based on a large number of studies, including recent ones. Consequently, even supposing that there has been no major recent discovery, Canada cannot argue that it could not anticipate the adoption of a measure restricting the use of asbestos.

8.297 On the other hand, the accumulation of international and Community decisions concerning the use of asbestos, even if it did not necessarily make it certain that the use of asbestos would be banned by France, could not do other than create a *climate* which should have led Canada to anticipate a change in the attitude of the importing countries, especially in view of the long-established trend towards ever tighter restrictions on the use of asbestos. We also note that the use of chrysotile asbestos was banned by Members of the WTO well before it was banned by France. Admittedly, in *Japan – Film* the Panel considered that the adoption in other Members' markets of measures similar to the measures in question could not make the latter foreseeable. However, here again it was a question of commercial measures. We consider that in the present case the situation is different since it concerns public health and the competent international organizations have already taken a position on the question. The adoption, in an already restrictive context, of public health measures by other States, faced with a social and economic situation similar to that in France, creates an environment in which the adoption of similar measures by France, is no longer unforeseeable.

8.298 Moreover, as noted above, at the end of the Uruguay Round France already had in place a number of measures regulating the use of asbestos. These included, in particular, measures relating to the exposure of workers taken after asbestos was recognized as a carcinogen by the IARC (Decree 77-949 of 17 August 1977) and the adoption of ILO Convention 162, as well as for the purpose of implementing Community directives applicable. The Panel also notes that Decree 88-466 of 28 April 1988 on products containing asbestos had prohibited the use of chrysotile asbestos in the manufacture of certain products.[232]

8.299 In these circumstances, it is difficult for Canada to claim that it had legitimate expectations of maintaining or even developing its exports of chrysotile and products containing it. If there was any benefit for Canada, the Panel does not consider Canada to have presented a detailed justification to show that that benefit was anything other than precarious.

8.300 We thus conclude that at the conclusion of the Uruguay Round Canada could reasonably have anticipated that France might, in the short term, adopt more restrictive measures on the use of asbestos.

8.301 The question that remains to be decided is whether Canada could reasonably have anticipated the introduction of a *ban* on chrysotile asbestos by France. We consider that the scientific literature

[232] See Annex II, reply of the European Communities to the Panel's question No. 4 at the Second Meeting with the Parties, paras. 254 to 261.

and the international regulations, as well as Members' public policy[233], gave numerous indications such as to create a context in which Canada could not reasonably not have anticipated that sooner or later chrysotile would be banned by France. We also recall that the legitimacy of measures justified under Article XX justifies a stricter burden of proof on the party invoking Article XXIII:1(b). In the present case, Canada has not presented a detailed justification in support of its claim that it could not reasonably have anticipated that France would, in the light of developments in the scientific evidence and the choices made by other Members, also decide to apply a total ban on asbestos on its market in the short term.

8.302 We note Canada's argument according to which it could not reasonably have anticipated the adoption of the Decree by France insofar as France failed to display the necessary consistency in its approach to chrysotile and other hazardous products, such as lead and copper. We do not consider this a pertinent argument. Although it is true that lead and copper, like asbestos, are hazardous and that France has not yet taken any measure with respect to lead and copper, essentially this means that Canada cannot legitimately expect the lead market not to be the subject of some public health measure, even though France has not yet taken any such measure. It is our opinion that each Member is free to adopt the health policies it deems appropriate and to give each such policy the priority it deems necessary. To accept Canada's argument would not only conflict with that principle by requiring an "all or nothing" approach impossible to realize in practice but would considerably facilitate the task of a Member invoking Article XXIII:1(b) and required to prove the existence of a legitimate expectation. Thus, it would be sufficient to identify a product which had not yet been regulated even though it was recognized as being hazardous. There would then be no need to provide detailed evidence of the existence of non-violation nullification or impairment.

8.303 In the present case, we do not consider that Canada has presented a detailed justification of why it could legitimately have expected that France would not adopt measures restricting the use of any asbestos product in a context in which measures to limit the use of asbestos were being proposed at the international level and when countries at the same level of social and economic development as France had already banned the use of chrysotile asbestos by the end of the Uruguay Round.

(c) Conclusion

8.304 On the basis of the above, we conclude that Canada has not established the existence of nullification or impairment of a benefit within the meaning of Article XXIII:1(b) of the GATT 1994 as a result of the application of the measure in question.

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[233] The use of chrysotile was banned in Sweden and Denmark in 1986, in Austria in 1990, in the Netherlands in 1991, in Finland and Italy in 1992 and in Germany in 1993 (see para. 3.32 above). Directive 91/659/EEC of 3 December 1991, OJ 1991, L 363, p. 36, had banned the use of asbestos for fourteen specific categories of product (see para. 3.34 above).

IX. CONCLUSIONS

9.1 In the light of the above, the Panel concludes as follows:

(a) On the basis of its findings in Section VIII.D above, the Panel concludes that the "prohibition" part of the Decree does not fall within the scope of the TBT Agreement. The part of the Decree relating to "exceptions" does fall within the scope of the TBT Agreement. However, as Canada has not made any claim concerning the compatibility with the TBT Agreement of the part of the Decree relating to exceptions, the Panel refrains from reaching any conclusion with regard to the latter.

(b) On the basis of its findings in Section VIII.E.2 above, the Panel concludes that chrysotile asbestos fibres as such and fibres that can be substituted for them as such are like products within the meaning of Article III:4 of the GATT 1994. Similarly, the Panel concludes that the asbestos-cement products and the fibro-cement products for which sufficient information has been submitted to the Panel are like products within the meaning of Article III:4 of the GATT 1994.

(c) With respect to the products found to be like, the Panel concludes that the Decree violates Article III:4 of the GATT 1994.

(d) However, on the basis of its findings in Section VIII.E.4 above, the Panel concludes that the Decree, insofar as it introduces a treatment of these products that is discriminatory under Article III:4, is justified as such and in its implementation by the provisions of paragraph (b) and the introductory clause of Article XX of the GATT 1994.

(e) Finally, the Panel concludes, on the basis of its findings in Section VIII.F above, that Canada has not established that it suffered non-violation nullification or impairment of a benefit within the meaning of Article XXIII:1(b) of the GATT 1994.

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