IN THE ARBITRATION
UNDER THE ARBITRATION RULES
OF THE
UNITED NATIONS COMMISSION ON INTERNATIONAL TRADE LAW
AND
THE NORTH AMERICAN FREE TRADE AGREEMENT

BETWEEN:

CHEMTURA CORPORATION
(FORMERLY CROMPTON CORP.)

Claimant/Investor

- AND -

THE GOVERNMENT OF CANADA

Respondent/Party

REDACTED MEMORIAL OF THE CLAIMANT/INVESTOR

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EXECUTIVE SUMMARY

1. Crompton Canada, a wholly-owned subsidiary of the Investor, Chemtura Corporation ("Chemtura"), has manufactured and sold agricultural pesticide products in Canada since the 1940s. Among its most profitable businesses in the 1990s were lindane-based pesticides, that were approved for use on cereal and cole crops, mustard, and most importantly, canola.

2. Canada, through its Pest Management Regulatory Agency (the "PMRA"), wrongfully terminated this business. In doing so, Canada acted contrary to its NAFTA obligations to the Investor Chemtura and caused it significant loss and damage. More particularly, Canada failed to meet the minimum standard of treatment in Article 1105 of NAFTA by:

   - Improperly demanding a "voluntary" withdrawal of lindane products based on irrelevant considerations, (i.e. trade rather than scientific concerns); and deregistering products without a sufficient evidentiary basis;
   - failing to abide by promised conditions of Crompton Canada's withdrawal of lindane products from the Canadian market, which gave rise to legitimate expectations and on which Crompton Canada had reasonably relied;
   - denying Crompton Canada a right to be heard prior to the suspension of its lindane product registrations;
   - failing to maintain a transparent regulatory process;
   - suspending Crompton Canada's lindane registrations without evidence or lawful authority;
   - acting in an arbitrary, grossly unfair and unjust manner in dealings with Crompton Canada; and
   - failing to act in good faith in respect of the treatment accorded to Crompton Canada.

3. Alternatively, Canada acted contrary to its NAFTA obligations in Article 1103 to accord the Investor Chemtura the treatment available to non-NAFTA investors in like circumstances in the fair and equitable treatment obligation contained in other treaties to which Canada is a party.

4. Canada also wrongfully expropriated Chemtura's lindane product business in Canada contrary to its NAFTA obligations in Article 1110 in the following way:

- the suspension of Crompton Canada's lindane product registrations constituted expropriation or measures tantamount to expropriation;
- the measures at issue were not taken for a public purpose;
- the expropriation discriminated against Chemtura;
- the expropriation was carried out without due process and was a breach of international law; and
- no compensation was paid as a consequence of the expropriation.

5. As a result of Canada's various breaches under the NAFTA, the Investor has suffered significant damages resulting from the loss of its lindane products seed treatment business.

6. The Investor's position regarding all of the above is set forth in this Memorial in the following manner. Part One provides a brief overview of the Investor's claim, and Part Two consists of a comprehensive discussion of the factual background. The legal analysis of Canada's breaches is set out in Part Three, followed by the relief sought under Part Four.

7. The Investor's Memorial is supported by the Statements of Evidence of Mr. Alfred Ingulli, who was Executive Vice-President, Crop Protection Division, of the Investor for many years before his retirement and who has been retained by the Investor to assist in this proceeding; Mr. Paul Thomson, who is Director, New Business Development and Technology, of the Investor; Mr. John Kibbee, who is Regional Technical Manager for Seed Treatments with Crompton Canada; and Mr. Edwin Johnson, who is a senior consultant on global environmental and regulatory issues at Technology Sciences Group Inc. and has assisted the Investor with various regulatory matters. Regarding damages, the Memorial is supported by the expert report of Messrs Manuel Abdala, Andrés Chambouleyron and Pablo Spiller of LECG LLC, who have provided a damages

assessment, and the expert report of Mr. James Aidala, who is a former Assistant Administrator for the U.S. Environmental Protection Agency's Office of Prevention, Pesticides, and Toxic Substances.

8. For convenience, Annex A to the Investor's Memorial contains a table of terms used in this Memorial and their definitions. Annex B contains a timeline of the major events in this dispute.

PART ONE - A BRIEF HISTORY OF THE CLAIM

9. Canola has been an agricultural success story in Canada. A hybrid of rapeseed, canola was bred in Canada in the 1970s. By the 1990s over 10 million acres were being harvested each year, primarily for the healthy oil pressed from its seed. Crompton Canada's lindane-based pesticides were a significant part of that success.[1]

10. Lindane is an insecticide and is an active ingredient in certain crop protection products. Prior to 1997, lindane had been sold in Canada for more than 40 years and had been registered in Canada for more than 60 years. In 1979, Crompton Canada developed its first lindane product for canola, namely Vitavax rs Flowable, which was first registered for use and sold in Canada in 1980. Crompton Canada eventually developed an entire line of lindane-based products (the "Lindane Products") for use on canola/rapeseed, mustard seed and cole crops to control flea beetle infestations, and on cereal crops to control wireworm. This line of products also controlled fungal diseases.[2]

11. Crop protection products in Canada are regulated by the *Pest Control Products Act* (the "Act"), and the *Pest Control Products Regulations* (the "Regulations").[3] The

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[1] Statement of Evidence of Alfred F. Ingulli ("Ingulli Statement"), paras. 16, 22.

[2] Ingulli Statement, paras. 15, 18.

[3] The Act and its Regulations were repealed, in effect, in 2006, and replaced by new legislation and regulations. The events giving rise to the Investor's claim occurred prior to the entry into force of the new Act and Regulations. Accordingly, all references to the Act and its Regulations are references to the Act and Regulations as they existed

Canadian Minister of Health ("Minister") has certain duties and responsibilities under that Act. The PMRA, a Canadian federal regulatory agency within the jurisdiction of the Canadian Department of Health ("Health Canada"), is charged with the regulation of pest control products in Canada, including developing pest management policies and guidelines, promoting sustainable pest management, enforcing compliance with the Act, and distributing pest management information to the public and key stakeholders.

12. Although lindane was registered in the United States for certain uses, it had never been registered for use on canola because the market was too small to justify the cost of registration.[4]

13. In the mid-1990s as canola acreage grew in the U.S., and in particular in North Dakota, U.S. canola farmers began to import lindane-treated canola seeds for planting from Canada, as the only flea beetle control products registered in the U.S. at that time were less effective and significantly more expensive than lindane products.[5]

14. In early 1998, the U.S. Environmental Protection Agency (the "EPA") publicly confirmed its policy that lindane-treated canola seed for planting could not be imported into the U.S. because lindane was not registered for use on canola in the U.S. With the EPA's announcement, U.S. canola growers no longer had access to

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during the period under scrutiny. The Act may be found at Exhibit A1 and the Regulations may be found at Exhibit A2.

[4] Regulatory agencies such as the PMRA and the U.S. Environmental Protection Agency require significant amounts of data in order for a product to be registered, and there are on-going data requirements in order to maintain existing registrations. The generation of such data is both time-consuming and expensive. Further, it is crop-specific. In other words, the fact that a crop protection product has been registered for use on, for example, barley does not necessarily negate, or even significantly minimize, the requirement for data to support a registration of that product for use on another crop, such as canola. As a result, there must be significant commercial benefits in order for a company to develop a product and to seek its registration, and indeed to maintain an existing registration. See Evidence of Paul Thomson ("Thomson Statement") , paras. 17-19.

[5] Ingulli Statement, para. 26.

lindane-treated canola seed and therefore were forced to use the significantly more expensive, less effective non-lindane seed treatments for canola.[6]

15. As a result of these developments, the United States Government began raising complaints with the Government of Canada (in response to complaints by U.S. canola farmers) over imports of lindane-treated canola seeds for planting from Canada because U.S. growers were at a disadvantage compared to Canadian growers, who had access to effective and low-cost lindane products.[7]

16. Motivated primarily by these trade concerns, the PMRA pressured Crompton Canada, and other lindane registrants in Canada, to enter into a withdrawal of the registration of all lindane products for use on canola. Following the commitment by the PMRA to Crompton Canada to abide by several critical conditions, the PMRA and Crompton Canada concluded a conditional withdrawal agreement in late October 1999 (the "Conditional Withdrawal Agreement").[8]

17. It is clear from all of the PMRA's correspondence that the PMRA's actions leading to the conditional withdrawal of lindane registrations for use on canola in Canada were improperly motivated by trade concerns, and not environmental, health or any other safety related concerns.[9]

18. The key conditions in the Conditional Withdrawal Agreement process were:

> (1) Crompton Canada's Lindane Products could be used to treat canola seed until July 1, 2001, with no stated restrictions on when that treated seed could be sold or planted;

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[6] Ingulli Statement, para. 27.

[7] Ingulli Statement, para. 28.

[8] Ingulli Statement, paras. 40-41.

[9] Ingulli Statement, para 32.

> (2) The PMRA would coordinate and collaborate with the U.S. EPA on a timely scientific review and re-evaluation of any new lindane data already submitted and/or to be submitted in accordance with any data call-in or regulatory request and ultimately provide a scientific assessment of lindane by the end of 2000;
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> (3) Crompton Canada's Lindane Products would continue to be registered for use on all remaining (non-canola) crops; and
>
> (4) The PMRA would expedite the registration of lindane-free products (i.e., the existing products with the lindane removed) and lindane replacement products (i.e. combination insecticide-fungicide products without lindane).[10]

19. The commitment to complete a proper scientific assessment of lindane by the end of 2000 was critical to Crompton Canada, as it was confident that such an assessment would reveal no scientific basis upon which to terminate its lindane registrations. Crompton Canada therefore anticipated that it would be able to resume production of lindane for use on canola in Canada and that sales of lindane products for use on canola would continue through and beyond 2001.[11]

20. Subsequent to the Conditional Withdrawal Agreement, Canada failed to meet all of its key conditions:

> (1) Canadian seed treaters were told that they would be subject to substantial fines if they sold treated canola seed after July 1, 2001. Canadian farmers were also told that they would be subject to substantial fines if they planted lindane-treated canola seed after July 1, 2001. The deadline of July 1, 2001 was supposed to apply only to sales of lindane products and to the treatment of seed, not to selling or planting treated seed;[12]
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> (2) The scientific review was not completed by the end of 2000, and the scientific review (an occupational exposure risk assessment) that was ultimately concluded in October 2001, (the

[10] Ingulli Statement, Exhibit B20.

[11] Ingulli Statement, para. 47.

[12] Ingulli Statement, paras. 81-114.

"Special Review") was highly flawed and improper, as confirmed thereafter by an independent government-appointed expert panel;[13]

(3) Based on that improper scientific review, the PMRA in February 2002 cancelled Crompton Canada's registrations of Lindane Products for all uses, despite the PMRA's agreement not to do so and despite the seriously flawed process leading to, and the equally flawed methodology and conclusions of, the PMRA's scientific review;[14] and

(4) The PMRA significantly delayed the registration of Crompton Canada's replacement product (Gaucho CS FL) by such an extent that Crompton essentially lost all of its canola seed treatment business, while at the same time the PMRA ignored its own procedures and requirements in its accelerated registration of a competitor's (Syngenta) non-lindane product, Helix.[15]

21. Following the release of the PMRA's occupational exposure assessment ("Occupational Exposure Assessment" or "Assessment"), which was the culmination of its Special Review, and the termination of Crompton Canada's registrations, Crompton Canada on three separate occasions requested an independent scientific review of the PMRA's process and methodology.[16] The Canadian Minister of Health, who is required under Canadian law to establish such a review panel when requested, refused to do so, forcing Crompton Canada to make an application to Federal Court of Canada to require the Minister to act in accordance with the law. Only after Crompton Canada applied to Federal Court to obtain its basic rights did the Minister establish an independent review panel (the "Review Board").

22. In August 2005, the Review Board found that the PMRA's process leading to the Assessment and its conclusions therein were highly flawed and recommended that the

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[13] Ingulli Statement, paras. 115-122.

[14] Ingulli Statement, paras. 127-148; Thomson Statement, paras. 51-81.

[15] Ingulli Statement, paras. 149-160; Statement of Evidence of John Kibbee, ("Kibbee Statement"), paras. 15-49.

[16] Ingulli Statement, Exhibits B71-B73. Note that a fourth request for review was also filed September 29, 2003. See Ingulli Statement, Exhibit B77.

PMRA re-evaluate lindane properly in accordance with the Review Board's recommendations.[17]

23. In particular, the Review Board found, among other things, that:

- Fairness required that lindane registrants (such as Crompton Canada) be afforded a meaningful opportunity to make representations to the PMRA, particularly where the decision is as dramatic as a cancellation of registrations. This was particularly so given lindane's long-standing approval for use in Canada. Such an opportunity was not given to Crompton Canada.

- The PMRA had an obligation to advise Crompton Canada that its focus would be occupational risk. The PMRA did not do so.

- The comment period afforded to Crompton Canada was wholly inadequate. The PMRA took nearly three years to conduct its scientific assessment and yet it provided Crompton Canada with only a few weeks to respond.

- A "major flaw" in the PMRA's process was its failure to consider risk mitigation measures, at least for the upcoming planting season.

- The Review Board concluded that the PMRA's process and analysis resulted in an outcome that was not fair to affected parties.

24. The Review Board also found flaws with several aspects of the PMRA's scientific analysis and conclusions.

25. It is important to understand that these findings were made by an independent panel, established under Canadian law, to review the PMRA's process and conclusions. Parties

[17] Exhibit A4, Report of the Lindane Board of Review, August 2005, ("Review Board Report").

filed written submissions and the Review Board heard oral testimony. The composition of the Review Board was determined entirely by the Canadian Minister of Health.

26. Following the issuance of Review Board's Report, the PMRA itself acknowledged the deficiencies and failures found by the Review Board. However, in the three years since that Report, the PMRA has yet to properly address these deficiencies and failures.[18]

27. The full factual background in support of the Investor's case is set out below.

PART TWO -FACTUAL BACKGROUND

I. CHEMTURA (CROMPTON)

28. Crompton Corporation ("Crompton") was established under the laws of the State of Delaware, with its head office at Middlebury, Connecticut. In July 2005, Crompton Corporation changed its name to Chemtura Corporation ("Chemtura"). Chemtura is a corporation established under the laws of the State of Delaware with its head office at Middlebury, Connecticut. Chemtura is publicly traded, widely held and listed on the New York Stock Exchange.[19]

29. Chemtura is engaged in the manufacture and sale of specialty chemical products. A significant part of Chemtura's business, and of Crompton's business until 2005, is (and was) the production and sale of crop protection products including seed treatment products, fungicides, insecticides, herbicides and plant growth regulators.[20]

30. Chemtura Canada Co./Cie ("Chemtura Canada") is a Canadian company incorporated under the laws of Nova Scotia and is an indirect, wholly-owned subsidiary of Chemtura. Prior to April 11, 2006, the name of Chemtura Canada was

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[18] Thomson Statement, Exhibit C18.

[19] Ingulli Statement, para. 6.

[20] Ingulli Statement, para. 7.

Crompton Co./Cie. ("Crompton Canada"). Prior to January 24, 2001, the name of that company was Uniroyal Chemical Co./Cie ("Uniroyal Canada."). Chemtura Canada has an administrative office and a manufacturing facility at Elmira, Ontario which produces various chemical products, including seed treatment products, that supply several divisions of Crompton. Chemtura Canada also has a technology centre located in Guelph, Ontario.[21]

31. Prior to 1989, Crompton Canada (at the time, Uniroyal Canada) sold directly to Canadian wholesalers and distributors. In 1989, Crompton Canada (then Uniroyal Canada) began to sell through "Gustafson", an unincorporated business of Uniroyal Canada.[22]

32. On November 20, 1998, Crompton Canada sold a 50% interest in the Gustafson business to Bayer Inc. ("Bayer Canada"). The Gustafson business became "Gustafson Partnership", owned 50% each by Uniroyal Canada and Bayer Canada. From November 20, 1998 until March 31, 2004, all of the seed treatment products produced by Crompton Canada in Canada for sale in Canada were sold and marketed through Gustafson Partnership. During that period, Crompton Canada was entitled to receive 50% of the profit of Gustafson Partnership. On March 31, 2004, Crompton Canada sold its 50% ownership of the Gustafson Partnership to Bayer Canada. Since that date, the seed treatment products produced and sourced by Crompton Canada for sale in Canada have been sold to and marketed through Bayer Canada under a distribution agreement.[23]

33. A similar marketing structure existed in the U.S. Prior to November 20, 1998, Gustafson, Incorporated, a U.S.-based company that marketed crop protection products in the U.S., was wholly-owned by Crompton. On that date, Gustafson,

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[21] Ingulli Statement, para. 8.

[22] Ingulli Statement, para. 9.

[23] Ingulli Statement, para. 10.

Incorporated became Gustafson, LLC and Crompton sold a 50% interest in Gustafson, LLC to Bayer Corporation (as it then was). On March 31, 2004, Crompton sold its remaining 50% interest in Gustafson LLC to (the successor corporation) Bayer Corporation.[24]

34. Because the material facts underlying this arbitration arose before 2005, this Memorial will refer to "Crompton or "the Investor" as the U.S. Investor, and "Crompton Canada" as the Canadian investment.

II. LINDANE

A. The Importance of Lindane

35. Lindane is an insecticide used by Crompton Canada in certain seed treatment formulations. Commercial lindane, a 99.5% pure gamma isomer of hexachlorocyclohexane ("HCH"), is a white or colourless crystalline solid. When lindane is manufactured, the atoms that comprise the lindane molecule can vary in their physical arrangement. Molecules of fixed composition, but with their constituent atoms arranged in different geometries, are referred to as isomers. Technical HCH as manufactured is a mixture of five isomers – alpha, beta, gamma, delta and epsilon. Unlike the gamma isomer (lindane), the alpha and beta isomers of HCH have been directly linked with adverse ecological and physiological effects. The gamma isomer does not exhibit these adverse effects.[25]

36. One of the main uses of lindane is to control flea beetles. A flea beetle is a tiny insect that lies dormant until canola seeds begin to sprout. Once the seeds sprout, the flea beetle becomes active and irreparably damages the canola crop by attacking the cotyledons (the "seed leaves" or primary sprouts) and the leaves of the canola sprout. The flea beetles eat away at the cotyledons and leaves until the plant is significantly

[24] Ingulli Statement, para. 11.

[25] Thomson Statement, para. 7.

weakened and unable to withstand the beetle damage. The plant then dies or survives but at a lower level of vigour, which results in yield loss. Typically, flea beetles attack during the first three to four weeks after germination – the time when the seedling is highly vulnerable to damage. Flea beetles are particularly destructive to canola, rapeseed, mustard, broccoli, Brussels sprouts, cabbage, cauliflower, rutabagas and other crucifers.[26]

37. Within Canada, flea beetles tend to be a pervasive problem in Western Canada, with some variation in the severity of the problem across the Prairies. Flea beetles are also a common and pervasive pest in other parts of Canada, such as Ontario.[27]

38. Other agricultural applications of lindane include use as an insecticide on wheat, barley, oats, rye, flax, corn, bean, soy bean and pea seeds for the control of wireworm. Lindane was also used in other plant applications in Canada – including as an insecticide dust for planter boxes – as well as in other household applications such as therapeutic shampoo effective in the control and cure of head lice where it is applied directly to the scalps of children and adults to eliminate this troublesome pest. Lindane has been registered for use as a pharmaceutical since the early 1960s for the control of head lice and scabies, although it is slowly being replaced by newer agents, such as permethrin for the treatment of scabies. The pharmaceutical product has also always been available for purchase without a prescription.[28]

B. The Development and Uses of Crompton's Lindane Products

39. Prior to being forced out of the lindane business in Canada, Crompton Canada manufactured and sold several lindane-containing seed treatment products. Crompton Canada has not and does not manufacture lindane itself (referred to as "technical lindane"). At various times, technical lindane was purchased from sources

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[26] Thomson Statement, para. 8.

[27] Thomson Statement, para. 9.

[28] Thomson Statement, para. 10.

in **[***]** and formulated into the Lindane Products by Crompton Canada in Canada. Formulation involves the mixing or diluting of one or more pesticides with active or inert ingredients, without a chemical reaction, to obtain a manufactured end use product. Crompton Canada formulated both flowable and powder products.[29]

40. "Flowable" products are generally used for the treatment of seeds at commercial seed treatment facilities. "Powdered" products are generally used for on-farm applications.[30]

41. Lindane was registered for pesticide use in Canada as early as 1938, as a powder for foliar application. In 1979-80, Crompton Canada (then Uniroyal Canada) developed and registered a flowable version of lindane (Vitavax rs Flowable). Crompton Canada's Vitavax rs Flowable is composed of three active ingredients – two fungicides (carbathiin[31] and thiram) and one insecticide (lindane). The flowable version of this product offered better, more efficient and more thorough coverage than the powdered lindane product, particularly in its use on seeds, and resulted in much lower dust levels and therefore lower occupational exposure than powdered formulations. Seed treatment is the only use of the flowable product.[32]

42. When Vitavax rs Flowable was first developed in 1979, canola/rapeseed was a relatively minor crop. Sometime after 1979, canola oil became recognized as healthy oil and was used primarily in food manufacturing, to replace palm oil – which has much higher levels of saturated fats. Over the next two decades, and continuing today, demand for canola increased substantially. Concurrent with increased recognition of the human health benefits of canola, the market for Vitavax rs

[29] Ingulli Statement, para. 13.

[30] Ingulli Statement, para. 14.

[31] Note that the fungicide which is called carbathiin in Canada is called carboxin in the United States.

[32] Ingulli Statement, para. 15.

Flowable grew as the demand for canola also grew. It became standard practice in Canada to treat canola seed with the Vitavax rs Flowable or Crompton Canada's other Lindane Products to avoid the potential damage from flea beetles and to improve plant stands, vigour, survival and yield.[33]

43. The most valuable part of a canola crop is the oil. The seeds are pressed for the oil and the remaining meal is sold for use as animal feed. Commercial uses of canola oil include margarine, cooking oil and printing inks (the addition of canola oil helps to produce an ink that does not rub off easily).[34]

44. By the mid-1990s, Vitavax rs Flowable became Crompton Canada's most profitable crop protection product in Canada. The full range of Lindane Products produced and sold by Crompton Canada in Canada at the relevant times were those in the table below, which also contains Crompton Canada's registration of technical lindane:[35]

Product	Registration #	Form	Uses	Other Characteristics
Vitavax rs Flowable Systemic Liquid Seed Protectant	15533	Flowable	For flea beetle control on canola, rapeseed, mustard and cole crops	
Vitavax rs Flowable (undyed) Seed Protectant	24467	Flowable	For flea beetle control on canola, rapeseed and mustard	Contains no colorant and only sold to commercial seed treaters who must add colorant when the product is applied to seed
Cloak Seed	22121	Flowable	For flea beetle control on canola,	Less lindane than Vitavax rs

[33] Ingulli Statement, para. 16. Note that the difference between canola and rapeseed is that canola contains lower levels of erucic acid and glucosinates, which allows the oil produced from canola to be consumed by humans.

[34] Ingulli Statement, para. 17.

[35] Ingulli Statement, para. 18.

Product	Registration #	Form	Uses	Other Characteristics
Treatment			rapeseed, mustard and cole crops	Flowable and offered at a lower price for areas with less severe flea beetle infestations, such as southern Alberta
Vitavax rs Dynaseal Flowable Systemic Seed Protectant	24482	Flowable	For flea beetle control on canola, rapeseed and mustard	Similar to Vitavax rs Flowable except Dynaseal includes cosmetic attributes that leave treated seeds with a glossy sheen
Vitavax rs Powder Seed Treatment	16451	Powder	For flea beetle control on canola, rapeseed and mustard	
Vitavax Dual Solution Systemic Fungicide and Insecticide	14115	Flowable	For wireworm control on wheat, barley, oats, rye	
Vitaflo Dual-Purpose Systemic Fungicide and Insecticide	11422	Flowable	For wireworm control on wheat, barley	
Vitavax Dual Powder Seed Protectant	15537	Powder	For wireworm control on wheat, barley, oats, rye, flax	
Lindane Technical	24164		For formulation use only	

45. Lindane products were extremely cost-effective. Alternative (non-lindane) products introduced after lindane's cancellation were priced between two and five times the

price of Crompton Canada's Lindane Products, although in the late 1990s there were no true alternative products available in Canada.[36]

46. Seeds are treated with Vitavax rs Flowable in one of two ways – the grower may treat the seeds on the farm or, more commonly, seeds are treated by commercial seedhouses and then sold to growers. The customer base included agricultural retailers, seed companies, independent seed distributors and farmers/growers. In the main, approximately 90% of Crompton Canada's sales were to the large facilities that treat the seeds which are subsequently sold to growers.[37]

47. Crompton Canada, prior to the termination of its lindane business, held approximately **[***]**% of the seed treatment flea beetle control market in Canada, the vast majority of which involved the treatment of canola seeds. The balance of the market for lindane-based seed treatment was shared between Aventis CropScience (formerly Rhône-Poulenc Limited and now merged with Bayer CropScience), Interprovincial Cooperative Limited and Zeneca Inc. (which subsequently merged with Novartis Crop Protection Inc. to form Syngenta Crop Protection Inc.).[38]

48. Canola acreage in Canada has been significant for many years. By contrast, canola has always been a fairly minor crop in the U.S. The average harvested acreage of canola in Canada between 1995 and 2005 was 11,589,000 acres compared to 981,000 acres in the U.S.[39]

49. The manufacture and sale of the Lindane Products was seasonal and determined by the canola planting season in Canada (principally Manitoba, Saskatchewan and

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[36] Ingulli Statement, para. 19.

[37] Ingulli Statement, para. 20.

[38] Ingulli Statement, para. 21.

[39] Ingulli Statement, para. 22.

Alberta). On the basis of preliminary estimates of the acreage to be planted with canola in each crop year, Crompton Canada would manufacture the Lindane Products from November in one year to March/April in the following year.[40]

50. Typically in each crop year (from the harvest in one year to the harvest in the next year), Crompton Canada's and Gustafson's principal time for selling the Lindane Products ran from November to April inclusive. All sales of the Lindane Products for each crop year were effectively made by the end of June. The principal time of seed treatment by purchasers was over the same period. Planting of treated seeds occurred primarily during April and May.[41]

51. The shelf-life of the Lindane Products is generally two years. This means that Lindane Products purchased in one crop year that were not fully used in that year could be carried over for use in the subsequent year. Given that Crompton Canada's production of the Lindane Products was based on early planting estimates, in any year there might be a surplus or shortage of product if less or more of the anticipated acreage was in fact planted with canola.[42]

III. TERMINATION OF THE CANADIAN MARKET FOR LINDANE PRODUCTS

A. United States Trade Issues

52. Canada exports a significant volume of canola products to the U.S. (worth approximately $500 million per year) and, in this context, the use of lindane on canola in Canada became a major trade irritant between the two countries in the late 1990s.[43]

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[40] Thomson Statement, para. 12.

[41] Thomson Statement, para. 13.

[42] Thomson Statement, para. 14.

[43] Ingulli Statement, para. 24.

53. Lindane use on canola in Canada became a trade irritant for two reasons. First, lindane was not registered in the U.S. for use on canola, since canola had been (and still is) a relatively minor crop in the U.S. Second, although still a minor crop, the total production of canola in the U.S. began to increase significantly (as compared to prior years) in 1997 and 1998. Further, the State of North Dakota accounts for approximately 90% of U.S. canola production. As a result, North Dakota growers – and North Dakota politicians, both within the State and in the U.S. Senate – began to pay increasing attention to the issues of canola and lindane.[44]

54. To understand the nature and context of this trade irritant issue, it is necessary to briefly review the product registration process in the U.S.

55. In order to be acceptable for use in the United States, a crop protection product must be registered for a particular use by the EPA. In the mid-1990s, the EPA established a program to re-assess the registration of products which had been registered prior to 1984. If a product continued to be eligible for registration after this re-assessment, the EPA would issue a Reregistration Eligibility Decision ("RED"). REDs are designed to provide guidance to registrants for the reregistration of individual pesticide products and usually identify various safe use measures that are required for the products containing a particular chemical to be reregistered. The issuance of a RED indicates whether a product qualifies for re-registration.[45]

56. Lindane had been registered in the U.S. for use on various crops since the 1940s, although it was not registered for use on canola.[46]

57. The reason for this was that canola was a fairly insignificant crop in the United States. It was not until 1997 that harvested canola acres exceeded 1,000,000 acres in the U.S. By

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[44] Ingulli Statement, para. 25.

[45] Thomson Statement, para. 16.

[46] Thomson Statement, para. 17.

comparison, harvested canola acres in Canada exceeded 12,000,000 acres that same year. Further, in the late 1990s, although most canola growers in the U.S. used a fungicide, many did not use an insecticide.[47]

58. Given these facts, and given the significant costs to generate the necessary data to support registration of a product for a particular use, the economics did not support registration of lindane for use on canola in the U.S.[48]

59. In early 1997, the EPA had requested additional data on lindane from the Spanish manufacturer of technical lindane, Inquinosa S.A. In late 1998, the EPA gave notice that it expected to issue a RED on lindane sometime in 1999. Crompton Canada worked with the EPA throughout the RED process, generating significant data in response to requests for data from the EPA, at significant cost to Crompton Canada. After 1999, as the process unfolded, Crompton Canada (and other lindane registrants) remained optimistic that the RED would be completed in the near future. As described below, this process ultimately led to a favourable review by the EPA of lindane, with the issuance of the RED in July 2002.[49]

60. However, prior to the EPA concluding its RED process, the trade irritant issues with respect to canola arose between Canada and the U.S. At this point, the only product registered in the U.S. for use on canola to combat the flea beetle was the stand-alone insecticide Gaucho. Although this was and is an effective product, it was much more expensive than, and not as effective as, lindane-based products. Further, the Gaucho product available at this time had to be used in conjunction with a separate fungicide

[47] Ingulli Statement, para. 22; Thomson Statement, para. 18.

[48] Thomson Statement, para. 19.

[49] Thomson Statement, para. 20.

product, unlike Vitavax rs Flowable and Crompton Canada's other Lindane Products, which were all-in-one insecticide-fungicide products.[50]

61. Since lindane was not registered in the U.S. for use on canola, U.S. canola growers, particularly in North Dakota, were required to use substantially more expensive, less effective pesticides on canola seed, and thus considered themselves to be at a competitive disadvantage to Canadian canola growers. As a result, U.S. canola growers (primarily North Dakota growers) began importing lindane-treated canola seed for planting.[51]

62. On September 17, 1997, the EPA was requested by Mr. E. L.Moore of Gustafson, Incorporated[52] to clarify its position on the importation of canola seeds (for planting) treated in Canada with pesticide products which were not registered for that use in the United States and, in particular, with Thiabendazole, Lindane and/or Thiram (these three active ingredients were the active ingredients of Premiere Plus, which at that time was registered in Canada by Zeneca). On January 12, 1998, the EPA wrote to Mr. Moore in response to his letter, stating that it was illegal to import canola seeds for planting treated with pesticides that were not registered for canola use in the United States.

63. On March 12, 1998, the EPA publicly confirmed that it was illegal to import seeds for planting treated with pesticides that were not registered for use on that crop in the United States. Therefore, as lindane was not registered for use on canola in the U.S., lindane-treated canola seed fell under the EPA's import prohibition policy, although lindane was registered and permissible for other seed treatment uses in the United

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[50] Thomson Statement, para. 21.

[51] Ingulli Statement, para. 26. Note that it is necessary to distinguish between lindane-treated canola seeds for planting, which are subject to pesticide-related regulation, and canola seeds for processing into canola meal and canola oil, which are subject to food-related regulation.

[52] As noted, Gustafson, Incorporated was at this time wholly-owned by Crompton. However, it was separately and independently managed, and its business was not in any way integrated into Crompton's Crop Protection Division.

States. The EPA at this time indicated that prior to this clarification, the EPA's position on this matter had been poorly explained. Accordingly, rather than requiring immediate enforcement, the EPA requested that the Food and Drug Administration (the "FDA") make enforcement of lindane-treated canola imports a low priority until June 1, 1998.[53]

64. On June 5, 1998, the EPA released a draft notice that seeds treated with non-U.S. registered pesticides must themselves be registered in the United States before lawful sale, distribution or importation. However, it was understood within the industry that the enforcement target of the import ban was lindane products, notwithstanding the fact that there were at this time 31 other active ingredients registered in Canada for use on canola that were not registered in the United States.[54]

65. It is important to understand that U.S. canola growers were not seeking a ban of lindane products. Rather, their interest was in establishing a "level playing field", according to Mr. Roger Johnson, Commissioner of Agriculture, North Dakota Department of Agriculture. On August 5, 1998, Mr. Johnson met with the EPA and requested that it quickly establish a "tolerance"(based on a product registration) for lindane on canola seeds for planting in the U.S. or persuade Canada to discontinue lindane use on canola. A tolerance is the maximum permitted amount of pesticide residue which can be found in a product. [55]

66. As will be discussed below, the EPA made it clear that it would not issue a tolerance or registration for lindane on canola until the RED process had been completed.[56]

67. Accordingly, there was no immediate option available to provide North Dakota canola growers with lindane products or with lindane-treated canola seeds for

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[53] Ingulli Statement, para. 27 and Exhibits B2 to B4.

[54] Ingulli Statement, para. 28 and Exhibit B5.

[55] Ingulli Statement, para. 32 and Exhibit B7.

[56] Thomson Statement, para. 27.

planting. As a result, nor could this trade irritant, a purely political issue, be immediately resolved.

68. Based on these U.S. trade concerns, the PMRA actively sought to obtain a conditional withdrawal of Canadian lindane registrations for use on canola. It is clear from all documents and correspondence dealing with these matters that the PMRA's primary motivation was to address the trade issues with the United States.[57]

69. Tellingly, in early 1999, the PMRA stated that the "ultimate fate of the current lindane registration is in the U.S. and will be decided in the [EPA's] Reregistration review".[58] In other words, the PMRA's position at that time was that a favourable outcome in the EPA's RED process would ultimately decide whether lindane could be used on canola in Canada.

B. The "Agreement" Between the PMRA and the CCGA

70. Following the announcement of the EPA's position on the import prohibition of lindane-treated canola seeds for planting, there were a series of meetings and discussions in late 1998 and through 1999 between the PMRA and Canadian canola and seed grower associations, as well as Canadian registrants of lindane-based canola seed treatment products. The PMRA's stated purpose for the discussions was to establish a regime for the "voluntary" discontinuance of both the sale of lindane-based canola seed treatment products by registrants and the use by growers of lindane-treated seed.[59]

71. In November 1998, the PMRA and the Canadian Canola Grower's Association (the "CCGA"), a national organization representing the interests of provincial grower associations on national and international issues that affect canola growers, reached an initial "agreement" on the terms of the removal of canola/rapeseed claims from lindane

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[57] Ingulli Statement, para. 33 and Exhibits B8 to B11.

[58] Ingulli Statement, Exhibit B17.

[59] Ingulli Statement, para. 35.

labels by December 31, 1999, and for discontinuance of the sale and use of lindane products on canola/rapeseed and the sale and use of treated seed after July 1, 2001.[60]

72. This "agreement" did not reflect the understanding or intentions of Crompton Canada, particularly with respect to the July 1, 2001 deadline. Since neither the CCGA nor its members were lindane registrants, the CCGA could not make any sort of binding agreement with respect to lindane registrations, nor could the PMRA unless and until it had established a valid scientific basis for the cancellation of lindane registrations on canola. Thus, at this initial stage, both the CCGA and the PMRA had entered into an "agreement", parts of which neither had the authority to enter into.[61]

73. It is telling to note that this initial agreement was reached prior to the PMRA commencing, let alone concluding, its "Special Review". In fact, this "agreement" was an early indication that the PMRA had clearly targeted lindane for cancellation, notwithstanding the absence of any scientific basis for such a position and therefore the absence of a statutory authority to cancel the use of lindane products.[62]

C. Canada-U.S. Record of Understanding

74. Shortly after reaching an agreement with the CCGA, and in an effort to address the trade irritant issues that lindane posed, Canada and the U.S. entered into a Record of

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[60] Ingulli Statement, para. 36 and Exhibit B12. The removal of canola uses from lindane labels is important because the Canadian *Pest Control Products Regulations* imposed mandatory labelling requirements on manufacturers of crop protection products. These requirements prescribe the precise usage claims that may be made in respect of a given product. Most importantly, no person may use a registered product in a manner that is inconsistent with those directions and limitations respecting its use contained on the label: see *Pest Control Products Regulations*, Exhibit A2, ss. 27-51.

[61] Ingulli Statement, para. 36.

[62] Ingulli Statement, para. 37. The ROU was signed by the United States Trade Representative, the U.S. Secretary of Agriculture, the Canadian Minister of International Trade, the Canadian Minister of Agriculture and Agri-Food and the Minister of Natural Resources/Minister Responsible for the Canadian Wheat Board.

Understanding ("ROU") on December 2, 1998, regarding areas of agricultural trade.[63] The preamble to this ROU states:

> […] Canada and the United States further agree that actions that disrupt trade should be avoided and commit to address issues before they become problems as the preferred way of resolving bilateral trade differences.

75. Article 13 of the ROU further states, in part, that:

> Canadian canola growers have requested Canadian registrants to agree voluntarily to remove canola/rapeseed claims from labels of registered canola seed treatments containing lindane by December 31, 1999. All commercial stocks [of pesticide] containing lindane for use on canola and lindane treated canola seed would not be used after July 1, 2001. This is contingent on registrants requesting voluntary removal. EPA, PMRA, growers and registrants will continue to work together to facilitate access to replacement products.

76. Nowhere in the ROU was there any claim that the lindane withdrawal agreed to by Canada was necessary for environmental or public health reasons. Further, the ROU does not restrict all uses of lindane – only lindane use on canola. In fact, given the preamble to the ROU and the limitation of the restriction for use on canola, the agreement to restrict lindane use at paragraph 13 can only be read as a means to address the complaints of U.S. canola farmers and to protect access to the U.S. market as the most significant export market for Canadian canola growers, all at the expense of Canadian lindane registrants, Crompton Canada being by far the largest one.

D. Negotiation of the Conditional Withdrawal Agreement

77. Faced with the dilemma of abiding by its ROU commitments to the U.S. and the limitations on the PMRA's statutory authority, Canada, through the PMRA, began efforts to obtain from industry a "voluntary" withdrawal of lindane use on canola by Canadian lindane registrants, including Crompton Canada. This was the start of three years of

[63] Ingulli Statement, B13. Note in some documents the ROU is described as being dated December 4, 1998.

misinformation, non-responsiveness, threats, coercion and other egregious behaviour by Canada, all (eventually) cloaked in environmentalism and worker protection, to fulfill its ROU undertakings to the U.S.[64]

78. Under Canadian law, controlled products, including lindane, must be registered in order to be imported, sold or used in Canada.[65] Once registered, however, Canada can only cancel or suspend the registration when "based on current information available […] the safety of the control product or its merit or value for its intended purposes is no longer acceptable."[66] Canada did not have the legally required foundation to cancel or suspend the registration of the Lindane Products.

79. The PMRA characterized the Conditional Withdrawal Agreement as a "voluntary" withdrawal. The "voluntary" nature of the agreement is vitiated by the fact that Crompton Canada was dealing directly with the very body with the power to regulate the use of all pest control products and thus with the power to regulate Crompton Canada out of business. Canada had entered into a commitment with the U.S. to end Crompton Canada's canola-based lindane business, leaving Crompton Canada no alternative but to negotiate a viable accommodation of the PMRA's demands.[67] It is also important to note that although Canada consistently referred to this as a voluntary withdrawal, Canada later took the position that this was not a voluntary withdrawal as provided for in the Regulations and therefore registrants were not entitled to the rights associated with such a process.

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[64] Ingulli Statement, para. 41.

[65] Pest Control Products Regulations, Exhibit A2, section 6.

[66] *Ibid*., Exhibit A2, Section 20.

[67] Ingulli Statement, para. 41.

80. As described below, there were several key conditions to Crompton Canada's acceptance of the "voluntary" withdrawal. For clarity, these conditions as they relate to the Lindane Products and to the non-lindane replacement products will be described separately.

1. Conditions relating to the Lindane Products

81. From December 1998 through October 1999, Crompton Canada and the PMRA exchanged several letters regarding the conditions under which Crompton Canada would agree to "voluntarily" withdraw canola use from its lindane registrations.[68]

82. From the outset, it was agreed that registrants could manufacture lindane products labelled for canola use until December 31, 1999. In conjunction with that, registrants were required to amend their product labels by December 31, 1999 to remove canola use as a permitted use. However, there were areas of disagreement, particularly with respect to the date of cessation of use of lindane products.[69]

83. Initially, a key condition of Crompton Canada's "voluntary" withdrawal was the ability to sell all remaining Lindane Products until the stocks produced to the end of the then-current crop year of production (December 31, 1999) were depleted. [70] This was consistent with the practice described in section 16 of the Regulations.[71] Crompton Canada's concern was that, as canola acreage varies from year to year, all the Lindane Products produced for a particular crop year might not be sold in that year. Accordingly, if all Lindane Products had not been sold and used, a costly disposal issue could arise. This condition also included, by necessary implication, that any purchaser of Lindane Products could use the lindane to treat seeds, and purchasers of such treated seeds could

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[68] Ingulli Statement, para. 43.

[69] Ingulli Statement, para. 44.

[70] Ingulli Statement, para. 45 and Exhibit B13.

[71] Exhibit A2, Regulations, section 16. Section 16 is the provision which is intended to provide for voluntary withdrawals.

plant the seeds, past the proposed July 1, 2001 deadline referred to in the CCGA's November 1998 letter which purported to summarize the terms of the "voluntary" withdrawal.

84. Given that the shelf-life of the Lindane Products is generally two years, the cessation of production as of December 31, 1999 meant that it was expected that Lindane Products would be used for the 2000 and 2001 crop years.[72]

85. As the "voluntary" withdrawal required by the PMRA was done without any existing or emerging science-based rationale, the sole new "fact" being the ROU entered into by Canada with the U.S., a second essential term requested by Crompton Canada was that the PMRA should undertake to perform a scientific study of lindane's safety and efficacy and to complete the study by the end of 2000. Crompton Canada was concerned about the subsequent right, after "voluntary" withdrawal, of reinstating lindane for use on canola seed once any possible science-based concerns, should any arise from the scientific review, had been resolved. It was for this purpose that Crompton Canada raised the subject matter of a scientific review by the EPA and by the PMRA.[73]

86. The PMRA advised Crompton Canada that a Special Review of all uses of lindane products was targeted for completion in December 2000. Since Crompton Canada expected that it would be at least able to sell its stock of existing product until 2001, the date for the completion of the scientific review was acceptable. The PMRA and the EPA were supposed to be coordinating their reviews. As it turns out, however, the PMRA relied on the EPA to review the science, with the exception of occupational exposure, which was the PMRA's exclusive focus in its Special Review. And on that issue of

[72] Ingulli Statement, para. 46.

[73] Ingulli Statement, para. 47.

occupational exposure, the PMRA's conclusions in late 2001 would be the exact opposite of the conclusions reached by the EPA in mid-2002.[74]

87. Throughout the fall of 1999, Crompton Canada and the PMRA continued to negotiate the terms of the "voluntary" withdrawal. Crompton Canada emphasized the importance of a completed scientific assessment by the end of 2000 and the continued ability of seed treaters to use stocks of product containing lindane on canola/rapeseed, as well as the ability of growers to plant lindane-treated canola after December 31, 1999 until such stocks were depleted. The PMRA, for its part, confirmed that if the EPA issued a tolerance, it would re-instate the registrations for the Lindane Products on an expedited basis.[75]

88. However, in the PMRA's view, an unlimited time to sell stock produced before December 31, 1999 was unacceptable, and after further discussions with PMRA officials, Crompton Canada agreed by letter dated October 27, 1999 to compromise by accepting a fixed date of July 1, 2001 for the end of sales of existing stocks of Lindane Products. There was no discussion between the PMRA and Crompton Canada of any restriction applicable to the sale of treated seeds or for the subsequent planting of treated seeds.[76]

89. Crompton Canada, believing in good faith that the PMRA would complete the agreed upon scientific study before the end of 2000, and confident that the results would be favourable such that it would be able to apply for reinstatement of its lindane registrations, finally agreed by letter dated October 27, 1999 to a "voluntary" withdrawal of sales of lindane stocks for canola seed treatment produced as of December 31, 1999, in accordance with the conditions set out in this letter.[77]

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[74] Ingulli Statement, para. 50 and Exhibit B17.

[75] Ingulli Statement, para. 50.

[76] Ingulli Statement, para. 56.

[77] Ingulli Statement, para. 57 and Exhibit B20.

90. On the following day, October 28, 1999, the PMRA accepted the terms of Crompton Canada's conditional withdrawal.[78]

91. Throughout these negotiations, a further critical condition was the registration of replacement products. These negotiations, and the commitments made by the PMRA, are described below.

2. Conditions relating to the Non-Lindane Replacement Products

92. Given the extent of the flea-beetle problem in Canada, an insecticide to control flea beetles is essential for farmers. Further, it is much more cumbersome and costly to use separate fungicide and insecticide products.[79]

93. Throughout 1998 and 1999, the PMRA represented to Crompton Canada that it would expeditiously process requests for registration of both lindane-removed versions of existing products (which would therefore be fungicide-only products) and non-lindane replacement products (i.e. insecticide-fungicide products with an insecticide other than lindane).[80]

94. By late 1998, when discussions about the conditional withdrawal agreement began, Crompton Canada and Gustafson were waiting for the PMRA to approve the registration of Gaucho 75ST, with the insecticide imidacloprid, for domestic use on canola seed. Also, at this time, Crompton Canada and Gustafson were in the process of developing an all-in-one insecticide-fungicide for canola, with imidacloprid as the insecticide.[81]

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[78] Ingulli Statement, para. 58 and Exhibit B21.

[79] Ingulli Statement, para. 60.

[80] Ingulli Statement, para. 61.

[81] Ingulli Statement, para. 62.

95. Gaucho, with the insecticide imidacloprid, had been fully reviewed and registered by the EPA for use on canola in the U.S. since November 18, 1994, and had been registered by the PMRA for use on canola seed destined for export in November 1996. This product was a stand-alone insecticide.[82]

96. As noted previously, on November 26, 1998, the CCGA wrote to the PMRA, purporting to summarize the agreement reached between the CCGA, the PMRA and the lindane registrants.[83] With respect to replacement products, the CCGA summarized the key points of the agreement:

> (1) The PMRA and the EPA will continue to work with registrants to facilitate access to lindane replacement products. […]
>
> (2) Stakeholder meetings would be scheduled for June and October 1999 to review progress toward the approval of lindane replacement products and to discuss progress in the following areas:
>
> a) Approval of seed treatments in which lindane is removed and which contain fungicides only (lindane-free formulations of existing seed treatment products).
>
> b) Approval of seed treatments in which lindane is removed and replaced with active ingredients that are currently approved as seed treatments for other crops or are currently approved for other uses (such as foliar applications in canola).
>
> c) Approval of new active ingredients which will replace lindane in canola seed treatments.
>
> […]
>
> (3) Any registrant wishing to gain approval for a lindane-free seed treatment in time for the 1999 canola seeding must make a formal request to PMRA by December 31, 1998. This applies only to

[82] Ingulli Statement, para. 63.

[83] Ingulli Statement, Exhibit B11. Note that although this letter did not accurately reflect Crompton Canada's agreement on certain points, it does accurately reflect that the PMRA made commitments in respect of the registration of both lindane-removed versions of existing products and non-lindane replacement products.

> requests in which lindane is removed from existing formulations of approved seed treatments.[84]

97. It was very clear from this letter, and it was understood in the industry, that lindane-free formulations and lindane replacement products were distinct products, and that the PMRA was committing to an expedited review and registration of both types of products.[85]

98. Following the PMRA/CCGA initial "agreement" to compel registrants to "voluntarily" withdraw canola use, Crompton Canada and Gustafson set out their conditions for the "voluntary" withdrawal by letter dated December 17, 1998 to the PMRA. Key conditions in respect of replacement products were as follows:

> […]
>
> 2. PMRA has granted the registration of the imidacloprid insecticide-based formulations Gaucho 75ST and Gaucho 480 for use on canola for planting in Canada at least six months prior to the withdrawal of canola from the labels of Uniroyal Chemical Co. lindane-based seed treatments. […]
>
> […]
>
> 4. A "lindane-free" carbathiin-thiram fungicide formulation will be approved for registration by PMRA for use on canola by February 1, 1999. […] Also as agreed, the "lindane-free" formulation will consist essentially of one of the currently registered Uniroyal Chemical Co. carbathiin-thiram-lindane formulations as a basis, but with the lindane insecticide removed, and the remaining formulation re-balanced with inert formulants.
>
> 5. A "lindane substitution" product will be approved for registration by July 1, 1999, consisting of the active ingredients carbathiin-thiram-imidacloprid, and based on the currently registered Vitavax RS Dynaseal formulation containing carbathiin-thiram-lindane. […]
>
> 6. PMRA and EPA will ensure that a harmonized review and registration of both the "lindane free" and "lindane substitution"

[84] Ingulli Statement, para. 64 and Exhibit B12.

[85] Ingulli Statement, para. 65.

> products occurs in the U.S., as well as Canada by July 1, 1999. […].[86]

99. This was followed-up by a second letter from Gustafson to the PMRA on January 11, 1999, focussing on the issue of the registration of replacement products, stating:

> […]
>
> You had expressed concern [in a telephone conversation] that PMRA was being obligated to provide outcomes that were beyond the sole control of PMRA. However, let me clarify our expectations. Our assessment in the determination of satisfactory progress of PMRA in this matter, whether related to the registration of replacement products or in harmonisation efforts, will be limited to those areas in which PMRA plays some critical role. We will not presume that PMRA should be expected to deliver that which is beyond its reasonable influence or control.
>
> We are interested in working with PMRA toward solutions. We appreciate your proposal for a mechanism of expedient registration of a "lindane free" (non insecticide) seed protectant for canola. It would seem that when a rational case can be made for simplifying registration requirements, particularly when risks are reduced, that innovative means can be employed to achieve results. […].
>
> Equally, a rationale can be justified for simplifying registration requirements for a "lindane substitution" formulation, where lindane is directly replaced by Gaucho in the present canola seed protectant formulations. Considering the aspects of safety, environment, U.S. tolerances etc. in comparison of the risks of using Gaucho over lindane, there would be a strong case to find a means to streamline data requirements in support of an expedient registration. Can you please advise me how we can go about finding a mechanism for this to move forward? [87]

100. The PMRA responded by letter dated February 9, 1999, stating:

> […]
>
> PMRA and the EPA continue to be committed to work with growers and registrants to facilitate access to replacement products

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[86] Ingulli Statement, para. 66 and Exhibit B14.

[87] Ingulli Statement, Exhibit B22

> as well as to work together to develop a harmonized policy for movement of pesticide treated seeds by December, 1999. […].
>
> Uniroyal/Gustafson has submitted a lindane-free fungicide formulation for use on canola and is interested in a priority review. PMRA has committed to fast tracking these simple formulation changes, given the importance of lindane-free formulations to the grower community.
>
> I understand your interest in having alternative products to fill the void that would be created by voluntary removal of lindane from your current canola/rapeseed dressing formulation. This same need, not surprisingly, is also seen by other suppliers. Recognizing the scope of this challenge and the range of clients requesting fast track consideration, we are in the process of developing an orderly approach to this special need situation. It will be important to respond to all of these requests in an equitable manner.[88]

101. While it is true that other registrants also wanted an expedited review for their lindane replacement products, it was Crompton Canada that had [***]% of the market while the remaining **[***]**% was divided between the other three registrants. Therefore Crompton Canada had the most to lose if its replacement product was not registered in a timely manner after having given up the most in its "voluntary" withdrawal of lindane.

102. A further exchange of letters ensued on the issue of replacement products. On March 2, 1999, Crompton Canada responded to the PMRA's February 9, 1999 letter stating:

> We are proceeding on the basis of good faith that progress will ensue in the timely registration of new replacement products. However, I will clearly state that our company will not voluntarily withdraw unless we have suitable alternative Uniroyal and Gustafson products registered to replace them.[89]

103. On March 25, 1999, the PMRA responded by letter stating that it was committed to facilitating access to alternatives:

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[88] Ingulli Statement, Exhibit B15.

[89] Ingulli Statement, Exhibit B16.

> Although the voluntary agreement does not promise registration of replacements for lindane seed treatments for Canada, the Pest Management Regulatory Agency (PMRA) is committed to working with growers and registrants to facilitate access to alternatives.
>
> To this end, we are working with registrants and a number of active ingredients that may emerge as viable alternatives for lindane in canola seed during applications. The Agency cannot establish the outcome of an assessment in advance of the review process, and therefore, cannot predict whether Uniroyal and Gustafson will have a registered product replacement.[90]

104. In August 1999, the PMRA advised Crompton Canada that Gaucho 75ST and Gaucho 480FL (both products were insecticide only) had been approved for registration for domestic use on canola. With these registrations, Crompton Canada had separate fungicide and insecticide registrations, but did not have a non-lindane all-in-one insecticide-fungicide product (such as Gaucho CS FL) registered. Given the inconvenience of using separate fungicide and insecticide products, these were not a commercially viable option.[91]

105. The only subsequent correspondence from the PMRA prior to the conclusion of the Conditional Withdrawal Agreement on this issue was the PMRA's letter dated October 21, 1999, in which it was repeated that the PMRA had committed to facilitate access to replacement products.[92] Crompton Canada proceeded to accept the "voluntary" withdrawal on the basis that the specific requests in its earlier correspondence regarding non-lindane replacement products would be honoured. In fact, not only was the registration of Crompton Canada's all-in-one replacement product, Gaucho CS FL, not

[90] Ingulli Statement, Exhibit B17.

[91] Ingulli Statement, Exhibit B72.

[92] Ingulli Statement, Exhibit B23.

expedited, it actually took the PMRA much longer to register this product than the PMRA's average registration times for this type of submission.[93]

IV. THE CONDITIONAL WITHDRAWAL AGREEMENT

106. Given its importance, the full text of Mr. Ingulli's October 27, 1999 letter, setting out Crompton Canada's conditions for the "voluntary" withdrawal of its lindane products for canola, is reproduced below:

> Further to my letter of October 26, 1999 and my subsequent phone conversation on October 27, 1999 with Dr. Wendy Sexsmith of PMRA, both Uniroyal and PMRA are in agreement with the provisions associated with Uniroyal's commitment to voluntarily remove canola/rapeseed from the product labels of Uniroyal Chemical Co. seed protectants that contain lindane insecticide by December 31, 1999, and these provisions are as follows:
>
> 1. All other registrants of products used to treat canola that contain lindane also agree to voluntarily withdraw canola from their product labels by the end of 1999.
>
> 2. PMRA and the EPA shall coordinate and collaborate on the timely review and re-evaluation of any new lindane data already submitted and/or to be submitted in accordance with any data call in or regulatory request and provide a scientific assessment of lindane by the end of 2000.
>
> 3. In the event that both government agencies determine that lindane has adverse toxicological effects and deems it unsafe for use on canola as a seed treatment, Uniroyal will not request the reinstatement of lindane use on canola in Canada.
>
> 4. In the event that PMRA determines that lindane is safe to be used on canola as a seed treatment or EPA should issue a canola tolerance or determine that lindane is exempt from requiring a tolerance in canola, Uniroyal shall request from PMRA the reinstatement of products and uses of lindane on canola that were voluntarily withdrawn. PMRA agrees to grant such reinstatement within 30 days after Uniroyal's application for reinstatement and payment of a fee of $154.00, without any other pre-conditions, including the possibility that PMRA has not completed its re-evaluation of

[93] Ingulli Statement, para. 73.

> lindane prior to EPA issuing a canola tolerance or an exemption from tolerance. Thereafter, Uniroyal reserves the right to recommence production of its lindane-containing product for use on canola/rapeseed in Canada and/or USA.
>
> 5. Uniroyal Chemical Co. lindane-based products will continue to be registered on all remaining crops, including mustard and cole crops listed on those product labels after the removal of canola/rapeseed. Uniroyal Chemical Co. reserves the right to continue to produce lindane product for such uses that remain on the label.
>
> 6. All stocks of Uniroyal's products containing lindane for use on canola/rapeseed are allowed to be used up to and including July 1, 2001.
>
> 7. Any stocks of Uniroyal's products containing lindane for use on canola/rapeseed that are produced prior to January 1, 2000 and that require rework by Uniroyal Chemical can be reprocessed by Uniroyal Chemical and used on canola/rapeseed. This is necessary as part of Uniroyal's Responsible Care and Product Stewardship program.
>
> I would appreciate it if PMRA would confirm in writing the above understanding, after which Uniroyal will request PMRA in writing to remove canola/rapeseed seed treatment use from the label of its lindane-containing product.[94]

107. The full text of the response letter of Dr. Franklin of the PMRA on October 28, 1999 was as follows:

> I am confirming that PMRA is in agreement with both your stated commitment to voluntarily remove canola/rapeseed from the product labels of Uniroyal Chemical Co. seed protectants that contain lindane by December 31, 1999 and the provisions that are outlined in the October 27, letter received from you by fax.
>
> I would like to thank you for remaining supportive of the November 1998 voluntary agreement and look forward to receiving the request in writing to remove the canola/rapeseed seed treatments from the labels of the products.[95]

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[94] Ingulli Statement, Exhibit B20.

[95] Ingulli Statement, Exhibit B21.

108. As part of the process leading to the Conditional Withdrawal Agreement, the PMRA had also committed to expedited reviews of lindane-removed versions of existing products and lindane replacement products (i.e. insecticide-fungicide products with an insecticide other than lindane).[96]

109. In reliance on the conditions of the "voluntary" withdrawal, Crompton Canada carried out, *inter alia*, the following steps and actions:

(a) on or about December 7, 1999, Crompton Canada filed for an amendment of the lindane control product registration to remove canola use from the labels;

(b) Crompton Canada produced the amount of the Lindane Products prior to December 31, 1999 adequate to ensure sufficient supply for the market as indicated by users over the following crop years of 2000 and 2001;

(c) Crompton Canada planned for the reduction in profit from the cessation of sales of the Lindane Products after July 1, 2001; and

(d) Crompton Canada pursued the formulation and registration of a lindane-removed version of Vitavax RS Flowable and a lindane-free insecticide-fungicide replacement product.[97]

110. Consistent with the product registration and the terms and conditions of the "voluntary" withdrawal, Crompton Canada produced Lindane Products labelled for use on canola seed until December 31, 1999.[98]

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[96] Ingulli Statement, para. 76.

[97] Ingulli Statement, para. 77.

[98] Ingulli Statement, para. 78.

V. CANADA'S FAILURES TO ABIDE BY ITS COMMITMENTS

A. The PMRA's Threats and Misinformation Regarding the July 1, 2001 Deadline

111. The Conditional Withdrawal Agreement clearly stated that lindane-containing seed treatment products could be sold and used to treat seed until July 1, 2001. In the absence of any further condition, the necessary implication was that there was no restriction in terms of when the treated seed could be sold or when the treated seed could be planted. Indeed, it is illogical to interpret the July 1, 2001 deadline as the date by which seed could be treated and the date by which the seed must be sold and planted. Such an interpretation would render the July 1, 2001 date meaningless.[99]

112. Crompton Canada's understanding of the July 1, 2001 deadline was consistent with the understanding of the other registrants, in their letters to the PMRA confirming their agreement to the conditional withdrawal. Both Zeneca and Rhône-Poulenc wrote to the PMRA in late 1999 confirming their understanding that lindane products could only be sold until July 1, 2001. The other registrant, Interprovincial Cooperative Limited ("IPCO"), confirmed to the PMRA its understanding that lindane products could not be used to treat seed after July 1, 2001.[100]

113. In other words, in the agreements of all the registrants to the conditional withdrawal, there was no suggestion of any restriction on the sale of treated seed or the planting of such seed after July 1, 2001.

114. Tellingly, by letters dated February 16, 2000 and May 11, 2001, the PMRA advised IPCO that the use of its lindane product was acceptable until July 1, 2001. The PMRA

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[99] Ingulli Statement, para. 81. For greater clarity, there are four main steps involved with the sale and use of lindane products: (1) the registrant/distributor sells the lindane products to customers, primarily seed treatment companies; (2) the seed treatment companies use the lindane products to treat seeds; (3) the treated seeds are then sold to farmers; and (4) the farmers then use, i.e. plant, the treated seeds. The Conditional Withdrawal Agreement only imposed a deadline on the first two steps.

[100] Ingulli Statement, Exhibits B24 to B26.

did not in any way state or suggest that the sale or planting of lindane-treated seed was prohibited after July 1, 2001.[101]

115. These agreements reflected the understanding of the registrants and the industry. From the very outset, all industry participants had stressed the importance of the industry being able to use and deplete existing stock, given the serious disposal problem that would be created if existing lindane supplies could be used up.[102]

116. The above understanding regarding the July 1, 2001 deadline was a condition upon which Crompton Canada had entered into the conditional withdrawal, and it was not until late 2000 when Crompton Canada became aware that the PMRA had decided differently, after having secured Crompton Canada's agreement to the removal of canola use from its labels.

117. In late 2000, Crompton Canada became aware of statements attributed to the PMRA to the effect that not only was the sale of lindane-based products for canola use prohibited after July 1, 2001, but the planting of any lindane-treated canola seeds was likewise prohibited. Further, Crompton Canada became aware that purchasers of the company's lindane-based products and users thereof were, in effect, being threatened with fines up to $250,000 if they sold lindane-treated canola seed after July 1, 2001.[103] This was the first time that Crompton Canada became aware of any such "interpretation" by the PMRA of the "voluntary" withdrawal agreement.[104]

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[101] Ingulli Statement, Exhibit B27.

[102] Ingulli Statement, para. 89 and Exhibit B28.

[103] Note that in various documents, the maximum fine is in some instances stated to be $200,000 and in other instances stated to be $250,000. At this time, the maximum fine under the Act was $250,000. For consistency, the references herein will be to $250,000.

[104] Ingulli Statement, para. 90.

118. At a meeting in November 2000 between the PMRA staff, the CCGA, the Canola Council of Canada ("the "CCC") and seed treaters, Mr. Jim Reid, the Chief Compliance Officer of the PMRA, in the context of a discussion of the carryover of stocks of treated seeds beyond July 1, 2001, described the enforcement policies of the PMRA and the fines for contraventions of the Act.[105] Following this meeting, Mr. Bill Leask, Executive Vice-President of the CSTA sent an email to various industry participants, entitled "Update: Lindane seed treatment on canola" on November 30, 2000. In that email, Mr. Leask indicated that the PMRA advised that canola seed could not be treated with lindane products after July 1, 2001 and that lindane-treated canola seed could not be sold after that date. The PMRA stated that enforcement could entail inspection and prosecution with a fine up to $250,000:

> As of July 1, 2001, lindane cannot be sold for treating canola seed and seed cannot be treated or sold. I assured PMRA that manufacturers would not be selling lindane containing products for canola nor would seed companies be treating seed after July 1, 2001.
>
> After July 1, 2001 enforcement could entail inspection and appropriate enforcement. The goal is compliance. If PMRA chooses to prosecute a company or individual selling lindane or lindane treated seed it would be a criminal offence. Fines could be as high as [$250,000].
>
> However, PMRA recognises that it will be very difficult for the seed companies to have no inventory of treated seed left on July 2, 2001. They understand the seed companies will do their best to minimize treated seed carryover. They are interested in working with the industry to ensure that there will not be disposal problems with treated seed and they recognize that the best use of the seed would be to sow it for production in 2002.[106]

119. In a "Fast Facts Fax" sent to various industry participants dated December 2000, the Canadian Association of Agri-Retailers stated that:

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[105] Ingulli Statement, Exhibit B29, para. 23.

[106] Ingulli Statement, Exhibit B30.

> The Pest Management Regulatory Agency (PMRA) has amended the [text not legible] 2001, Lindane cannot be sold for treating canola seed, nor can seed treated with Lindane be sold. After July 1, PMRA can inspect facilities to ensure there are no Lindane products or Lindane treated seed on site. After this date the selling of Lindane or Lindane treated seed would be a criminal offence, and fines could be as high as [$250,000].[107]

120. On January 12, 2001, Mr. Adam Vaughan of Gustafson spoke with Mr. Ross Pettigrew of the PMRA. Mr. Pettigrew advised him that the $250,000 figure was being mentioned in the industry probably in response to a question about what the penalties would be for a contravention of the Act. He felt that this number was used as a motivation to get lindane used up. Mr. Pettigrew also advised that the PMRA would be conducting inspections.[108] The accuracy of the description of this conversation is confirmed by an email from Mr. Pettigrew to Ms. Jocelyn Cabilete of Health Canada on March 14, 2001.[109]

121. On January 16, 2001, Mr. Bill Leask of the CSTA released a Lindane memo, which summarized legal advice that the CSTA had received, as well as the CSTA's proposed plan of action. The legal advice confirmed that the Act and Regulations covered both seed treatments and treated seed. The advice also confirmed that the Act provided penalties of up to $250,000 and 2 years in jail and also noted that section 16 of the Regulations provides for the substantial exhaustion of stocks through sales where there has been a voluntary withdrawal. On the basis of section 16, the CSTA intended to approach the PMRA with a view to obtaining an extension. The CSTA also indicated that it would be conducting a survey of all seed companies to determine the amount of lindane seed treatments and treated seed in the industry. [110]

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[107] Ingulli Statement, Exhibit B31.

[108] Ingulli Statement, Exhibit B32.

[109] Ingulli Statement, Exhibit B33.

[110] Ingulli Statement, Exhibit B34.

122. In the circumstances, Crompton Canada wrote to the PMRA on February 12, 2001, expressing concern that the PMRA had made statements that were contrary to the terms and conditions of Crompton Canada's conditional withdrawal. Crompton Canada also expressed concern that the condition requiring a scientific review by the end of 2000 had not been respected. On the issue of the July 1, 2001 deadline, Mr. Ingulli stated:

> Uniroyal Chemical Co. and the seed trade have been concerned by recent reports coming from agricultural groups stating "After July 1, PMRA can inspect facilities to ensure there are no Lindane products or Lindane treated seed on site. After this date the selling of Lindane or Lindane treated seed would be a criminal offence, and fines could be as high as $200,000". Please be aware that this statement has been circulating and has been attributed to PMRA.
>
> Both the registrants and the seed industry have acted in good faith by endeavouring to use up all lindane seed treatment stocks as quickly as possible. We hope that they will be used up entirely by July 1, 2001. Uniroyal ceased production of lindane-based canola seed treatments as agreed to, before December 31, 1999.
>
> We do not believe that these unofficial comments regarding fines are in fact in the spirit of the voluntary withdrawal. What justification would there be for this to be considered a criminal offence? This is simply using up existing stocks of a product that was produced as per the lindane withdrawal agreement and is being used in accordance with the label directions through normal channels. The withdrawal agreement involved a voluntary withdrawal and did not contain any stipulations regarding levying of fines for using up the existing seed treatments through normal channels by end users.
>
> If the goal is to prompt seed companies, manufacturers and growers to make sure that all lindane has been used up prior to the July 1 date, then the reverse has resulted. Many seed companies are now worried about treating their canola with lindane in case they end up with carry-over seed, which they would have to dispose of as hazardous waste at their own expense. The canola acreage for 2001 cannot be accurately predicted ahead of time because it is dependent on commodity prices. Seed companies would be at risk of having "illegal seed" if there were a major decline in acreage. […]
>
> […]
>
> […] The voluntary lindane withdrawal was intended to eliminate a potential trade issue and was not due to a health and/or safety issue and was not based on a completed risk assessment. The voluntary

> withdrawal did not have a scientific basis. The only basis for this withdrawal was the fact that no tolerance exists in the United States for lindane on canola.[111]

123. A position statement prepared by the CSTA, the CCC and the CCGA in March 2001 also describes the nature of the voluntary withdrawal process provided for under the Regulations:

> The manufacturing of lindane based seed treatments ceased as of December 31, 1999, as per the voluntary withdrawal agreement. The pipeline of product is finite and is being phased out as seed treatments. As was always the understanding, there is some carryover projected beyond the current planting season. It reflects the difference between current sales forecasts versus projected sales forecasts at the time the manufacturing was completed.
>
> Given the agreement that there would be carryover and the fact [of Section 16 of the *Pest Control Products Regulations*,] [i]t seems reasonable that after July 1, 2001, seed companies continue to deplete supplies until they have no further stocks. This prevents undesirable higher-risk disposal options. By far the best use is to plant the product as intended rather than using approved landfills.[112]

124. An email was sent to seed companies and registrants on March 26, 2001 by Judy Fredette of the CSTA, in which she describes a meeting between the CCGA, the CCC, the CSTA and the PMRA. She described the status as follows:

> The Canola Growers, Canola Council, and CSTA had a constructive meeting with officials from the Pest Management Regulatory Agency (PMRA) on Friday, March 23rd. During that meeting, a position was offered based on the CSTA document circulated two weeks ago and subsequently endorsed by the Canola Growers and Canola Council. PMRA has heard that case as to why carryover product should be dealt with through normal use of the product.
>
> PMRA has indicated that it will conduct an audit of registrants, seed companies, and seed treaters to assess how much lindane seed treatment and treated seed is in the system. Your complete

[111] Ingulli Statement, Exhibit B35.

[112] Ingulli Statement, Exhibit B36.

> co-operation will speed the process and thus a decision. Based on this information, discussions with EPA, and the case we set forth, a decision is expected in 3-4 weeks about how to proceed.
>
> There are no guarantees as to the decision. At this point, the rules still stand regarding the July 1, 2001 deadline. An audit had already been planned for the end of June as well, and members should be ready to expect that second audit as well. [113]

125. In a meeting between Fred Hnatiw of Gustafson and Ross Pettigrew of the PMRA on April 10, 2001, Mr. Pettigrew indicated that the standard answer to anyone inquiring about the July 1 date would have been that the PMRA has the authority to impose fines of up to $250,000 and that he would have given this message if asked about the consequences of not meeting the July 1 deadline.[114]

126. The consistent and repeated messages from the PMRA to the industry that fines could be imposed and that audits would be carried out created a chill throughout the market and caused farmers and seed treaters to seek alternative products.

127. It is telling to note that the PMRA's response to the allegation that it caused this market reaction was that it was simply informing the industry about the provisions of the legislation. But by the very Conditional Withdrawal Agreement itself – in which the PMRA allowed registrants to sell lindane-based products for use on canola after December 31, 1999, even though canola use had been de-registered – the PMRA had agreed not to enforce its legislation. The PMRA itself acknowledged that the "Agency agreed that the Minister's discretionary authority with respect to enforcement of compliance respecting lindane on canola seed would not be exercised prior to July 1, 2001.[115]

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[113] Ingulli Statement, Exhibit B37.

[114] Ingulli Statement, Exhibit B38.

[115] Ingulli Statement, Exhibit B40.

128. In an undated document released on October 31, 2001, the PMRA issued the results of its inspection program, which indicated the quantity of lindane seed treatments and lindane-treated canola seed which remained in the market after July 1, 2001. However, the PMRA again declined to indicate its position with respect to the sale or planting of lindane-treated canola seed for the 2002 season.[116]

129. The CCC, in a letter to the PMRA on December 17, 2001, requested that the PMRA approve the sale and use of the current stocks of lindane-treated seed for the 2002 growing season, but not the use of any remaining lindane seed treatments. The letter confirmed that the four registrants of lindane products for use on canola supported the sale and use of treated seed for the 2002 season.[117]

130. On December 17, 2001, Crompton Canada wrote to the PMRA to indicate its support for continued use of roll-over stocks of lindane-treated canola seeds for the 2002 growing season. This position was without prejudice to its position with respect to the sale and use of the Lindane Products for the 2002 season.[118] By letters dated December 10, December 12, and December 13, 2001, IPCO, Aventis, and Syngenta, respectively, also expressed support for the use of current inventories of lindane-treated seed for the 2002 growing season.[119]

131. More than one month later, on January 21, 2002, the PMRA responded by stating that since Crompton Canada and Aventis had reserved their rights with respect to the use of lindane products for the 2002 season, the PMRA interpreted this to mean that the industry

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[116] Ingulli Statement, Exhibit B41.

[117] Ingulli Statement, Exhibit B42.

[118] Ingulli Statement, Exhibit B43.

[119] Ingulli Statement, Exhibit B44.

was not in agreement. Therefore, the PMRA was not prepared to agree to the planting of treated seed for the 2002 season.[120]

132. This interpretation by the PMRA had no basis in fact or logic. It was perfectly reasonable for Crompton Canada and Aventis to support the planting of treated seed for the 2002 season, while maintaining their position that lindane products should also be permitted to be used for that season. Nevertheless, in order to assist the industry, Crompton Canada and Aventis, by letters dated January 24 and 25, 2002, agreed to relinquish their rights to sell existing lindane products for use on canola in the 2002 planting season, provided that the PMRA allowed the planting of existing stocks of lindane-treated canola seed in that season.[121]

133. In response to the foregoing, the PMRA agreed by letter dated March 4, 2002 to the CCC not to take enforcement action with respect to the use of lindane-treated seed for the 2002 growing season, provided the CCC accepted certain conditions.[122]

134. On March 5, 2002, the CCC provided an action plan in response and on March 8, 2002, the PMRA accepted this plan as satisfactory.[123]

135. However, as a result of the confusion created in the market by the position attributed to the PMRA, sales of Crompton's Lindane Products for treatment of canola seeds virtually ceased in the spring of 2001. As a result, Crompton was not able to deplete the Lindane Products produced up to December 31, 1999 through sales, contrary to what had been contemplated under the terms and conditions of its "voluntary" withdrawal.[124]

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[120] Ingulli Statement, Exhibit B45.

[121] Ingulli Statement, Exhibits B46 and B47.

[122] Ingulli Statement, Exhibit B48.

[123] Ingulli Statement, Exhibit B49.

[124] Ingulli Statement, para. 113.

136. Crompton Canada and Gustafson were faced with not only the loss of revenues and profits but also the cost and difficulty of destruction of any unused Lindane Products. (Deregistered pesticides are normally disposed of through use in the field as opposed to destruction as a hazardous product.)[125]

137. As noted above, the PMRA characterized the Conditional Withdrawal Agreement as a "voluntary withdrawal". The withdrawal was not voluntary, nor did it comply with the procedure for a voluntary withdrawal prescribed in the *Pest Control Products Regulations*. Section 16 of the Regulations prescribes the following procedure for withdrawal of the sale of a control product:

> Where the registrant intends to discontinue the sale of a control product, he shall so inform the Minister and the registration of that control product shall, on such terms and conditions, if any, as the Minister may specify, be continued to allow any stocks of the control product to be substantially exhausted through sales.
>
> [Emphasis added]

138. Section 16 reflected standard practice, that is, to allow exhaustion of stocks through sales. In the present case, the PMRA not only acted contrary to standard practice but indeed acted contrary to the specific commitments made in the Conditional Withdrawal Agreement.

B. Failure to Complete a Scientific Assessment of Lindane by the End of 2000

139. The second condition of the Conditional Withdrawal Agreement required:

> PMRA and the EPA shall coordinate and collaborate on the timely review and re-evaluation of any new lindane data already submitted and/or to be submitted in accordance with any data call in or regulatory request and provide a scientific assessment of lindane by the end of 2000.

[125] Ingulli Statement, para. 114.

140. No such scientific assessment was completed by 2000.[126]

141. The PMRA had announced the commencement of a Special Review into lindane products on March 15, 1999, pursuant to Section 19 of the Act. In its announcement, the PMRA defined the rationale and scope of the Special Review as follows:

> **Rationale**
> The decision to review lindane-containing products was influenced by the following:
>
> - Lindane is under national and international scrutiny as a result of its persistence, potential for long-range transport and widespread occurrence in the environment. Many unanswered questions remain regarding the potential impact on humans and wildlife of various isomers of lindane found in the environment.
>
> - Canada, the United States (U.S.), European countries and Russia have recently negotiated an international protocol on persistent organic pollutants under the Convention on Long-Range Transboundary Air Pollution of the United Nation's Economic Commission for Europe. This agreement established obligations aimed at restricting or eliminating chemical substances that contribute to transboundary pollution, including a commitment to restrict the uses of lindane and to conduct a reassessment of all remaining uses. In North America, Canada, the U.S. and Mexico are considering taking regional action on lindane under the North American Agreement on Environmental Cooperation.
>
> **Scope**
> The scope of issues surrounding Lindane is potentially broad. Initially the Pest Management Regulatory Agency ("PMRA") will examine the chemistry of existing Lindane products registered in Canada, and the extent to which these products may contribute to levels of various isomers in the environment. The PMRA will consult with other Canadian government departments and international regulatory agencies, e.g. U.S. Environmental Protection Agency, to benefit from ongoing reviews of Lindane. The PMRA's current understanding of Lindane suggests the issues are complex and merit a Special Review at this time. As a better

[126] Ingulli Statemnt, para. 116.

> understanding of the potential for adverse effects becomes known, the scope of this review may change.
>
> **Data Required**
> No data is required at this time. Registrants and interested parties will be notified of specific data requirements as necessary in the near future.
>
> **Registration of Products Containing Lindane**
> Pending completion of this Special Review, the PMRA will not consider use expansions. In addition, all new products, registration renewals and amended registrations that are granted in 1999 will expire December 31, 1999. All subsequent new products, registration renewals and amended registrations will be for a period not exceeding one year until this Special Review is complete. This registration status of all Lindane-containing products will depend on the outcome of this review. The target date for completion of this review is December 2000.[127]

142. The notice announcing the Special Review, which cites unspecific environmental concerns with lindane but no toxicological or occupational concerns, requested no data or other information from lindane registrants, provided no procedures or schedule for the conduct of the Special Review, and provided no obvious way for affected parties to participate in the regulatory process, apart from an address that is given for "inquiries".[128]

143. As seen by the announcement itself, the Special Review was to be completed by 2000.

144. However, it was not until late 2001 that the PMRA released its Occupational Exposure Assessment which was ostensibly the culmination of this Special Review.[129]

145. In a meeting at Gustafson's Guelph office on April 10, 2001, Ross Pettigrew of the PMRA told Fred Hnatiw of Crompton Canada (and others present) that the PMRA put no resources toward completing the lindane scientific review because everyone at PMRA

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[127] Ingulli Statement, Exhibit B50.

[128] Ingulli Statement, para. 118.

[129] Ingulli Statement, para. 120.

felt the issue would go away by the July 1, 2001 deadline and there would be no need to expend the resources on a review.[130]

146. In an affidavit sworn August 9, 2001, Ms. Sexsmith stated that the PMRA's targeted completion of the Special Review by the end of 2000 "had been delayed for reasons beyond the Agency's control". As an example, she then stated:

> [T]he EPA is currently waiting for industry to provide a re-analysis of data relating to potential carcinogenicity issues concerning lindane products. That information relates to the assessment of health risks.[131]

147. Notwithstanding this statement, two months later the PMRA released its Occupational Exposure Assessment, which was based entirely on occupational exposure concerns.

148. The PMRA's actions throughout this saga demonstrate a motivation to address trade irritants, followed by a motivation to address political concerns and are inconsistent with both with due process and legitimate scientific analysis.

149. Given the failures by the PMRA to abide by the terms of the Conditional Withdrawal Agreement, Crompton Canada filed a request on May 8, 2001 for reinstatement of the use on canola and rapeseed on the labels of the five Lindane Products which had previously been registered for canola use and in respect of which canola use had been withdrawn pursuant to the Conditional Withdrawal Agreement. This request was made based on the position taken by the Minister as to the legality of prior and future sales, and on the PMRA's failure to conduct the scientific review in a timely manner and provide a scientific assessment of lindane by the end of 2000. [132]

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[130] Ingulli Statement, Exhibit B52.

[131] Exhibit A3, para. 20.

[132] Ingulli Statement, Exhibit B50, para. 123 and Exhibit B53.

150. On May 29, 2001, the PMRA refused to reinstate the requested lindane registrations. The PMRA wrote:

> The PMRA believes that the conditions under which Uniroyal can properly require reinstatement to its lindane product registrations of the canola/rapeseed use have not yet been met and that to grant your request at this time would not be consistent with the terms of the voluntary agreement.[133]

151. As described further below, the PMRA would confirm this refusal again on February 11, 2002.

C. Termination of the Canadian Market for all Lindane Products

152. As noted, on October 26, 2001, the PMRA released its Occupational Exposure Assessment, which was the culmination of the PMRA's Special Review.[134]

153. The PMRA subsequently advised Crompton by letter dated December 19, 2001, that registration of eight of its Lindane Products would be terminated, in one of two ways, i.e. either through the suspension of registrations or through the "voluntary discontinuation" of lindane registrations by the registrant.[135]

154. In the event a registrant agreed to voluntarily discontinue the affected registrations, the registrant would have a period of time within which the products could be sold)by the registrants and distributors/retailers), and used (by users/growers). For lindane products registered for control of wireworm on wheat, barley, oats, rye flax, corn, beans, soybeans and peas, the end use date was December 31, 2004:

> The time-frame proposed by registrants, and which is acceptable to the PMRA, for phase-out of sale and use of these lindane

[133] Ingulli Statement, Exhibit B54.

[134] Ingulli Statement, Exhibit B55.

[135] Ingulli Statement, Exhibit B56.

> products [registered for use on wheat, barley, oats, rye, flax, corn, beans, soybeans and peas] is as follows:
>
> - last date for sale of product by registrants: December 31, 2002
> - last date for sale of product by distributors or retailers: December 31, 2003
> - last date for use of product by users/growers: December 31, 2004
>
> […] Retail sale and use of product in 2003 and use in 2004 would be to allow for an orderly phase out and there would in fact be significantly less use of lindane in those years compared with 2002 and earlier. The end result would be the all [sic] lindane registrations would be cancelled on December 31, 2004 […].[136]

155. Registrants were requested to provide, by January 4, 2002, information on existing inventory and historical sales for products registered for the above-mentioned non-canola uses to ensure that the above would be an appropriate phase out period. [137]

156. For lindane products for control of flea beetles on mustard, cabbage, broccoli, Brussels sprouts, cauliflower and rutabaga, the PMRA stated that there were effective alternatives to lindane. Accordingly, the PMRA would accept a voluntary discontinuation of products for those uses but only for sale (by registrants, distributors and retailers) until April 1, 2002, and for the use of existing stocks until October 1, 2002, at which time the registrations would be cancelled.[138]

157. The PMRA wrote again to Crompton Canada on January 17, 2002. In this correspondence, it was explained that if a registrant chose not to "voluntarily" discontinue the affected registrations, the affected registrations would be suspended and any right to sell the registered product would be terminated as of the date of suspension.

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[136] Ingulli Statement, para. 129 and Exhibit B56.

[137] Ingulli Statement, Exhibit B51.

[138] Ingulli Statement, para. 131.

The PMRA enclosed a model letter of discontinuance. This correspondence referred to Crompton Canada's five Lindane Products for use on mustard and cole crops.[139]

158. By letters dated January 23 and January 28, 2002, Crompton Canada responded to the PMRA's letter of January 17, 2002, indicating that Crompton Canada did not concur with the PMRA's proposal for "voluntary" discontinuance.[140] Crompton Canada also indicated that there was no basis for immediate suspension of the affected registrations. Crompton Canada did, however, provide the requested sales figures and inventory information with respect to the flagged registrations necessary for determining a gradual phase out, consistent with section 16 of the *Pest Control Products Regulations*.

159. On February 11, 2002, the PMRA wrote to advise Crompton Canada that, based on the Occupational Exposure Assessment, the registrations of its five Lindane Products (for use on mustard and cole crops) had been suspended, effective immediately, for all uses.[141]

160. These products were the Lindane Products for which Crompton Canada had voluntarily withdrawn registration of the canola/rapeseed uses only, pursuant to the terms and conditions of the Conditional Withdrawal Agreement. It is worth recalling that Condition #5 of the Conditional Withdrawal Agreement stated:

> 5. Uniroyal Chemical Co. lindane-based products will continue to be registered on all remaining crops, including mustard and cole crops listed on those product labels after the removal of canola/rapeseed. Uniroyal Chemical Co. reserves the right to continue to produce lindane product for such uses that remain on the label.

161. The February 11, 2002 suspension decision eliminated Crompton Canada's rights under Condition #5 to market the products for use on crops other than canola seed.

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[139] Ingulli Statement, para. 132 and Exhibit B57.

[140] Ingulli Statement, Exhibit B58.

[141] Ingulli Statement, Exhibit B59.

162. On February 11, 2002, Crompton Canada received a second letter from the PMRA in which the PMRA again refused Crompton Canada's request to amend its registrations to add canola/rapeseed uses.[142] The PMRA indicated that the basis for the refusal to amend was also the Occupational Exposure Assessment.

163. On February 21, 2002, the PMRA wrote to Crompton Canada advising that its remaining registrations (i.e. the three Lindane Products for use on cereal crops) had been terminated through suspension.[143]

164. As a result of the PMRA's actions, all of Crompton Canada's lindane registrations were suspended. As such, Crompton Canada could not sell certain of its Lindane Products after February 11, 2002, and could not sell any Lindane Product after February 21, 2002.[144]

165. The PMRA terminated these lindane registrations without the right to phase-out use, notwithstanding that Crompton Canada had provided the sales and inventory information requested by the PMRA in order to be granted this right. The PMRA gave as its reason that Crompton Canada had stated in providing the information that it was not concurring with the proposed "voluntary" discontinuation and that Crompton Canada did not provide the required form letter of "voluntary" discontinuance by the January 31, 2002 deadline.[145]

166. According to the Regulations, a registration can be cancelled or suspended where the Minister has safety-based concerns.[146] Alternatively, a registrant can choose to

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[142] Ingulli Statement, Exhibit B60. This was in response to Crompton's May 8, 2001 request to the PMRA for re-instatement of canola uses on the label, which the PMRA had initially denied on May 29, 2001.

[143] Ingulli Statement, Exhibit B59.

[144] Ingulli Statement, para. 139.

[145] Ingulli Statement, para. 140.

[146] Exhibit A2, Regulations, s. 20.

discontinue the sale of a product and the registration shall be continued to allow any stocks of the product to be substantially exhausted through sales, subject to any conditions imposed by the Minister.[147]

167. In this case, the PMRA told registrants that they could either "voluntarily" withdraw or that their registrations would be terminated through suspension.

168. As Crompton Canada did not agree to "voluntarily" discontinue use of its Lindane Products, it was not granted the right to a phased-out termination of lindane use as provided for in section 16 of the Regulations.

169. It is important to recognize that the PMRA purported to be acting upon its "significant concerns" about occupational exposure and that those concerns purportedly warranted termination of the lindane registrations. However, these concerns were evidently not so significant that the immediate termination of the registration was required. Instead, provided that registrants agreed to the PMRA's terms, the product could be used for another two years. Since Crompton Canada did not agree to those terms, however, the PMRA terminated its registrations immediately.

170. Crompton Canada is not aware of any additional restrictions imposed on other registrants for the use of their lindane products until the end of 2004 to address the PMRA's apparent occupational exposure concerns.[148]

171. On April 5, 2002 the PMRA issued a Re-evaluation Note – REV2002-02 – *Update on the Special Review of Lindane and the Status of Lindane Registrations*. In this Re-evaluation Note, the PMRA confirmed that only one registrant (Crompton) had not accepted the "voluntary" program. The companies who did accept the "voluntary" program had

[147] Exhibit A2, Regulations, s. 16.

[148] Ingulli Statement, para. 144.

different terms under which lindane products could be sold and distributed. Crompton Canada's registrations, however, were subjected to immediate suspension.[149]

172. On May 28, 2002, Crompton Canada wrote to the PMRA to express concerns about statements that the PMRA was communicating to the industry:

> Crompton Co./Cie has become aware of comments, attributed to the PMRA, in respect of Crompton's product, Vitavax RS Flowable (PCP # 15533). In particular, we understand that PMRA personnel, Ms. Andrea Sawatzky and Mr. Barry Gordon of the Alberta Regional office and Mr. Jim Reid of Compliance and Regional Operations (Ottawa) have expressed the view that Vitavax RS Flowable cannot be sold and/or used on mustard (the "Comments").
>
> As you must be aware, the Comments are contrary to section 22 of the Pest Control Product Regulations. The Comments are also contrary to a recent comment made by Ross Pettigrew in an electronic mail message to Mr. R. Dupree of Crompton on March 27, 2002. In that message of March 27, 2002 Mr. Pettigrew noted:
>
> > As you know, with suspension, the product is no longer registered and the registrant is not allowed to sell or distribute any product. (The distributor can still sell any product in inventory prior to the date of suspension). [emphasis added]
>
> We understand that PMRA is basing the Comments on the "Update on the Special Review of Lindane and the Status of Lindane Registrations" issued April 5, 2002. That statement, and in particular the comments in that statement relating to use of lindane products as a seed treatment on, *inter alia*, mustard, arise in the context of a "voluntary" agreement between certain registrants and the PMRA. As you are aware, Crompton is not party to any such agreement. Accordingly, Crompton relies on the rights arising from section 22 of the Pest Control Product Regulations.
>
> Crompton intends to continue to rely on section 22 of the Regulations as confirmed by Mr. Pettigrew's electronic mail statement.
>
> Please confirm that PMRA staff, whether in Ottawa or in a regional office, will cease making erroneous comments such as those referred to above.[150]

[149] Ingulli Statement, Exhibit B62.

173. On October 17, 2002, nearly five (5) months later, the PMRA responded to this letter stating that distributors could continue to sell product which they had in inventory on the day preceding February 11, 2002.[151]

174. Finally, on September 8, 2003, the PMRA refused to renew the outstanding registration for technical lindane, on the basis that the registrations for the end-use products had been terminated.[152]

D. The PMRA's Flawed Special Review Process and Assessment

175. The PMRA's Occupational Exposure Assessment, dated October 26, 2001, was the culmination of its Special Review, which had been initiated on March 15, 1999. In the Assessment, the PMRA stated that it had concerns with respect to the adequacy of the margins of exposure for workers during seed treatment and handling of treated seed both on-farm and in commercial seed treatment facilities.[153]

176. The PMRA, in March 1999, had announced a Special Review of pesticide control products containing lindane. The notice of the Special Review indicated that the primary focus of the review was to "examine the chemistry of existing Lindane products registered in Canada, and the extent to which these products may contribute to levels of various isomers in the environment".

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[150] Ingulli Statement, Exhibit B63.

[151] Ingulli Statement, Exhibit B64.

[152] Ingulli Statement, Exhibit B65.

[153] Thomson Statement, para. 51.

177. Throughout the more than 30-month period that the PMRA undertook its Special Review, the focus had been almost entirely on environmental issues and toxicity, to the extent that the PMRA ever actually indicated its areas of focus.[154]

178. Moreover, at no time during the Special Review process leading to the PMRA's October 26, 2001 conclusions did the PMRA request relevant data from registrants, contrary to long-standing practices in pesticide regulation. This is notwithstanding that Crompton Canada and its technical consultant, Technology Sciences Group Inc. ("TSG")[155] and other registrants, on several occasions offered to provide data to the PMRA. The only data requested by the PMRA was product chemistry data on the technical material to verify purity and impurity profiles. This data, which is trivial in nature, was promptly provided by Crompton.[156]

179. However, the PMRA never requested data regarding occupational exposure during its Special Review, and therefore denied Crompton Canada this opportunity.[157]

180. On April 20, 1999, Mr. Ed Johnson on behalf of Centre Internationale d'Études du Lindane ("CIEL"), proposed a meeting with the PMRA and offered to provide data to assist the PMRA.[158]

181. At a May 11, 1999 meeting between the PMRA and representatives of CIEL, as well as Rob Dupree of Crompton Canada, Mr. Richard Aucoin of the PMRA outlined the PMRA's concerns leading to the Special Review. The notes of Mr. Johnson from that meeting stated as follows:

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[154] Thomson Statement, para. 52.

[155] TSG is a consulting firm which provides a wide range of scientific expertise including toxicology, ecotoxicology, environmental fate, efficacy, chemistry, and exposure and risk assessment.

[156] Thomson Statement, para. 53

[157] Thomson Statement, para. 53.

[158] Thomson Statement, Exhibit C3.

[…]

2. R. Aucoin outlined concerns leading to the Special Review. These are predominantly based on the international treaties and reviews which are ongoing and the residue issues in the Arctic.

Their schedule is to focus on the chemistry aspects now and the health and environmental issues in the fall. They are roughly in place with the EPA reregistration review and will rely on that work as well as other governmental decisions. They do not have the resources to review all the studies available themselves.

Arctic residues in Inuit Indians and marine mammals is a major issue. They are finding alpha and beta isomers as well as gamma. They admitted that information on reisomerization of lindane is unclear but they would be interested in that. CIEL presented its information, that reisomerization is possible in photochemical degradation of lindane in the atmosphere, but the process is very inefficient and does not likely account for the levels being observed. This information is from the literature, however, and Dr. Pistel noted that in controlled environments (GLP studies) no reisomerization was found. We also noted the vast reduction in lindane usage worldwide and the corresponding decrease in what researches are finding in Arctic rainwater (80 per cent reduction over the last decade). […]

3. Environment Canada is looking at the volatilization from lindane seed treatment. PMRA notes published information on volatilization from corn seed treatment and agreed to provide references.

[…]

4. Bob Stewart and Friedbert Pistel reviewed the data development program and provided copies of a bibliography of studies submitted to EPA or the EU and those underway. PMRA once again noted their inability to review all of these themselves, but expressed interest in current product chemistry data and some neurotox studies which are agreed to provide. We also noted that the EPA review appears to be progressing normally from a scientific and technical perspective and no special issues have been raised as a result of the new data.[159]

[Emphasis added]

[159] Thomson Statement, Exhibit C5.

182. The comments relating to the Arctic relate to some findings by the Canadian Department of Indian and Northern Affairs, which found that certain industrial pollutants were accumulating in the Arctic. It was found that air currents crossing from China over the Pacific Ocean tended to result in industrial pollutants settling in the Arctic regions. These pollutants included certain isomers of HCH. The HCH isomers found in the Arctic were the alpha and beta isomers of HCH, not the gamma isomer, of which lindane is composed.[160]

183. Mr. Dupree's notes confirm that PMRA's political considerations were a significant reason for the PMRA's Special Review. The PMRA also indicated that they did not have resources to spend much time on lindane, and would rely heavily on reviews from the EPA and European regulators. The PMRA also indicated they would be advising registrants of what data the PMRA required to fill data gaps.[161]

184. In fact, if the PMRA had waited for the EPA to issue its RED, it would have learned that the EPA reached the opposite conclusion from that of the PMRA in respect of occupational exposure. In particular, the RED indicated that there was no major concern in this regard: "All occupational risks of concern are mitigated with the use of certain personal protective equipment or engineering controls".[162]

185. Subsequent to May 11, 1999, Crompton Canada continued to offer to provide data to the PMRA to assist in its Special Review. For instance, on January 7, 2000, Ed Johnson of TSG, on behalf of Crompton Canada, wrote to the PMRA to offer data.[163] Similarly, on July 28, 2000, Mr. Ingulli of Crompton wrote again to the PMRA to offer data.[164]

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[160] Thomson Statement, para. 56.

[161] Thomson Statement, para. 57, Exhibit C6.

[162] Thomson Statement, Exhibit C1, page xi.

[163] Thomson Statement, Exhibit C6 and Exhibit C7.

[164] Thomson Statement, Exhibit C7.

186. At the October 4, 2000 meeting between representatives of the PMRA and Crompton Canada, the PMRA did raise the issue of occupational exposure and indicated some concerns because the use pattern for seed treatments in Canada often differed from that of other countries. It was suggested that extrapolating from databases such as the Pesticide Handler Exposure Database therefore might not be the best approach. At this meeting, Crompton Canada again offered to provide data.

187. Notwithstanding that the PMRA did not request any further data on the issue of occupational exposure,[165] Mr. Dupree of Crompton Canada wrote to the PMRA on October 6, 2000 to advise that Crompton Canada had submitted an occupational exposure study on Vitavax rs Flowable to the PMRA in 1992. This study, completed in 1991, had been submitted to PMRA to upgrade the database and not to fulfill any outstanding data requirement.[166] This was the last communication relating to occupational exposure, and the PMRA did not raise this issue again with Crompton Canada prior to the release of its Occupational Exposure Assessment one year later.[167]

188. It is important to note that the PMRA did not request an occupational exposure study, or any occupational exposure data. For this reason, and given the fact that the PMRA had never substantially raised the issue of occupational exposure, Crompton Canada had never understood occupational exposure to be a serious concern of the PMRA. If the PMRA had raised this issue as a serious concern, Crompton would have clearly identified that the 1991 study did not reflect current seed treatment practices, which resulted in much reduced levels of exposure.[168]

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[165] Thomson Statement, para. 62.

[166] Thomson Statement, Exhibit C8.

[167] Thomson Statement, para. 65.

[168] Thomson Statement, para. 64.

189. On October 31, 2001, representatives of the PMRA met with the manufacturers of lindane technical to inform these companies about the PMRA's Occupational Exposure Assessment. Representatives of the PMRA then met with registrants of lindane end-use products on November 5, 2001. The draft meeting notes for both meetings prepared by Mr. Jeff Parsons of the PMRA state:

> Participants were informed that the findings of the risk assessment would warrant regulatory action (suspension of registration) with the possibility that lindane use (as a seed treatment) could be permitted for one additional use season (i.e. 2002).[169]

190. In other words, even though parties were given a (minimal) period of time to comment, the PMRA had already decided to suspend the registrations, irrespective of the comments that registrants might submit.

191. On November 5, 2001, the PMRA communicated its findings to registrants by phone and following the call, provided registrants with the relevant documentation. The PMRA initially provided registrants with seven days to comment on the Assessment. Following requests by registrants, this was extended to 14 days, and upon further request, an additional six days were provided in order to receive missing data. In the end, the registrants had until December 3, 2001 to comment. This amount of time was clearly insufficient for the preparation of a proper response. In the PMRA's correspondence extending the deadline to December 3, the PMRA also requested that the registrants provide detailed information regarding the liquidation of products containing lindane. In other words, notwithstanding this "comment period", the PMRA's decision to de-register lindane products was already a *fait accompli*.[170]

192. Thus, for an active ingredient that had been registered in Canada for more than 60 years, had been used in Canada for more than 40 years, and in respect of which the PMRA had

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[169] Thomson Statement, para. 68, Exhibit C11.

[170] Thomson Statement, para. 70, Exhibit C12.

taken 30 months to conduct an assessment, registrants – after repeated requests for extensions – were given a total of 4 weeks to comment.

193. At any time after the start of the Special Review on March 15, 1999 and before the issuance of the PMRA's October 26, 2001 Occupational Exposure Assessment, a period of over two and a half years, Crompton Canada could have addressed the PMRA's occupational exposure concerns, for example, by abandoning its dust formulations, by developing or acquiring, as appropriate, new exposure studies relevant to the use of lindane in Canada, and by proposing additional risk mitigation measures for the remaining liquid formulations. Crompton Canada was never given this opportunity.[171]

194. Moreover, the Assessment was flawed in several respects. In particular, there was no discussion of risk mitigation; the estimates of occupational exposure were overstated; the margins of exposure and safety were unsupportable and well outside normal ranges; and the occupational exposure standards used for lindane were different (and stricter) than the standards used for Syngenta's product, Helix. The PMRA should have requested data because the PMRA knew from its review of Helix that the occupational exposure information that the PMRA was using did not correspond to exposure under currently accepted industry practices.[172]

195. Indeed, the Helix study was more current than the 1992 study on lindane and reflected current application practices. The PMRA knew that the application practices used in the 1992 study were no longer applicable. That study had considered a more open seed treatment system and less protective clothing than was being used in 2001. The current practices resulted in tremendously lower occupational exposure. The PMRA relied on the obsolete study to support increased exposure levels even though it knew the study was not reflective of current, actual exposures. It knew that this was the case because Syngenta had conducted a modern occupational exposure study for Helix. When this was

[171] Thomson Statement, para. 71.

[172] Thomson Statement, para. 72.

brought up at the Review Board, the PMRA said that the Helix study was proprietary to Syngenta, which is true. However, the PMRA could have requested that Crompton Canada conduct a new study with its Lindane Products. If the PMRA had been interested in determining actual exposure levels, it was a simple matter of requesting such a data from the industry. The PMRA did not do so.[173]

196. Registrants submitted consolidated comments on both the process and conclusions of the PMRA's Special Review. Some of the main points raised in the registrants' consolidated comments were as follows:

- The process is unusual in that it:
    - deviates from that announced in SRA99-01,
    - does not allow for input of new or current information from registrants,
    - does not involve a re-evaluation of all elements (eg., environmental, agronomic) and,
    - does not allow for consultation;
- There are serious questions regarding the exposure and toxicology assessments which require clarification on the information used and the conclusions;
- The theoretical concerns described in the occupational exposure risk assessment do not match real world observations;
- We do not think that the PMRA is looking into this issue in the larger context of the importance of lindane seed treatments to agriculture and the possible disruption that precipitous action by the PMRA could cause;
- The PMRA does not seem to be looking for a long-term solution to the issue of lindane use by not considering the canola uses in the context of the re-evaluation;

[173] Thomson Statement, para. 73.

- The PMRA appears to be ready to take action with no regard for the actions being considered by the U.S. EPA. It appears that there are significant differences between the possible course of action by the PMRA and EPA, which will result in a serious trade disadvantage for Canadians. In fact, the EPA is considering adding canola as a new use for lindane seed treatment products. We are concerned that the lack of harmonization between the regulatory agencies will have serious impact on Canadian farmers.

- We are concerned that the PMRA has not taken into account all of the different scenarios for treating seed and handling treated seed (eg. pre-treatment, on-farm treatment, drill-box treatment) which are dependent on product type/crop/site of treatment/frequency of application combinations. Because the PMRA OERA [PMRA's Occupational Exposure Assessment] uses only selected data and relies on extrapolation, we request that additional work be done to qualify and quantify the potential exposure resulting from the many scenarios. Perhaps an independent review of all available data and exposure scenarios should be undertaken. We believe that our concerns are validated by the differences found when comparing the conclusions from the PMRA and U.S. EPA occupational risk assessments.

- There appears to be a discrepancy between the way that lindane is being regulated within Health Canada by the PMRA and by the Drugs Directorate. Lindane shampoos are available for direct application to humans for louse control but the PMRA is contemplating stopping the use of lindane by workers who wear personal protective clothing. [174]

197. In a separate letter dated November 7, 2001, Agsco Inc,[175] submitted specific comments concerning the basis for the PMRA's Occupational Exposure Assessment:

> […]
>
> You stated in the phone conference on November 5, that the three studies that you used to arrive at your conclusions on lindane were

[174] Thomson Statement, Exhibit C13.

[175] Agsco Inc. was a distributor of seed and fertilizer products which was subsequently acquired by the parent company of United Agri Products, Inc.

> at best sketchy and relied in part on data for crops no longer registered. Is that good science? You also noted that it was the only data available, so that is what was used. How is it possible that to get a product registered you require complete and updated data but to cancel product you can just use whatever happens to be available. Part of my frustration with this situation is due to the registration process that we went through to [get] our liquid seed treatment registered in the first place. It took eight years to get DB-Green L registered in Canada even though other maneb/lindane products had been on the market for some time. Every time we provided information or data to meet PMRA requirements a new one was requested. Never once did we get a response that you would just use the data that was "available".[176]

198. Similarly, in a letter to the PMRA dated November 16, 2001, IPCO conveyed its concern regarding the basis for the PMRA's Assessment:

> We are very concerned with the Occupational Risk Exposure Assessment used to evaluate the product does not come anywhere near reflecting the current use patterns of lindane containing seed treatments in modern crop production and greatly overestimates both applicator and/or user exposure.
>
> This precipitous action does not reflect the earlier re-evaluation announcement on lindane SRA99-01, leaving little time for registrants to gather data in rebuttal to regulatory action based on a single exposure study analysis. There is insufficient time for consultation on alternative actions to investigate exposure or to modify application/seeding systems to reduce risks. This action flies in the face of the procedure laid out clearly in the Lindane Re-Evaluation Announcement.[177]

199. In an independent evaluation of the Assessment submitted to the PMRA on November 13, 2001, the TSG, on behalf of lindane manufacturers and formulators, commented as follows:

> 1. The reevaluation is comprehensive in that most relevant data is cited but is limited due to reliance upon the reviews of other bodies, particularly the U.S. EPA.

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[176] Thomson Statement, Exhibit C14.

[177] Thomson Statement, Exhibit C15.

> 2. The approaches that are recommended for short-term and intermediate-term occupational risk assessment are not scientifically supportable and fail to fully utilize the extensive data available for lindane. As described below, the selection of studies, the choice of the toxicological endpoints, and the use of an additional uncertainty factor, are questionable. Each of these factors introduces unnecessary and unsupportable conservatism into the assessment.[178]

200. In response to the consolidated comments, the PMRA invited registrants to submit any data or information not considered by the PMRA in its Occupational Exposure Assessment.

201. On December 3, 2001, Crompton Canada therefore forwarded to the PMRA an internal study it had commissioned titled "Handler Exposure Assessment for Lindane Use as a Commercial Seed Treatment". The study, published on November 30, 2001, assessed a combination of toxicology and exposure information to provide margin of exposure estimates for workers handling lindane during the treatment of seeds and the planting of treated seeds. The results of the study are summarized in its abstract:

> Handling VITAVAX® RS, or other formulations that include lindane as an [active ingredient], therefore results in acceptable levels of exposure to lindane for all tasks. These tasks should therefore be allowable with the current label requirements for at least one layer of full work clothing, a respirator, and chemical-resistant gloves.[179]

202. Other registrants similarly provided data, all of which indicated the occupational risks were far below those reported by the PMRA. Notwithstanding the concerns raised by the registrants and contradictory information concerning the occupational risks identified in the Assessment, the PMRA on December 19, 2001 - 16 days after it received the final comments from registrants – confirmed its Assessment.[180] The validity and

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[178] Thomson Statement, Exhibit C16.

[179] Thomson Statement, Exhibit C17, p. 5.

[180] Thomson Statement, para. 81.

appropriateness of the PMRA's assumptions and conclusions in the Assessment were evaluated by the Lindane Review Board, as discussed further below.

E. The PMRA's Failures with respect to Registration of Replacement Products

203. As part of the Conditional Withdrawal Agreement process, the PMRA committed to Crompton Canada (and to other registrants, and indeed to the industry) to fast track the registration of lindane-removed versions of existing products (i.e. fungicide-only products) and lindane replacement products (i.e. insecticide-fungicide products with lindane replaced with other insecticides). It is important to understand the distinction between the two types of products.

204. Given the extent of the flea-beetle problem in Canada, an insecticide to address flea beetle is essential for farmers. Further, it is much more cumbersome and costly to use separate fungicide and insecticide products.[181]

205. In early 1999, Crompton Canada, and its 50%-owned distributor Gustafson Partnership, were working to develop an effective all-in-one fungicide-insecticide for use on canola, based on (by-then) registered separate fungicide and insecticide products. Due to formulation issues, Gustafson's all-in-one replacement, Gaucho CS FL, was not submitted for registration until March 2000. However, given the fact that the PMRA had committed to an expedited review of lindane replacement products and that the individual fungicides and insecticides were already registered by the PMRA for use on canola, Crompton Canada believed that Gaucho CS FL would be registered and available by late 2000, in time for the 2001 planting season.[182]

206. By November 2000, however, the PMRA had registered the all-in-one, lindane-free Helix and Helix XTra, which were produced by Crompton's competitor Syngenta.

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[181] Ingulli Statement, para. 60.

[182] Kibbee Statement, paras. 9-12.

207. Syngenta's predecessor had submitted this product for registration in November 1998, and by the time the Gaucho CS FL application was filed, the PMRA was well-advanced in its assessment of Helix/Helix XTra. As a result, the PMRA had no interest in expediting Gustafson's product, notwithstanding the PMRA's commitments throughout the Conditional Withdrawal Agreement process. This was yet another breach of commitments by the PMRA.[183]

208. However, even in the absence of fast-tracking, Gaucho CS FL should have been registered by early to mid-2001 at the very latest and therefore available for the 2002 planting season, the first season in which lindane products were not available.[184]

209. Instead, the PMRA did not register Gaucho CS FL until July 2002. By this time, Helix had secured a significant first-mover advantage (having been available for both the 2001 and 2002 seasons) and became the dominant seed treatment product for use on canola in Canada.

210. As will be shown below, the PMRA's treatment of the Gaucho CS FL application was not only manifestly unfair, but its treatment of the Helix application was unusually, and prejudicially, favourable, much more favourable than a normal application would be treated.

1. The PMRA's Failure to Abide by its Commitments to Expedite the Registration of Gaucho CS FL

211. Notwithstanding the PMRA's clear commitments in the lead up to the Conditional Withdrawal Agreement in October 1999 to facilitate registration of lindane replacement products, the PMRA began to back track from its commitments in early 2000.[185]

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[183] Kibbee Statement, paras. 26, 45; Ingulli Statement, para. 161.

[184] Kibbee Statement, para. 17.

[185] Ingulli Statement, para. 149.

212. In 1999, Crompton Canada had obtained registration of Vitavax rs Fungicide, the lindane-removed version of Vitavax rs Flowable. Also in 1999, Gustafson Partnership obtained registration of Gaucho 480, a stand-alone insecticide for use on canola.[186]

213. Although seed treaters could use both products together, this was much less efficient than using an all-in-one product, such as Gaucho CS FL. Moreover, Crompton Canada had made it clear from the outset, as part of the Conditional Withdrawal Agreement process, that it required an expedited registration of an all-in-one lindane product replacement.[187]

214. The Gaucho CS FL product was an all-in-one formulation of carbathiin, thiram and imidacloprid. It was, in effect, the Vitavax rs Flowable/ Vitavax rs Dynaseal product, with the lindane replaced by imidacloprid.[188]

215. On March 21, 2000, Mr. Adam Vaughan of Gustafson Partnership wrote to the PMRA seeking registration of Gaucho CS FL, stating as follows:

> Gaucho® CS Flowable will be used as a seed treatment (U.S.C. #10) for insect and disease control for canola, mustard and rapeseed. It contains the following active ingredients: imidacloprid (PCP # 24468), carbathiin (PCP # 18722), and thiram (PCP # 18959). Each of these active ingredients is currently registered for seed treatment for canola, mustard and rapeseed. Two formulations are being proposed for Gaucho® CS Flowable. […]
>
> Please note that Gaucho® CS Flowable is a Lindane replacement product. It is intended to replace Vitavax RS Dynaseal™, which has been voluntarily withdrawn from the market as per the attached letter from Uniroyal and Gustafson to the PMRA. The applicant respectfully requests that this submission be reviewed by September 15, 2000 in the same timeframe as per this original agreement. This product is essentially the "joining" of two separate liquid seed treatments, Gaucho 480 FL and Vitavax RS

[186] Ingulli Statement, para. 150.

[187] Ingulli Statement, para. 151.

[188] Ingulli Statement, para. 152.

> Fungicide into one product. This facilitates treating of the seed and reduces exposure for the end user. Our organizations have taken the necessary actions to support the spirit of this voluntary withdrawal process.[189]

216. In a letter dated April 20, 2000 to Mr. Vaughan, Mr. Gil Flores of the PMRA responded:

> Thank you for your letter of March 21, 2000 regarding Gaucho® CS Flowable-Lindane replacement for Vitavax RS Dynaseal™ and the need for an expedited review by September 15, 2000.
>
> It is my understanding that the Industry requested a commitment for expedited reviews for lindane replacement products and the Pest Management Regulatory Agency (PMRA) only committed to facilitate access to lindane-free products by fast tracking simple formulation changes, given the importance of lindane-free formulations to the grower community.
>
> I am unaware of any other commitment to expedite the reviews of any specific products like Gaucho® CS Flowable.
>
> I understand your interest in wanting Gaucho® CS Flowable registered as a lindane replacement product and a replacement for Vitavax RS Dynaseal™ to fill the void that would be created by voluntary removal of lindane. This same need, not surprisingly, is also seen by other suppliers. Recognizing the scope of this challenge and the range of clients requesting fast track consideration, it is important to respond to all of these requests in an equitable manner.
>
> Regardless of the process that emerges, it will not entail a predetermined position to register products prior to reviewing supporting information. The Agency cannot establish the outcome of an assessment in advance of the review process. The Agency will be in touch with you and other interested clients as soon as possible regarding appropriate process and procedures to expeditiously handle lindane replacement applications.
>
> PMRA has looked at its overall workload and special considerations requests for the forthcoming year. At this point in time no special consideration can be given to Gaucho® CS Flowable.
>
> Given the above background, you will understand that I am not in a position to grant expedited review for your submission. Your

[189] Ingulli Statement, Exhibit B66.

> submission will progress through the review process according to the time lines allotted to these types of submissions as per the Management of Submissions Policy.[190]

217. Mr. Ingulli wrote to Dr. Franklin on May 15, 2000 to seek clarification, stating:

> In recent communication with our joint venture company, Gustafson Partnership, I was informed that in a letter dated April 20, 2000 from Dr. Gil Flores of PMRA, copy attached, he declined an expedited review for Gustafson's recent submission for Gaucho CS [FL], an all in one formulation of carbathiin, thiram and imidacloprid. The letter cited an unawareness of any commitment to expedite a submission such as Gaucho CS [FL]. This comes as a surprise to me and to Gustafson, and in our view is inconsistent with our understanding of the voluntary lindane withdrawal agreement.
>
> Our records indicate the following:
>
> The registration of Gaucho CS [FL] (carbathiin/thiram/ imidacloprid) is specifically mentioned in point number 5 of our letter of agreement dated December 17, 1998, copy attached, as a condition of the voluntary withdrawal.
>
> Subsequent dialogue with the agency on the specifics of the December letter led to an understanding that the agency would be willing to work within areas that PMRA could manage but could not commit to matters dealing outside of its jurisdictions such as EPA registrations and tolerances. These commitments and clarifications were captured in Mr. Hallatt's letter of January 11, 1999 to Dr. Sexsmith of PMRA, copy attached.
>
> Point 3 in your letter of February 9th, copy attached, makes specific reference to lindane replacement products as follows:
>
> "The Pest Management Regulatory Agency (PMRA) and the U.S. Environmental Protection Agency (EPA) will continue to work with registrants to facilitate access to lindane replacement products; and the CCGA and Canola Council of Canada (CCC) agree to work with the aforementioned bodies to facilitate these activities."
>
> The above was restated in your letters of October 21, 1999 and December 23, 1999, copies attached. This statement reflects a specific lindane replacement strategy and is broader than the

[190] Ingulli Statement, Exhibit B67.

> fungicide replacement only approach stated in Mr. Flores' letter of April 20, 2000.
>
> In my letter of March 2, 1999, copy attached, I restated our qualified agreement to the voluntary lindane withdrawal, which called for registration of suitable replacement products. Your response of March 25th, copy attached, confirms working on lindane replacements. The letter specifically states "the agency cannot establish the outcome of an assessment in advance of the review", but does not suggest our specific request for expedited review would be denied.
>
> The product submission in question, Gaucho CS [FL], is an all in one formulation of two registered products Vitavax RS Fungicide PCP #25862 and Gaucho 480 Fl PCP #26124. This product is a balanced formulation of already registered active ingredients on canola which provides superior application qualities and reduced exposure to applicators. With the registration of Gaucho CS [FL], PMRA would be making available to the canola growers of Canada, a direct replacement for Uniroyal's lindane-containing Vitavax RS flowable. This product currently provides flea beetle control on more than 65% of Canada's canola acreage.
>
> The registration of replacement products and orderly transition was the sole basis of our voluntary agreement to withdraw our lindane based products. Clearly, Uniroyal with more than 65% market share in a field of four lindane registrants, is the most important part of that voluntary withdrawal. We are not asking for any advantage over other potential registrants, rather a fulfillment of the spirit of the voluntary withdrawal.[191]
>
> [Emphasis in original]

218. Dr. Franklin responded to Mr. Ingulli by letter dated June 21, 2000:

> As you may recall, during the discussion around the voluntary withdrawal of lindane seed treatment for canola, the PMRA "opened the door" for potential lindane replacements, for a short period of time, making it clear that the submissions had to be reviewable. Three products were submitted, but only two were considered reviewable at that time. Subsequent to that one replacement (Gaucho) has been registered.
>
> Any communication with your company did not indicate a commitment to expedite Gaucho CS [FL]. Although we are aware

[191] Ingulli Statement, Exhibit B68.

> and have on record your correspondence to us (December 17, 1998 and January 11, 1999), the returning correspondence carefully reiterates what the proposed agreement was (attached February 9, 1999). In addition, the PMRA committed to expedite any simple formulation changes where lindane was being removed. This was done for several products.
>
> The PMRA and the Environmental Protection Agency continue to be committed to work together to facilitate access to lindane replacement products through the Joint Review programs that are in place. As part of that ongoing commitment, the Joint Review program (*Procedures for Joint Review Applications of Chemical Pesticides 1999*) accommodates new actives that meet the U.S. reduced risk criteria (12 month review timelines) or new actives that are considered lindane, organophosphate or methyl bromide replacements (18 month review timeline).
>
> The consideration for special priority review within Canada for lindane replacements for canola seed treatments was a one-time opportunity, not an ongoing situation. That is why your product, having not been part of the original opportunity, falls within normal *Management of Submissions Policy* timelines (12 months in this case).
>
> Given your request of April 20, 2000, and other requests that we have received, we did investigate the possibility of "opening the door" again to registrants with respect to lindane replacements outside the Joint Review program. Given our current workload and the request to accommodate a variety of similar requests, it was determined that no additional special consideration could be given.
>
> I hope this clarifies the situation, and I also understand that this was further discussed with you by PMRA staff on June 2, 2000. It is unfortunate if there was a misunderstanding on this issue.[192]

219. Dr. Franklin's letter refers to a "one-time opportunity" and to the PMRA having "opened the door" for "potential lindane replacements for a short period of time". In fact, as can be seen by the November 26, 1998 letter from the CCGA to the PMRA, the only "one-time opportunity" that had an express time period was with respect to the expedited approval of lindane-removed fungicides. Applications for such products had to be filed by December 31, 1999, and Crompton Canada did meet that deadline

[192] Ingulli Statement, Exhibit B69.

for Vitavax rs Fungicide. However, there was never any stated deadline by which applications for lindane replacement products had to be filed.[193]

220. By letter dated July 28, 2000, Mr. Ingulli wrote to Dr. Franklin to request a meeting to discuss this issue. On October 4, 2000, Mr. Ingulli and Mr. Dupree of Crompton Canada and Mr. Turner of Gustafson met with Dr. Franklin and Ms. Sexsmith of the PMRA. Although replacement products were briefly discussed, the focus was on the PMRA's Special Review and the PMRA declined to make any further commitments with regard to replacement products.[194]

221. The treatment of Gaucho CS FL must be contrasted with that of Syngenta's products Helix and Helix XTra. As noted above, Mr. Flores of the PMRA stated on April 20, 2000, that the PMRA "only committed to facilitate access to lindane-free products by fast tracking simple formulation changes". However, in a registration note dealing with Helix dated on February 16, 2000, the PMRA expressly stated that "[t]he EPA and the PMRA have been expediting the review of Helix, endeavouring to coordinate a registration decision to facilitate access to a lindane replacement product".[195]

222. In other words, Helix was being given the treatment that Crompton Canada and Gustafson had been promised in respect of Gaucho CS FL, while the PMRA itself was reneging on those commitments. Ironically, the application for Helix had originally been filed by Novartis, which did not hold any lindane registrations and therefore had not been given any commitments for expedited treatment as part of the Conditional Withdrawal Agreement process.[196]

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[193] Ingulli Statement, para. 157.

[194] Ingulli Statement, para. 158 and Exhibit B69.

[195] Ingulli Statement, para. 159; Kibbee Statement, Exhibit D4.

[196] Ingulli Statement, para. 160.

2. The PMRA's Registration of Gaucho CS FL

223. Development of the Gaucho CS FL product began in earnest early in 1999, based on dialogue between Crompton Canada, Gustafson and the PMRA regarding plans for the conditional withdrawal of the use of lindane on canola. The product was developed as a direct result of those discussions. Crompton Canada and Gustafson were to develop a formulation, as similar to Vitavax rs Dynaseal as possible, where lindane was replaced by imidacloprid. The objective was to submit the formulation as soon as possible so that it would be reviewed in an expedited fashion by the PMRA in exchange for a withdrawal of Crompton Canada's Lindane Products for use on canola.[197]

224. The development of the formulation was more difficult than anticipated, and was not submitted for registration until March 21, 2000, approximately one year after the originally anticipated date.[198]

225. Based on an expedited review commitment made by the PMRA as part of the Conditional Withdrawal Agreement process, approval was anticipated within approximately 3 months. Given that the Gaucho CS FL was simply a new formulation of active ingredients that were already approved by the PMRA for use on canola as a seed treatment at equivalent rates, the registration was classified as a Category B submission. This is a less complicated submission, and takes less time to process than a submission for a formulation containing active ingredients which have themselves not yet been registered.[199]

226. At that time, the PMRA's standard time frame for a Category B submission was 462 days, including 45 days for final verification of the label, provided no deficiencies are

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[197] Kibbee Statement, para. 9.

[198] Kibbee Statement, para. 10.

[199] Kibbee Statement, para. 16.

found.[200] In other words, for this type of application, one would expect to have received a registration within 462 days after the application was submitted. Using this time frame – and ignoring the commitment for an expedited review – Gaucho CS FL should have been registered by June 26, 2001.

227. The actual performance of the PMRA for all Category B submissions at the time of the Gaucho CS FL submission was an average of 423 days.[201] Even more specifically, the Gaucho CS FL submission was a Category B.2.6 submission (new combinations of technical grade active ingredients). The average time for approval for a B.2.6 submission was 457 days, and 90% were completed within 789 days.[202]

228. The approval was not obtained within the 3 month time frame anticipated from the PMRA's commitment for expedited review. It was not approved within the PMRA's performance standard of 462 days, nor was it approved within the average Category B submission time frame of 423 days, nor the average Category B.2.6 submission time frame of 457 days. More than 90% of all Category B.2.6 submissions were approved more quickly than Gaucho CS FL. Indeed, it is possible that Gaucho CS FL was the slowest of all approvals for that type of submission at that time.[203]

229. Gaucho CS FL was finally registered on July 17, 2002. This was 848 days or almost two years and four months after submission. This is twice as long, or 425 days longer, than the average Category B submission approval.[204] Even in the PMRA's letters from April 2000 and June 2000 (in which the PMRA denied making commitments for expedited registration for lindane replacement products), the PMRA stated that registration would

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[200] Kibbee Statement, para. 17 and Exhibit D2.

[201] Kibbee Statement, Exhibit D3, page 5.

[202] Kibbee Statement, page 11.

[203] Kibbee Statement, para. 20.

[204] Kibbee Statement, para. 21.

take 12 months, in accordance with PMRA policy. In fact, the registration of Gaucho CS FL took 28 months.

230. It is important to understand that sale of canola seed treatment products is concluded by approximately June of each year, and that seed treatment generally occurs between November and April. As a result, a registration granted in July 2002 has no value for the 2002 planting season.[205]

231. It was extremely discouraging to Gustafson and Crompton Canada that the product was not available for the 2001 canola treating season, and devastating that it was unavailable for the 2002 season. Gustafson's alternative products, a combination of Gaucho 480 and Vitavax rs Fungicide, required use of additional coating additives such as talc and polymers, and could only be used in those commercial seed treatment facilities with coating systems rather than the simpler standard treating systems. These alternatives were not well accepted in the marketplace due to the inconvenience and special process requirements, particularly when competitors had ready to use, all-in-one insecticide-fungicide products available.[206]

3. The PMRA's Registration of Helix/Helix XTra

232. Novartis (which later merged with AstraZeneca to become Syngenta) submitted its application for registration of Helix in November 1998.[207]

233. Helix is a combination of the active ingredients difenoconazole, fludioxonil, metalaxyl-m and thiamethoxam. At the time of the Helix submission, thiamethoxam had never been registered in Canada, making Helix a Category A submission, which is a much more complex submission than Gaucho CS FL. In addition, difenoconazole and fludioxonil

[205] Kibbee Statement, para. 23.

[206] Kibbee Statement, para. 24.

[207] Kibbee Statement, para. 26.

had also not been registered for use as a canola seed treatment, adding further complexity and data requirements to the submission.[208]

234. Helix was submitted for registration prior to the lindane withdrawal, and could not be considered as qualifying as a replacement product as that term was used in the "voluntary" withdrawal process because Novartis, the submitter of Helix, did not have a lindane product registered, and therefore did not benefit from any commitments arising from that process. And yet, Helix was in effect given the expedited treatment promised by the PMRA to lindane registrants for their lindane replacement products.[209]

235. Notwithstanding that there were several deficiencies with the Helix submission and that it was a Category A submission, Helix was granted registration in a period much shorter than would normally be expected, and in a period much shorter than the period in which Gaucho CS FL was registered, notwithstanding that Gaucho CS FL was a Category B submission without any significant deficiencies, and was comprised of already registered active ingredients.[210] The deficiencies and irregularities associated with the Helix submission and its registration are described below.

236. **Occupational Exposure:** The PMRA found the occupational exposure data from Helix to be unfavourable, and as a result, Syngenta was required to provide additional occupational exposure data to address this concern. An occupational exposure study is a very major study, requiring a great deal of preparation, controlled monitoring at multiple sites, analysis of hundreds of samples, and complex statistical analysis of the results and lengthy reports. This type of study requires a minimum six months and probably longer.[211]

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[208] Kibbee Statement, para. 27.

[209] Kibbee Statement, para. 28.

[210] Kibbee Statement, para. 29.

[211] Kibbee Statement, para. 30.

237. According to PMRA policy at the time, registrants had 90 days to provide data to address deficiencies, or the registration was rejected and the registrant was required to start the registration over.[212] During the relevant period under scrutiny, Mr. Kibbee of Crompton Canada is not aware of any deviations of this policy, except in the case of Helix.[213]

238. As noted above, it would not have been possible for Syngenta to have commenced, conducted, and completed an occupational exposure study within 90 days. Indeed, the registrant must obtain a Research Permit in order to conduct the study, and it normally takes the PMRA 180 days in order to grant such a permit. The PMRA allowed Syngenta to conduct such a study, and submit the results, while keeping the registration application open and continuing the review. Syngenta conducted the supporting study during the time between the documented submission and approval of Helix. The time frame for approval (i.e., by November 27, 2000) means that the submission could not have been rejected and then re-submitted. This resulted in Helix being registered at least two years earlier than it would have been if the PMRA had followed its standard practices.[214]

239. **Change in formulation after submission for registration:** Syngenta's original submission was for a formulation delivering the 400 gram thiamethoxam/100 Kg rate only (this formulation ultimately became Helix XTra). Part way through the review of the submission, the PMRA allowed Syngenta to submit a new formulation that delivered 200 gram thiamethoxam/100 Kg. (this formulation ultimately became Helix). Submissions of this type are called "tailgating" and are strictly prohibited.[215] In other words, an applicant cannot submit a modified formulation of an existing submission as

[212] Kibbee Statement, Exhibit D2, page 4; Exhibit D6.

[213] Kibbee Statement, para. 32.

[214] Kibee Statement, para. 33 and Exhibit D1.

[215] Kibbee Statement, para. 34 and Exhibits D7 and D8.

part of that existing submission; rather, the modified formulation must be submitted as a new application. For some reason, the PMRA made an exception for Helix.[216]

240. Moreover the Helix Regulatory Note indicated that there was a lack of evidence that Helix XTra had any better efficacy than Helix, and yet this did not result in rejection Helix XTra.[217]

241. **Efficacy of the fungicides:** As is also clear from the Helix Regulatory Note, there was a lack of evidence that the fungicides provided adequate efficacy; there was a lack of evidence that both difenoconazole and fludioxonil were needed; and there was a lack of evidence that they were included at the lowest effective rate, all of which are contrary to the PMRA's efficacy guidelines and indeed the PMRA's mandate. The PMRA apparently chose to ignore these deficiencies in the Helix submission.[218]

242. **Labelling:** Prosper is a canola treatment that was registered by Gustafson Partnership and now owned by Bayer that is very similar to the Helix product, and was registered in 2003. The Prosper product label includes the statement: "This chemical demonstrates the properties and characteristics associated with chemicals detected in ground water. The use of PROSPER FL insecticide-fungicide in areas where soils are permeable, particularly where water table is shallow, may result in ground water contamination." This statement, while appropriate if the data indicates it is required, is not a beneficial statement from a marketing perspective. Helix is not required to (and does not) include such a statement in Canada. It is interesting to note that the U.S. label for Helix does include a ground water contamination warning statement. Given the much higher water

[216] Kibbee Statement, para. 35 and Exhibits D7 and D8.

[217] Kibbee Statement, para. 35 and Exhibit D5, pp. 28-29.

[218] Kibbee Statement, para. 36 and Exhibit D5, pp. 20-25.

solubility of Helix, and otherwise similar properties and use rates, it is not apparent why the PMRA would require Prosper to have a warning but not Helix.[219]

243. **Permitted risk mitigation measures:** Unlike the treatment of lindane products in the PMRA's Special Review, Helix was afforded several risk mitigation measures to address concerns regarding occupational exposure, including a product stewardship program (a concept never previously accepted as a solution to occupational exposure concerns and without any definable, quantifiable or known impact on actual exposure); specification of the personal protective equipment necessary to help reduce exposure to acceptable levels; and labelling to prohibit use of compressed air for cleaning.[220]

244. **Seed colouration:** The favourable treatment of the Helix products by the PMRA continued past the approval of the initial Regulatory Note. At the beginning of the 2003 canola treating season, much to the surprise of the industry and the competitors, Syngenta brought to the market a new version of the Helix product which was coloured green, rather than blue as is required for canola treatments by the applicable PMRA standard.[221] This colouration standard was developed for the protection of human health, by allowing effective visual verification of the absence of treated seed in canola meant for human consumption.

245. There was much dissention on this product being in the marketplace, including concern from the Canadian Grain Commission (the "CGC"). The CGC is responsible for monitoring contamination of canola for human consumption.[222]

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[219] Kibbee Statement, pp. 37-39.

[220] Kibbee Statement, para. 40.

[221] Kibbee Statement, para. 41, Exhibit D9.

[222] Kibbee Statement, para. 42.

246. Given the well defined requirements, the concerns expressed by the CGC, and the obvious threat to the Canadian public from the contamination of canola food products from treated seed, it would have seemed obvious that the PMRA would have made an immediate decision to correct the situation, and to cancel the registration of the green coloured Helix product. After several months and several requests by the industry and the CGC, the PMRA finally acceded to the concerns from the industry and Syngenta was required to withdraw the green coloured product from the market.[223]

247. **"Temporary" registration of Helix:** Syngenta was granted a temporary Helix registration by the PMRA on November 27, 2000 and a temporary registration for Helix XTra on November 29, 2000. Notwithstanding that this was a temporary registration, the PMRA has never granted a permanent registration for Helix or Helix XTra.[224]

248. The Helix Regulatory Note (REG2001-03) was published February 9, 2001. It stated that a Regulatory Decision Document ("RDD") would be published upon completion of certain toxicology testing and other items. These items should have been completed and reviewed some time ago, but an RDD has not yet been published. Since there is a comment period for RDD's but not for Regulatory Notes, neither Crompton Canada, nor any of the stakeholders or the public has had an opportunity to challenge the fairness of the Helix decision through the normal process.[225]

249. The PMRA in a March 30, 2001 newsletter confirmed that an RDD would be issued once Syngenta had provided the outstanding information:

> Syngenta Crop Protection Ltd. will provide additional toxicology and value studies as well as a stewardship program as a condition of this temporary registration. Following the review of this data, the PMRA will publish a proposed regulatory decision document

[223] Kibbee Statement, para. 44.

[224] Kibbee Statement, para. 45.

[225] Kibbee Statement, para. 46, Exhibit D5.

> and request comments from interested parties before making a final regulatory decision.[226]

250. It is incredible that the PMRA has simply allowed this "temporary" registration to continue for seven years (and counting), thereby precluding industry and the public from having an opportunity to comment.[227]

251. Further, a new use (on oriental mustard) was added to the Helix registration in August 2007. In other words, notwithstanding that it is a temporary registration in respect of which the PMRA has not issued an RDD, the PMRA continues to treat it as a permanent registration and to accept the addition of new uses.[228]

4. Impact in the Marketplace

252. As a result of the late 2000 registration of Helix/Helix XTra, this product was available for both the 2001 and 2002 growing seasons.

253. By contrast, as a result of the PMRA's delays, Crompton Canada was unable to offer an all-in-one product for either the 2001 or the 2002 growing seasons. Crompton Canada could therefore only offer separate insecticide fungicide products, which must be applied individually. Obviously, customers would (and did) prefer the use of an all-in-one insecticide-fungicide for convenience and efficiency.

254. Gaucho CS FL was not registered by the PMRA until July 17, 2002. This significant delay enabled Helix to become the dominant seed treatment product in the market.

255. It is apparent that the PMRA needed to register a lindane replacement as soon as possible to give growers an effective flea beetle control product in the absence of lindane. Helix was the first such product to be submitted for registration, and the PMRA drastically bent

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[226] Kibbee Statement, Exhibit D10.

[227] Kibbee Statement, para. 48.

[228] Kibbee Statement, para. 49.

the registration rules to expedite its registration. Once Helix was registered, the pressure was off the PMRA, and all other replacement products suffered the consequences.

VI. THE LINDANE REVIEW BOARD PROCEEDING AND ITS FINDINGS

256. Section 23 of the Regulations entitles registrants to obtain a technical review of decisions affecting pesticide registrations:

> An applicant or registrant who has received a notice under section 21 may, within 30 days from the day on which the notice was received by him, apply in writing to the Minister for a hearing setting out in the application the matters that he intends to raise at the hearing.[229]

257. Pursuant to section 24 of the Regulations, once the Minister has received such a request, he is obliged to appoint a Board of Review:

> Where the Minister receives an application for a hearing, he shall appoint a Board […], consisting of not less than three persons and shall refer the subject matter of the application to the Board.[230]
>
> [Emphasis added]

258. On February 18, 2002, Crompton Canada, through its counsel, wrote to the Minister of Health to request an immediate review, pursuant to section 23 of the Regulations, of the PMRA's decision of registrations.[231]

259. On February 18, 2002, a second letter was sent by Crompton Canada's counsel to the Minister of Health requesting an immediate review of the February 11, 2002 letter from the PMRA deregistering five of its Lindane Products.[232]

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[229] Exhibit A2, Regulations, s. 23.

[230] Exhibit A2, Regulations, s. 24.

[231] Ingulli Statement, Exhibit B71.

[232] Ingulli Statement, Exhibit B72.

260. On March 14, 2002, Crompton Canada, through counsel, also requested a review of the PMRA's letter of February 21, 2002 deregistering Crompton Canada's remaining Lindane Products. This was the third request of its kind that had been made by Crompton Canada.[233]

261. On May 13, 2002, three months after the first two requests for review, Crompton Canada received a letter from the Minister of Health (dated May 6, 2002) indicating that all reviews had been referred to the PMRA "for appropriate action" and directing further communications on the matter to be forwarded to the Executive Director of the PMRA.[234]

262. Crompton Canada wrote to the Minister on June 3, 2002 to request clarification of the Minister's letter.[235] In particular, Crompton Canada took objection to the Minister's direction that Crompton Canada should deal with the PMRA in its request for a review of the PMRA's actions. The very purpose of a review under section 23 of the Act was to have an independent adjudicator review the PMRA's decisions. The Minister never responded to this letter.

263. Crompton Canada commenced litigation in June 2002 in the Federal Court of Canada in order to seek the independent review to which it was entitled. After Crompton Canada commenced proceedings to compel the Government of Canada to perform its statutory duty, counsel to the Minister, in an update to the Federal Court of Canada dated May 15, 2003, advised that the Minister would establish a review board. Finally, on October 22, 2003, the Minister of Health did so, and in May 2004, the Lindane Board of Review (the "Review Board") began its work.[236]

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[233] Ingulli Statement, Exhibit B73.

[234] Ingulli Statement, Exhibit B74.

[235] Ingulli Statement, Exhibit B75.

[236] Ingulli Statement, Exhibit B76.

264. The Review Board was established to review the decisions of the PMRA to terminate the registrations of Crompton Canada's Lindane Products. The Review Board was presided over by Dr. Len Ritter, Dr. Robert Seilken and Dr. Joe Frank.[237]

265. The decisions which gave rise to the review were the following:[238]

Date of Request	Decision Under Review	Products
February 18, 2002	Refusal to Amend Registrations (February 11, 2002)	Vitavax rs Flowable Systemic Liquid Seed Protectant; Reg. No. 15533 Vitavax rs Powder Seed Treatment; Reg. No. 16451 Cloak Seed Protectant Liquid; Reg. No. 22121 Vitavax rs Flowable (Undyed) Seed Protectant; Reg. No. 24467 Vitavax rs Dynaseal Flowable Systemic Seed Protectant; Reg. No. 24482
February 18, 2002	Suspension of Registrations (February 11, 2002)	Vitavax rs Flowable Systemic Liquid Seed Protectant; Reg. No. 15533 Vitavax rs Powder Seed Treatment; Reg. No. 16451 Cloak Seed Protectant Liquid; Reg.

[237] Dr. Ritter is the Executive Director of the Canadian Network of Toxicology Centres; Professor of Environmental Biology and adjunct Professor of Biomedical Science at the University of Guelph; and Fellow of the Academy of Toxicological Sciences. Dr. Sielken is a Biostatistician and President of Sielken and Associates Consulting, and adjunct Professor of Statistics at Texas A&M University. Dr. Frank is a Senior Toxicologist at the Worker Health and Safety Branch of the California Department of Pesticide Regulation. Thomson Statement, para. 82.

[238] Crompton Canada abandoned its request for review of three products during the hearing, due primarily to industry preferences with regard to flowable versus powder applications of lindane products: Vitavax rs Powder Seed Treatment (Reg. No. 16451), Vitavax Dual Solution Systemic Fungicide and Insecticide (Reg. No. 14115) and Vitavax Dual Powder Seed Protectant (Reg. No. 155370). Exhibit A4, Review Board Report.

Date of Request	Decision Under Review	Products
		No. 22121 Vitavax rs Flowable (Undyed) Seed Protectant; Reg. No. 24467 Vitavax rs Dynaseal Flowable Systemic Seed Protectant; Reg. No. 24482
March 14, 2002	Suspension of Registrations (February 21, 2002)	Vitaflo Dual Purpose Systemic Fungicide and Insecticide; Reg. No. 11422 Vitavax Dual Solution Systemic Fungicide and Insecticide; Reg. No. 14115 Vitavax Dual Powder; Reg. No. 15537
September 29, 2003	Refusal to Renew (September 8, 2003)	Lindane Technical, Reg. No. 24164

266. The Review Board's mandate was as follows:

> (a) The Review Board shall inquire into the subject matter of the application and give the person who applied for the hearing and all other persons who may be affected by the subject matter of the hearing an opportunity to make representations to the Review Board at the hearing;
>
> (b) As soon as possible after the hearing, the Review Board shall
>
> (i) make a report containing its recommendations respecting the subject matter of the hearing and its reasons therefore and shall send a copy of the report to the Minister and to the person who applied for the hearing; and
>
> (ii) send to the Minister all documents and other materials that the Review Board used at the hearing.[239]

267. For its overview of the proceeding, the Review Board set forth the risk assessment process as it should have unfolded in respect of lindane:

[239] Exhibit A4, Review Board Report, August 2005, para. 37.

- The first stage of the process is the risk assessment itself. In brief, during the risk assessment, the regulatory body takes on the responsibility of identifying toxicity and exposure potential for the product being assessed. Toxicity potential is assessed on the basis of product chemistry, environmental fate information, metabolism studies, prescribed toxicity studies and general toxicity and other scientific knowledge available at the time of the assessment.

- For products currently in use, as was the case for Lindane, exposure potential is based on use patterns and practices allowed by currently approved labels. While regulators utilize numerous resources in developing risk assessments, they typically rely extensively on the product registrants for providing much of the empirical data. The exercise is not, however, a joint industry/regulatory effort, but rather, a regulatory assessment by PMRA of an industry product. This is an essential point as the scientific process of risk assessment must not be influenced by factors unrelated to the science of the product under consideration. This is not to say that other factors are unimportant, rather, such issues ought to be considered post-risk assessment.

- The second stage in the process is consideration of risk mitigation measures that may be appropriate to respond to the risks identified, if any. The risk assessment is, therefore, the foundation upon which any risk mitigation measures are considered and built. It is the tool used by risk managers to guide their efforts.

- Since risk management considerations are driven by the findings in the risk assessment, it is essential that the risk assessment inform risk managers as to the strength and quality of the database it is based on. For toxicity issues for example, it should clearly identify any data gaps, as well as the strengths and weaknesses of the underlying data and assumptions. The risk assessment should also inform the risk managers whether new or alternative studies or information would improve the assessment.

- With respect to exposure, the assessment should address all exposure scenarios allowed by the label. Furthermore, it should identify potential changes in cultural practices or engineering controls that would be expected to have a significant impact on exposure potential. This sort of information can be invaluable as risk managers move forward. For example, in some cases, use patterns or practices not reflected on the approved labels may have already reduced exposure potential. This type of information may present opportunities to remove outdates labels that allow unsafe activities and improve exposure estimates that reflect newer and safer practices.

- Whereas the risk assessment stage is typically conducted as a regulatory responsibility by PMRA, the risk management state is a dynamic process that involves all affected parties where regulators typically oversee and orchestrate the process as opposed to conducting the total effort. It is important that all interested parties work together to develop and implement a sound and reasonable

> mitigation strategy. In the second stage, there is a need for joint responsibility, necessarily involving extensive interaction and communication between the regulator and interested parties. This is considered critical by the Board.[240]

268. The Review Board made several findings that the PMRA's process was unfair and not in accordance with the PMRA's mandate.[241] These findings may be briefly summarized as follows:

- Registrants should be afforded a meaningful opportunity to make representations to PMRA, particularly where the decision is as dramatic as a cancellation of registrations.
- This is particularly so in respect of Lindane, which had a long-standing approval for use in Canada.
- The PMRA had an obligation to advise Crompton that its focus was going to be on occupational risk, since the Special Review made no mention of occupational risk and all communications with Crompton were primarily in respect of environmental risk.
- The comment period afforded Crompton was inadequate.
- There was considerable haste on the part of the PMRA after the risk assessment was released to bring the matter to a close. This haste was "particularly perplexing" given that Lindane had been in use for over 40 years.
- Given the timing of the announcement and the limited use season for Lindane, other options for effective control could have been invoked in the short-term. In other words, it was not necessary to cancel Crompton's registrations immediately. The PMRA's stated concern was worker exposure which could have been addressed through mitigation. Moreover, other registrants were granted a wind-down period, which suggests that the concerns about worker exposure were not so pressing and significant as to require an immediate cessation of use.
- Addressing mitigation is fundamental to the scientific inquiry leading to a regulatory decision, and this did not occur in the case of Lindane.

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[240] Exhibit A4, Review Board Report, pp. 4-5.

[241] Several of the key statements from the Review Board's Report in respect of procedural fairness are set out in Appendix C.

- The PMRA should have been aware of the current status of industry practices regarding worker exposure.

- The PMRA's risk mitigation stage was not adequate, the decision was made without consideration of adequate risk mitigation opportunities, and resulted in an outcome that was not fair to affected parties.

269. The Review Board also found that the PMRA made several unacceptable scientific findings.[242] The main conclusions of the Review Board may be summarized as follows:

- While the evidence for sensitivity to the young cannot clearly be refuted, the evidence in support is "minimal" and "suggestive" rather than conclusive.

- With respect to immunotoxicity endpoint, the PMRA relied on studies published in the open scientific literature, which it would not normally do. Further, the PMRA did not consider the extent to which contaminants could be a major contributing factor in the underlying immunotoxicity. The evidence for Lindane-related immunotoxicity is not compelling.

- The additional 10x uncertainty factor is not justified. The PMRA itself acknowledged that an additional uncertainty factor as low as 3x would be considered adequate by many toxicologists for the specific endpoints at issue. In this regard, the PMRA's own witness indicated that a factor as low as 3x would have been considered adequate.

- The PMRA's conclusion of common toxicological endpoints and aggregated exposure for both inhalation and dermal exposure is not sufficiently supported by the evidence and available data.

270. The Review Board clearly found that the PMRA made several critical mistakes which had to be corrected. The Review Board accordingly recommended to the Minister of Health that the PMRA re-consider the registration of lindane, in light of the Review Board's recommendations.

271. Tellingly, in the PMRA's "Information Note – Lindane", dated April 26, 2006, the PMRA itself acknowledged the deficiencies raised by the Review Board, in particular:

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[242] Several of the important statements made by the Review Board in respect of the PMRA's scientific findings are set out in Appendix D.

- Interested parties were not given adequate opportunity to offer new or additional data or research to the PMRA that could affect the risk assessment; and

- The outcome of the workers' risk assessment for lindane was affected by consideration of outdated labels, limited exposure data and a conservative approach taken by the PMRA with respect to the assessment of the toxicity of lindane.

272. Given the deficiencies in the PMRA's initial scientific assessment, the PMRA proposed to initiate discussions with all affected former registrants of lindane products and other interested parties to seek input into the risk assessment and to explore possible measures that address the health-related concerns for workers. The PMRA further stated that it was considering new information regarding toxicology data and that it was reviewing its policy regarding the use of uncertainty factors in risk assessment. The PMRA, in the Information Note, stated that the "completion of the follow-up review of lindane data is expected by the end of 2006".[243]

273. Notwithstanding that the Review Board released its Report in August 2005, the PMRA did not request any follow-up information from Crompton Canada until February 28, 2006.[244]

274. Following the PMRA's February 28, 2006 letter, Crompton Canada and the PMRA exchanged further correspondence and, in March 2007, Crompton Canada submitted a new occupational exposure study.[245]

275. On April 30, 2008, Crompton Canada received the PMRA's draft risk assessment on lindane. At the time of this Memorial, Crompton Canada is preparing its comments on this document.[246]

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[243] Thomson Statement, para. 89.

[244] Thomson Statement, para. 87.

[245] Thomson Statement, para. 90.

[246] Thomson Statement, para. 91.

VII. RELATED DEVELOPMENTS IN THE UNITED STATES

276. As noted above, the EPA commenced the RED process in respect of lindane in 1997. This process involved a call-in of data from registrants. Based on early discussions, Crompton anticipated that the RED for lindane might be completed as early as 1999. After 1999, as the process unfolded, Crompton (and other lindane registrants) remained optimistic that the RED would be completed in the near future.[247]

277. As part of the Conditional Withdrawal Agreement, Canada committed to coordinate a review of lindane with the EPA and to conclude that review by the end of 2000.

278. Notwithstanding that commitment by the PMRA, Crompton and Crompton Canada were concerned that the PMRA would not complete its scientific review in a timely manner and that there might continue to be a potential trade irritant issue with the U.S.[248]

279. For that reason, Crompton began to consider the possibility of seeking a U.S. tolerance for lindane in Canola. In the U.S., a "tolerance" is the permitted amount of pesticide residue which can be found in a product. [249]

280. Crompton worked with Inquinosa, the manufacturer of technical lindane, to pursue a tolerance, and in June 1999, Inquinosa submitted an application to the EPA for a tolerance for lindane in canola products. [250]

281. The EPA responded to this request for a tolerance by advising Inquinosa that it would not grant a canola tolerance at that time, but rather that the company should seek the full

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[247] Thomson Statement, para. 20.

[248] Thomson Statement, para. 25.

[249] In most countries, including Canada, the term "maximum residue limit" or "MRL" is used rather than tolerance, but it has the same meaning as "tolerance". Thomson Statement, para. 25.

[250] Thomson Statement, para. 26.

registration of a lindane product for use on canola, in order to have lindane for canola use considered as part of the RED process. [251]

282. Gustafson LLC held a U.S. registration for a lindane product for use on non-canola crops. Gustafson LLC transferred the registration to Crompton. Crompton then applied to the EPA on November 17, 1999 to amend the registration to add canola seed treatment to the permitted uses for this registration.[252]

283. The EPA indicated that it would not register lindane for use on canola, or issue a tolerance for lindane on canola, until the RED process had been completed. Although the RED process was focussed on lindane for use on crops other than canola, the implication was that a favourable assessment of lindane in the RED process would have opened the door for a canola registration and/or tolerance.[253]

284. The EPA released its RED on lindane on July 31, 2002. It found that all then-currently registered seed-treatment uses for lindane could continue to be registered. As well, the EPA considered the pending canola seed treatment uses as part of its assessment in the RED. Significantly, the RED indicated that there was no major concern with occupational exposure: "All occupational risks of concern are mitigated with the use of certain personal protective equipment or engineering controls". [254] Occupational exposure was the very basis upon which the PMRA had cancelled the lindane registrations for all crops in Canada.

285. Apart from minor label changes, the RED did not identify any remaining risk concerns with lindane, and registrants were asked to provide additional data as is the normal

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[251] Thomson Statement, para. 27.

[252] Thomson Statement, para. 28.

[253] Thomson Statement, para. 31.

[254] Thomson Statement, Exhibit C1, EPA's July 31, 2002 Reregistration Eligibility Decision (RED) for Lindane, page xi.

practice in the re-registration process. The EPA also indicated that no new uses (such as canola) would be added until these new data requests had been fulfilled. The existing registrations for seed treatment uses remained in effect during this data collection process. The principal data request arising from the 2002 RED was for a plant metabolism study. This study was provided and was satisfactory to the EPA.

286. The EPA released a report on HCH and its isomers in early 2006. Crompton provided comments on this report, but it was clear that additional resources would be required to fully address the points in the report. Accordingly, Crompton had to make a decision as to whether the costs necessary to maintain on-going lindane registrations exceeded the benefits.[255]

287. At this time, the PMRA had already terminated all of Crompton Canada's registrations. Crompton Canada had commenced several proceedings in the Federal Court of Canada, requesting among other things an independent review board to assess the decisions taken by the PMRA. Crompton had also commenced this arbitration under NAFTA.[256]

288. Although Crompton continued to be interested in pursuing a registration and/or tolerance for lindane in canola products in the United States, the purpose of the registration/ tolerance was to address the potential trade irritant between Canada and the U.S., because it was the Canadian canola market that was significant in financial terms.[257]

289. Further, in March 2006, Crompton had acquired Trace Chemicals, which held U.S. registrations for non-lindane products which met the same market need as Crompton's then-current lindane-containing products.[258]

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[255] Thomson Statement, para. 32.

[256] Thomson Statement, para. 33

[257] Thomson Statement, para. 34.

[258] Thomson Statement, para. 35.

290. In other words, there was no financial reason to incur the cost of obtaining the additional data that may have been necessary to maintain the on-going U.S. registrations, given the availability of non-lindane alternatives now in Crompton's product offerings. The same would have also been true for the other U.S. registrants of lindane products.[259]

291. As a result, Crompton and the other U.S. registrants of lindane products (AGSCO Inc., Drexel Chemical Co. & JLM International Inc.) and the EPA agreed to a voluntary withdrawal. This voluntary withdrawal pre-dated the EPA's 2006 Addendum to the 2002 RED. Cancellation of manufacturing-use product registrations was effective October 4, 2006. According to this withdrawal, all of Crompton's products were required to be used by December 31, 2007, and they were used by that date.[260]

292. Thus, the EPA never "banned" lindane, nor did it identify any environmental or occupational exposure concerns regarding lindane to justify cancellation. Rather, the industry had to make a commercial decision about the costs required to maintain the lindane registrations going forward.[261]

293. If Crompton Canada's Lindane Products had continued to be registered in Canada, Crompton would have actively pursued a U.S. registration and/or tolerance for lindane on canola.[262]

294. Once the EPA issued its RED on July 31, 2002, it would have been open to Crompton to actively pursue a registration and/or tolerance for lindane on canola. Given that the EPA's RED had found no unacceptable safety concerns, it is likely that the EPA would

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[259] Thomson Statement, para. 36.

[260] See Thomson Statement, Exhibit C2, the EPA's 2006 Addendum to the 2002 RED.

[261] Thomson Statement, para. 38.

[262] Thomson Statement, para. 39.

have been prepared to either register lindane for use on canola, or at minimum to grant an import tolerance.[263]

295. Finally, if the PMRA had completed a proper scientific assessment on lindane by the end of 2000, as it had committed to do so, Crompton would have actively pursued its U.S. application for registration and/or tolerance of lindane for use on canola. In this case, it is reasonable to expect that Crompton would have obtained this registration and/or tolerance by approximately January 2003 in time for the 2003 planting season. [264]

[263] Thomson Statement, para. 40.

[264] Thomson Statement, para. 41. See also the Statement of Evidence of Edwin Johnson and the Expert Report of James Aidala. It should also be noted that Gustafson LLC had obtained U.S. registrations for thiram and carboxin for use in January 2003, eliminating potential trade irritant issues for those products such as Crompton Canada's Lindane Products, which contained thiram and carboxin.

PART THREE - LEGAL ANALYSIS

I. OVERVIEW OF THE LEGAL ARGUMENT

296. Part Three of this Memorial demonstrates how Canada has failed to act in a manner consistent with its obligations contained in Section A of NAFTA Chapter 11 and is organized as follows.

> Section I: Overview of the Legal Argument;
>
> Section II: Jurisdiction of this Tribunal;
>
> Section III: Governing Law, Interpretation and Burden of Proof;
>
> Section IV: Article 1105 (Minimum Standard of Treatment)
>
> Section V: Article 1103 (Most Favoured Nation Treatment);
>
> Section VI: Article 1110 (Expropriation); and
>
> Section VII: Damages, Interest and Costs.

297. Submissions concerning Canada's failure to meet its minimum standard of treatment obligation in its treatment of the Investor and its lindane seed treatment business, as set forth in section IV of this Part Three of the Memorial, establish the following:

- The PMRA's decision to suspend Crompton Canada's lindane product registrations was clearly improper and discreditable;
- The PMRA breached the Investor's and Crompton Canada's legitimate expectations in regard to the PMRA's commitments under the Conditional Withdrawal Agreement and the Canadian Regulatory Regime for Seed Treatment Products;
- The PMRA denied Crompton Canada due process by suspending its lindane product registrations without affording the Investor a meaningful opportunity to be heard;
- The PMRA failed to maintain a transparent regulatory environment;

- The PMRA suspended Crompton Canada's lindane product registrations without lawful authority;

- The PMRA's conduct vis-à-vis the Investor and Crompton Canada was arbitrary, grossly unfair and unjust; and

- The PMRA failed to act in good faith in its dealings with and treatment of the Investor and Crompton Canada.

298. The alternative claims concerning Canada's failure to meet its most favoured nation ("MFN") treatment obligation vis-à-vis the Investor and its lindane seed treatment business, as set forth in section V of this Part Three of the Memorial, deal with the following:

- The Investor's main contention is that fair and equitable treatment under the customary international law minimum standard is grounded in the broader principle of good faith and is not limited by pre-defined categories of conduct that may give rise to a breach of the standard.

- In the event the tribunal rejects the Investor's main submission in this regard, it is the Investor's alternative submission that:

    - BITs negotiated by Canada contain a free-standing obligation to provide fair and equitable treatment, not tied to the minimum standard in customary international law, which offers better substantive treatment than that available to the Investor under NAFTA Article 1105; and

    - Canada failed to afford to the Investor and its seed treatment investment the more favourable standard of fair and equitable treatment, available to them in third party treaties negotiated by Canada.

299. The Investor's final submission is that Canada failed to meet its obligation to not unlawfully expropriate the Investor's lindane seed treatment business in Canada, which is set forth in section VI of the Memorial submission and establishes the following:

- The suspension of Crompton Canada's lindane product registrations constituted expropriation or measures tantamount to expropriation;

- The measures were not taken for a public purpose, contrary to Article 1110(1)(a);

- The expropriation was not carried out on a non-discriminatory basis, contrary to Article 1110(1)(b);

- The expropriation violated due process and constituted a breach of international law, contrary to Article 1110(1)(c); and
- No compensation was paid in relation to the expropriation, contrary to Article 1110(1)(d).

300. The procedural history of this dispute under Chapter 11 of NAFTA is set out in Annex E.

II. JURISDICTION OF THIS TRIBUNAL

301. The Investor's claim is within the jurisdiction of this Tribunal. The claim meets the requirements set out in Section B of Chapter 11 of NAFTA, including the application of the UNCITRAL Arbitration Rules for seeking compensation from an Investor-State dispute settlement tribunal for any harm caused by the breach of a Party's obligation under Section A of Chapter 11.

302. Sections A and B of NAFTA Chapter 11 are, in effect, the contract between the disputing parties and the arbitration agreement between them. Pursuant to paragraph 1 of Article 18 of the UNCITRAL Arbitration Rules, as applicable, a copy of NAFTA Chapter 11 is included with this Memorial in the Book of Authorities.

303. To bring a claim, the Investor must be an "Investor of a Party". At the relevant times, the Investor, Crompton, was (and Chemtura is) a corporation organized under the laws of the State of Delaware in the United States of America and was (and Chemtura is) publicly traded on the New York Stock Exchange. Crompton accordingly is an "Investor" within the meaning of Article 1139 of NAFTA.

304. At the relevant times, Crompton wholly-owned the investment, Crompton Canada, a subsidiary company organized under the laws of the Province of Nova Scotia in Canada. Crompton Canada has a manufacturing facility in Elmira, Ontario, which produces various products for several divisions of Chemtura, including seed treatment products. Crompton Canada also has an administrative office in Guelph, Ontario. Crompton Canada, in turn, from November 1998 to March 2004, held a 50% ownership interest in Gustafson Partnership, a Canadian distributor of seed

treatment products. Crompton Canada constitutes an "investment" within the meaning of Article 1139 of NAFTA.

305. Section A of NAFTA Chapter 11 sets out the obligations of NAFTA Parties to provide a certain standard of treatment to the investors of another Party. Section A includes the obligation to grant the better of national treatment (Article 1102) or most-favoured nation treatment (Article 1103) to investors (Article 1104), to meet minimum standards of treatment (Article 1105), and to pay, in a timely fashion, the fair market value in the case of an expropriation or of measures tantamount to expropriation (Article 1110).

306. Canada has caused material loss or damage to the Investor and its investment by reason of, or arising out of, its breach of its obligations contained in Section A of NAFTA Chapter 11.

307. As described in this Memorial, the actions of Canada constitute measures which have resulted in harm to the Investor and to its investment in Canada.

III. GOVERNING LAW, INTERPRETATION AND BURDEN OF PROOF

308. The Investor claims that Canada has acted in a manner that is inconsistent with its obligations under NAFTA Articles 1105 (Minimum Standard of Treatment), Article 1103 (Most Favoured Nation Treatment), and Article 1110 (Expropriation). The Investor also claims that it has suffered loss or damage therefrom.

A. The Object and Purpose of NAFTA

309. NAFTA Article 102 sets out the objectives of the Agreement and the manner in which it is to be interpreted and applied by the Parties:

> 1. The objectives of this Agreement, as elaborated more specifically through its principles and rules, including national treatment, most-favored-nation treatment and transparency, are to:
>
> (a) eliminate barriers to trade in, and facilitate the cross-border movement of, goods and services between the territories of the Parties;

> (b) promote conditions of fair competition in the free trade area;
>
> (c) increase substantially investment opportunities in the territories of the Parties;
>
> (d) provide adequate and effective protection and enforcement of intellectual property rights in each Party's territory;
>
> (e) create effective procedures for the implementation and administration of this Agreement, for its joint administration and for the resolution of disputes; and
>
> (f) establish a framework for further trilateral, regional and multilateral cooperation to expand and enhance the benefits of this Agreement.
>
> 2. The Parties shall interpret and apply the provisions of this Agreement in the light of its objectives set out in paragraph 1 and in accordance with applicable rules of international law.
>
> [Emphasis added]

310. This is echoed in NAFTA Article 1131(1) which provides that tribunals constituted under Section B of Chapter 11 "shall decide the issues in dispute in accordance with this Agreement and applicable rules of international law".

B. Principles of Interpretation Applicable to NAFTA

1. The Vienna Convention on the Law of Treaties

311. Article 33(1) of the UNCITRAL Arbitration Rules requires the Tribunal to apply the law designated by the parties as applicable to the substance of the dispute, namely the NAFTA itself and "applicable rules of international law". NAFTA tribunals have accordingly had regard to both the *Vienna Convention on the Law of Treaties* (the "*Vienna Convention*") and the Statute of the International Court of Justice in carrying out their mandate under Article 1131. Article 1131 of the NAFTA similarly refers the Tribunal to both the Agreement and the "applicable rules of international law".

312. Article 31(1) of the *Vienna Convention* provides that treaties are to be interpreted in good faith, in accordance with the ordinary meaning of their terms, taken in context and in the light of their object and purpose. In the context of the NAFTA, the object and purpose of

the treaty are set out in Article 102(1), reproduced above, and include the promotion of "conditions of fair competition in the free trade area" and the substantial increase in investment opportunities in the territories of the parties.

313. Article 31(3) of the *Vienna Convention* also provides that any subsequent agreement and practice of the parties regarding the interpretation of the treaty or the application of its provisions, and "any relevant rules of international law applicable in the relations between the parties", are to be taken into account.

314. Finally, Article 32 of the *Vienna Convention* provides that recourse may be had to supplementary means of interpretation when the interpretation according to Article 31 results in a meaning which is ambiguous or obscure, or is manifestly absurd or unreasonable.

315. Article 39 of the Statute of the International Court of Justice sets forth the generally recognized sources of international law as follows:[265]

> The Court, whose function it is to decide in accordance with international law such disputes as are submitted to it, shall apply
>
> (a) international conventions, whether general or particular, establishing rules expressly recognized by the contesting parties;
>
> (b) international custom, as evidence of the general practice accepted as law;
>
> (c) the general principles of law recognized by civilized nations;
>
> (d) subject to the provisions of Article 59, judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of international law.

[265] See e.g. *International Thunderbird Gaming Corporation v. United Mexican States*, UNCITRAL (NAFTA), Final Award, January 26, 2006, at para. 90; *Methanex v. United States*, UNCITRAL (NAFTA) Final Award, at Pt. II, Ch. B, para. 3.

316. Accordingly, these principles should guide the Tribunal's interpretation and application of the "rules of international law" in this arbitration.

2. Approach taken by NAFTA Tribunals

317. Prior NAFTA tribunals have recognized the importance of interpreting the NAFTA in light of its objects and purposes. In *Ethyl Corporation*, the tribunal rejected Canada's argument that the NAFTA should be interpreted narrowly:

> The Tribunal considers it appropriate first to dispose with any notion that Section B of Chapter 11 is to be construed "strictly". The erstwhile notion that "in case of a doubt a limitation of sovereignty must be construed restrictively" has long since been displaced by Article 31 and 32 of the Vienna Convention.[266]

318. In *S.D. Myers*, the tribunal began its analysis of Chapter 11 with the preamble to the NAFTA, which states that the parties resolve to "create an expanded and secure market for the goods and services produced in their countries", "to ensure a predictable commercial framework for business planning and investment", "and to do so in a manner consistent with environmental protection and conservation".[267]

319. In *Metalclad*, the tribunal confirmed the importance of the NAFTA objectives identified in Article 102(1) in interpreting Article 1105, ultimately concluding that Mexico had breached its fair and equitable treatment obligation:

> An underlying objective of the NAFTA is to promote and increase cross-border investment opportunities and ensure the successful implementation of investment initiatives […][268]

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[266] *Ethyl Corporation v. Canada*, UNCTRAL (NAFTA), Award on Jurisdiction, June 24, 1998, at para. 55.

[267] See *S.D. Myers v. Canada*, UNCITRAL (NAFTA), Partial Award, November 12, 2000, at para. 196.

[268] *Metalclad Corporation v. United Mexican States*, UNCITRAL (NAFTA), Award, September 2, 2000, at paras. 75-76. See also *Pope & Talbot v. Canada*, UNCITRAL (NAFTA), Award on the Merits Phase 2, May 31, 2002, at para. 70.

320. Thus, NAFTA tribunals have consistently interpreted the specific obligations contained in Chapter 11 within the broad liberalizing context of the treaty and its stated objectives.

C. The Burden of Proof

321. Article 24(1) of the UNCITRAL Arbitration Rules provides that "[e]ach party shall have the burden of proving the facts relied on to support his claim or defence".

322. This principle has generally been interpreted to require that a party asserting a fact adduce some evidence which *prima facie* supports that party's allegation, whereupon the burden of proof shifts to the opposing party.[269]

323. A party's failure to adequately support its claim or defence may therefore lead to that claim's or defence's refusal. In *Feldman*, the tribunal faulted the respondent for failing to present evidence to rebut the investor's *prima facie* claim:

> Here, the Investor in our view has established a presumption and a *prima facie* case that the Claimant has been treated in a different and less favourable manner than several Mexican owned cigarette resellers, and the Respondent has failed to introduce any credible evidence into the record to rebut that presumption.[270]

324. Each party to this arbitration is, therefore, responsible for adducing evidence in support of its positive assertions throughout the course of the proceeding.

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[269] Bin Cheng, *General Principles of Law as Applied by International Courts and Tribunals* (Grotius Publications: Cambridge, 1987), p. 327. See also *United States – Measures Affecting Imports of Woven Wool Shirts and Blouses from India*, Adopted May 23, 1997, WT/DS33/AB/R, p. 14, cited by the tribunal in *International Thunderbird Gaming Corporation v. United Mexican States*, UNCITRAL (NAFTA), Final Award, January 26, 2006, at para. 95, n. 2, […] ["v]arious international tribunals, including the International Court of Justice, have generally consistently accepted and applied the rule that the party who asserts a fact, whether the claimant or respondent, is responsible for providing proof thereof. Also, it is a generally accepted canon of evidence in civil law, common law and, in fact, most jurisdictions, that the burden of proof rests upon the party, whether complaining or defending, who asserts the affirmative of a claim or defence.").

[270] *Marvin Feldman and the United Mexican States*, ICSID Case No. ARB(AF)/99/1, Final Award, at para. 177.

IV. CANADA HAS BREACHED ITS OBLIGATIONS UNDER NAFTA ARTICLE 1105

A. Overview

325. The actions of Canada, through the PMRA, involved or resulted in, among other things, (a) decisions that were clearly improper and discreditable as they were based on irrelevant considerations or a lack of sufficient evidence to support the decisions made; (b) breach of legitimate expectations; (c) a denial of due process and, in particular, a meaningful opportunity to be heard; (d) absence of clear rules and transparency; (e) acting beyond the scope of lawful authority; (f) arbitrary, grossly unfair and unjust conduct and (g) failing to act in good faith. These actions individually and collectively constitute a breach of NAFTA Article 1105(1).

B. NAFTA Article 1105

326. NAFTA Article 1105(1) provides as follows:

> Each party shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security.

327. The fair and equitable treatment standard of treatment under Article 1105 is absolute, unlike the non-discrimination provisions in Articles 1102 and 1103. In other words, the fact that domestic investors might be treated equally poorly is of no consequence. Article 1105 provides a minimum standard of treatment that NAFTA governments must meet.

328. Article 1105(1) has been the subject of a "Note of Interpretation" by the NAFTA Free Trade Commission (“FTC Note of Interpretation” or “Interpretation Note”) made on July 31, 2001. Subsequent to the issuance of that Note, NAFTA Chapter 11 tribunals have interpreted Article 1105 in accordance with that Note. The section below discusses the Note, followed by a review of the case law.

1. Framework for Application of the FTC Note of Interpretation

329. The relevant portions of the FTC Note of Interpretation provide as follows:

> B. Minimum Standard of Treatment in Accordance with International Law
>
> 1. Article 1105(1) prescribes the customary international law minimum standard of treatment of aliens as the minimum standard of treatment to be afforded to investments of Claimants of another Party.
>
> 2. The concepts of "fair and equitable treatment" and "full protection and security" do not require treatment in addition to or beyond that which is required by the customary international law minimum standard of treatment of aliens.
>
> 3. A determination that there has been a breach of another provision of the NAFTA, or of a separate international agreement, does not establish that there has been a breach of Article 1105(1).

330. Of the three paragraphs providing interpretations of the minimum standard obligation, paragraph B.3 is the least controversial. Paragraph B.3 simply states that the breach of a treaty obligation, whether in NAFTA or another treaty, does not establish that there has been a breach of Article 1105(1).

331. However, it is important to stress that those actions which can or might constitute breaches of other treaty obligations might, of course, also be a breach of Article 1105(1). Paragraph B.3 simply confirms that a separate treaty breach is not, by the fact of that breach alone, a breach of Article 1105(1).

332. Paragraphs B.1 and B.2 address more specifically the content of the minimum standard. It is the interpretation of these paragraphs, and particularly paragraph B.2, that have been the subject of debate. There can, however, be no question that Article 1105(1) recognizes the international law obligation of each NAFTA party to treat foreign investors fairly and equitably.

333. The obligation to treat foreign investors fairly and equitably is grounded in the broader international obligation to act in good faith. Dr. F.A. Mann has explained this relationship as follows:

> The paramount duty of States imposed by international law is to observe and act in accordance with the requirements of good faith. From this point of view it follows that, where these treaties express a duty which customary international law imposes or is widely believed to impose, they give very strong support to the existence of such a duty and preclude the Contracting States from denying its existence.
>
> These remarks apply, in particular, to the overriding effect of the standard of fair and equitable treatment.[271]

334. The FTC Note of Interpretation must, therefore, be viewed within this framework.

2. NAFTA Case Law on the FTC Note of Interpretation

335. Since the issuance of the FTC Note of Interpretation, NAFTA tribunals[272] have uniformly stated that the customary international law standard is not static, but rather has evolved since the 1927 decision in *Neer*.[273] The NAFTA Parties themselves have also agreed that the customary international law standard is not frozen in time.[274]

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[271] F.A. Mann, "British Treaties for the Promotion and Protection of Investments" (1981) 52 *Br. Yrbk. Int'l L*. 241 at pp. 249-50.

[272] *Pope & Talbot v. Canada,* UNCITRAL (NAFTA), Award in Respect of Damages, May 31, 2002; *Waste Management Inc v. Mexico*, ICSID Case No. ARB(AF)/98/2, Final Award, June 2, 2002; *Mondev International Ltd. v. United States of America*, ICSID Case No. ARB(AF)/99/2, Final Award, October 11, 2002; *ADF Group Inc. v. United States of America*, ICSID Case No. ARB(AF)/00/1, Final Award, January 9, 2003; *International Thunderbird Gaming Corp. v. United States of America*, UNCITRAL (NAFTA), Final Award, January 26, 2006.

[273] *United States (L.F. Neer) v. United Mexican States*, (1926), 4 R.I.A.A. 60 (Mexico-U.S. General Claims Commission).

[274] See *ADF Group Inc. v. United States of America*, ICSID Case No. ARB(AF)/00/1, Final Award, 9 January 2003 at para. 17; *Ibid*., Transcript of the Oral Hearing, Vol. II, April 16, 2002 at p. 501 (United States statement that the customary international law standard is not frozen in time). *Ibid*., Canada's Second Submission Pursuant to NAFTA Article 1128, July 19, 2002 at para. 33 ("Canada's position has never been that the customary international law regarding the treatment of aliens was 'frozen in amber at the time of the Neer decision'. Obviously, what is shocking or egregious in the year 2002 may differ from that which was considered shocking or egregious in 1926. Canada's position has always been that customary international law can evolve over time, but that the threshold for finding violation of the minimum standard of treatment is still high."). *Ibid*., Second Submission of the United Mexican States, July 22, 2002 at p. 11.

336. The Interpretation Note was issued while the *Pope & Talbot* dispute was on-going. The tribunal in that proceeding had issued its Final Award of the Merits on April 10, 2001, but had not yet ruled on damages.

337. In that case, Canada had rigidly relied upon the *Neer* award to argue that only treatment amounting to an outrage, bad faith, wilful neglect of duty or "an insufficiency of government action so far short of international standards that every reasonable and impartial man would readily recognize its insufficiency".[275] In its Award of Damages, the tribunal pronounced its views on the Interpretation Note. In considering Canada's reliance on the *Neer* standard, the tribunal stated:

> The Tribunal rejects this static conception of customary international law for the following reasons.
>
> First, as admitted by one of the NAFTA Parties, and even by counsel for Canada, there has been evolution in customary international law concepts since the 1920's. It is a fact of international law that customary international law evolves through state practice. International agreements constitute practice of states and contribute to the grounds of customary international law.
>
> Secondly, since the 1920's, the range of actions subject to international concern has broadened beyond the international delinquencies considered in *Neer* to include the concept of fair and equitable treatment. This development was focused in the work of the OECD on its Draft Convention on the Protection of Foreign Property, which recognized that such concept was already customary in bilateral agreements then in effect. That draft did not rest upon an effort to discern the ingredients of international law but upon an independent consideration of how host countries should treat foreign owned property. However, the comments to the draft made two observations that are pertinent here: fair and equitable treatment requires treatment at least as good as that accorded by a state to its own nationals and that concept was embodied in "customary" international law.
>
> 61. Thirdly, the standard of fair and equitable treatment was central to BITs negotiated since the work of the OECD. Many of

[275] *Pope & Talbot v. Canada,* UNCITRAL (NAFTA), Government of Canada Counter-Memorial (Phase Two) at para. 260, October 10, 2000, citing *Neer* at para. 4.

> those agreements, as the Tribunal has previously observed, require state conduct to be evaluated under the fairness elements apart from the standards of customary international law. And even those that do not provide that those elements are owed independently of the requirements of customary international law do add the fair and equitable treatment protections to those rights formerly protected by customary international law. That is, the BITs are not limited to protection against "international delinquencies.
>
> 62. Canada's views on the appropriate standard of customary international law for today were perhaps shaped by its erroneous belief that only some 70 bilateral investment treaties have been negotiated; however, the true number, now acknowledged by Canada, is in excess of 1800. Therefore, applying the ordinary rules for determining the content of customary international law, one must conclude that the practice of states is now represented by those treaties.
>
> 63. The International Court of Justice has moved away from the *Neer* formulation:
>
> > Arbitrariness is not so much something opposed to a rule of law, as something opposed to the rule of law. … It is a wilful disregard of due process of law, an act which shocks, or at least surprises a sense of judicial propriety.
>
> 64. That formulation leaves out any requirement that *every* reasonable and impartial person be dissatisfied and perhaps permits a bit less injury to the psyche of the observer, who need no longer be outraged, but only surprised by what the government has done. And, of course, replacing the neutral "governmental action" with the concept of "due process" perforce makes the formulation more dynamic and responsive to evolving and more rigorous standards for evaluating what governments do to people and companies.[276]
>
> [Citations omitted. Emphasis added]

338. The tribunal in *Mondev* went through a similar analysis in confirming that the minimum standard is not static in time:

[276] *Pope & Talbot v. Canada,* UNCITRAL (NAFTA), Award in Respect of Damages, May 31, 2002 at paras. 58, 59, 60, 61, 62, 63 and 64, and citing the International Court of Justice's decision in *Elettronica Sicula SpA (ELSI),* (*United States v. Italy*) (1989) ICJ 15 at p. 76.

115. The Tribunal would observe, however, that the *Neer* case, and other similar cases which were cited, concerned not the treatment of foreign investment as such but the physical security of the alien. Moreover the specific issue in *Neer* was that of Mexico's responsibility for failure to carry out an effective police investigation into the killing of a United States citizen by a number of armed men who were not even alleged to be acting under the control or at the instigation of Mexico. In general, the State is not responsible for the acts of private parties, and only in special circumstances will it become internationally responsible for a failure in the conduct of the subsequent investigation. Thus there is insufficient cause for assuming that provisions of bilateral investment treaties, and of NAFTA, while incorporating the *Neer* principle in respect of the duty of protection against acts of private parties affecting the physical security of aliens present on the territory of the State, are confined to the *Neer* standard of outrageous treatment where the issue is the treatment of foreign investment by the State itself.

116. Secondly, *Neer* and like arbitral awards were decided in the 1920s, when the status of the individual in international law, and the international protection of foreign investments, were far less developed than they have since come to be. In particular, both the substantive and procedural rights of the individual in international law have undergone considerable development. In the light of these developments it is unconvincing to confine the meaning of "fair and equitable treatment" and "full protection and security" of foreign investments to what those terms - had they been current at the time – might have meant in the 1920s when applied to the physical security of an alien. To the modern eye, what is unfair or inequitable need not equate with the outrageous or the egregious. In particular, a State may treat foreign investment unfairly and inequitably without necessarily acting in bad faith.

117. Thirdly, the vast number of bilateral and regional investment treaties (more than 2000) almost uniformly provide for fair and equitable treatment of foreign investments, and largely provide for full security and protection of investments. Investment treaties run between North and South, and East and West, and between States in these spheres *inter se*. On a remarkably widespread basis, States have repeatedly obliged themselves to accord foreign investment such treatment. In the Tribunal's view, such a body of concordant practice will necessarily have influenced the content of rules governing the treatment of foreign investment in current international law. It would be surprising if this practice and the vast number of provisions it reflects were to be interpreted as

> meaning no more than the *Neer* Tribunal (in a very different context) meant in 1927.[277]
>
> [Citations omitted. Emphasis added.]

339. The tribunal in *Mondev* concluded:

> 125 . […] there can be no doubt that, by interpreting Article 1105(1) to prescribe the customary international law minimum standard of treatment of aliens as the minimum standard of treatment to be afforded to investments of claimants of another Party under NAFTA, the term 'customary international law' refers to customary international law as it stood no earlier than the time at which NAFTA came into force. It is not limited to the international law of the 19th century or even of the first half of the 20th century, although decisions from that period remain relevant. In holding that Article 1105(1) refers to customary international law, the FTC interpretations incorporate current international law, whose content is shaped by the conclusion of more than two thousand bilateral investment treaties and many treaties of friendship and commerce. Those treaties largely and concordantly provide for 'fair and equitable' treatment of, and for 'full protection and security' for, the foreign Claimant and his investments.[278]
>
> [Emphasis added]

340. The *ADF* tribunal further confirmed that the customary international law standard expressed in Article 1105 is in a constant state of development:

> 179. In considering the meaning and implications of the 31 July 2001 FTC Interpretation, it is important to bear in mind that the Respondent United States accepts that the customary international law referred to in Article 1105(1) is not "frozen in time" and that the minimum standard of treatment does evolve. The FTC Interpretation of 31 July 2001, in the view of the United States, refers to customary international law "as it exists today." It is equally important to note that Canada and Mexico accept the view of the United States on this point even as they stress that "the threshold [for violation of that standard] remains high." Put in slightly different terms, what customary international law projects

[277] *Mondev International Ltd. v. United States of America*, ICSID Case No. ARB(AF)/99/2, Final Award, October 11, 2002, at paras. 115, 116 and 117.

[278] *Ibid.,* at para. 125.

> is not a static photograph of the minimum standard of treatment of aliens as it stood in 1927 when the Award in the Neer case was rendered. For both customary international law and the minimum standard of treatment of aliens it incorporates, are constantly in a process of development.[279]

341. Similarly, in *UPS* the tribunal acknowledged that it would be "remarkable" were obligations imposed by customary international law not to evolve over time:

> 84. […] the obligations imposed by customary international law may and do evolve. The law of state responsibility of the 1920s may well have been superceded by subsequent developments. It would be remarkable were that not so.[280]

342. The above decisions establish the following principles:

- the minimum standard prescribed by customary international law is not frozen in time by the *Neer* Award, but rather is an evolving standard, and in any event, the statements in the *Neer* Award were not made in the context of an investor-state investment dispute;
- the content of the customary international law minimum standard is shaped by the more than 2000 BITs which, for the most part, provide for "fair and equitable treatment";
- a state may treat foreign investment unfairly and inequitably without necessarily acting in "bad faith", and
- the governmental action in issue need not necessarily "shock" an observer; it may be sufficient if an observer is surprised by the impropriety of the governmental action.

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[279] *ADF Group Inc. . United States of America*, ICSID Case No. ARB(AF)/00/1, Final Award, 9 January 2003, at para. 179.

[280] *United Parcel Service v. Canada*, NAFTA (UNCITRAL), Decision on Jurisdiction, November 22, 2002, at para. 84.

3. NAFTA Case Law on the Content of the Minimum Standard

343. As Christoph Schreuer recently observed, the FTC Interpretation of Article 1105(1) is binding in the NAFTA context and now largely accepted by NAFTA tribunals.[281] Adherence to this interpretation does not, however, yield a taxonomy of conduct relevant to the customary international law minimum standard or a general definition of fair and equitable treatment. The task of identifying particular conduct which is unfair or inequitable thereby giving rise to a breach of the minimum standard has, accordingly, been left to arbitral tribunals.

344. In the first NAFTA case to consider the FTC's Interpretation Note, the *Pope & Talbot* tribunal found that Canada's conduct was so egregious it would violate the minimum standard of treatment in Article 1105(1) even on the *Neer* standard. Among those actions by Government officials determined to breach the minimum standard were (i) threats; (ii) assertions of non-existent policy reasons (as the basis for burdensome demands for documents); (iii) refusals (by officials) to provide promised information; (iv) threats of reductions and even termination of the investments' export quotas; and (v) misrepresentations of fact in memoranda to the Minister.[282]

345. The *Mondev* tribunal subsequently articulated a threshold question to be asked in analyzing whether the fair and equitable treatment obligation has been breached:

> [T]he question is whether, at an international level and having regard to generally accepted standards of the administration of justice, a tribunal can conclude in the light of all the facts that the impugned decision was clearly improper and discreditable, with the result that the investment has been subjected to 'unfair and inequitable treatment'.[283]

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[281] See Christoph Schreuer, "Fair and Equitable Treatment", 2:5 *Transnational Dispute Management*, November 2005.

[282] *Pope & Talbot v.Canada,* UNCITRAL (NAFTA), Award in Respect of Damages, May 31, 2002, at paras. 67-69.

[283] *Mondev International Ltd. v. United States of America*, ICSID Case No. ARB(AF)/99/2, Final Award, October 11, 2002, at para. 127.

346. In *obiter dicta*, the *Loewen* tribunal further observed that:

> "[m]anifest injustice in the sense of a lack of due process leading to an outcome which offends a sense of judicial propriety is enough, even if one applies the Interpretation according to its terms.[284]

347. By late 2002, a general standard of conduct in connection with the NAFTA minimum standard of treatment was emerging. The tribunal in *Waste Management* observed as follows in this regard:

> […] Taken together, the S.D. Myers, Mondev, ADF and Loewen cases suggest that the minimum standard of treatment of fair and equitable treatment is infringed by conduct attributable to the State and harmful to the claimant if the conduct is arbitrary, grossly unfair, unjust or idiosyncratic, is discriminatory and exposes the claimant to sectional or racial prejudice, or involves a lack of due process leading to an outcome which offends judicial propriety – as might be the case with a manifest failure of natural justice in judicial proceedings or a complete lack of transparency and candour in an administrative process. In applying this standard it is relevant that the treatment is in breach of representations made by the host State which were reasonably relied on by the claimant.
>
> Evidently the standard is to some extent a flexible one which must be adapted to the circumstances of each case.[285]

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[284] *R. Loewen and Loewen Corp. v. United States of America*, ICSID Case No. ARB(AF)/98/3, Final Award, June 26, 2003, at para. 132.

[285] *Waste Management, Inc. v. United Mexican States*, ICSID Case No. ARB(AF)/00/3, Final Award, 30 April 2004, at paras. 98 and 99. See also *International Thunderbird Gaming Corp. v. United States of America*, UNCITRAL (NAFTA), Final Award, January 26, 2006, at para. 194 ("[…] The tribunal views acts that would give rise to a breach of the minimum standard of treatment prescribed by the NAFTA and customary international law as those that, weighed against the given factual context, amount to a gross denial of justice or manifest arbitrariness falling below acceptable international standards"); *GAMI Investments Inc. (U.S.) v. United Mexican States*, UNCITRAL (NAFTA), Final Award, November 15, 2004, at para. 103 ("[…] a claim of maladministration would likely violate Article 1105 if it amounted to an 'outright and unjustified repudiation' of the relevant regulations"); *Metalclad v. Mexico*, ICSID Case No. ARB(AF)/97/1, Award, 30 August, 2000, at para. 99 ("Mexico failed to ensure a transparent and predictable framework of Metalclad's business planning and investment. The totality of these circumstances demonstrates a lack of orderly process and timely disposition in relation to an investor of a Party acting in the expectation that it would be treated fairly and justly in accordance with the NAFTA.")

348. Building on this approach, the tribunal in *ADF* gave further definition to several categories of conduct that could result in a breach of the fair and equitable treatment obligation in Article 1105, including the following:

(a) a measure that may be characterized as "idiosyncratic or aberrant and arbitrary" in the context of similar measures in other countries' domestic laws;[286]

(b) a breach of legitimate expectations;[287]

(c) acting beyond the scope of lawful authority;[288] and

(d) an administrative decision that is "flawed by arbitrariness".[289]

349. The above decisions, all of which post-date the Interpretation Note, demonstrate types of conduct which will fall short of the Article 1105 minimum standard. They are not, however, the final word on the interpretation of the content of Article 1105. One author has noted that:

> […] 'the inclusion of fair and equitable treatment' in Article 1105(1) represents the exemplification of an internationally vague term, designed to give adjudicators a quasi-legislative authority to articulate a variety of rules necessary to achieve the treaty's object and purpose in particular disputes.[290]

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[286] *ADF Group Inc. v. United States of America*, ICSID Case No. ARB(AF)/00/1, Final Award, 9 January 2003, at para. 188.

[287] *Ibid.,* at para. 189.

[288] *Ibid*., at para. 190.

[289] *Ibid*., at para. 191.

[290] Charles H. Brower, II, "Claimant-State Disputes under NAFTA: A Tale of Fear and Equilibrium", 29 *Pepp. L. Rev.* 43 (2001-2002) at p. 78.

350. Indeed, Rudolf Dolzer and Margrete Stevens observe, relying upon a statement by F.A. Mann, that the term "fair and equitable treatment" has a general and far reaching application in investment treaties:

> The terms "fair and equitable treatment" envisage conduct far beyond the minimum standard and afford[ing] protection to a greater extent and according to a much more objective standard than any previously employed form of words. A tribunal would not be concerned with a minimum, maximum or average standard. It will have to decide whether in all the circumstances the conduct in issue is fair and equitable or unfair and inequitable. No standard defined by other words is likely to be material. The terms are to be understood and applied independently and autonomously."[291]
>
> [Emphasis added]

351. Accordingly, the above awards establish a non-exhaustive list of conduct that may constitute a breach of Article 1105(1), including the following:

- A decision that is "clearly improper and discreditable", *i.e.* lack of sufficient evidence to support the decision and/or basing the decision on irrelevant considerations;
- A lack of due process, including denial of the right to be heard, leading to an outcome which offends a sense of judicial propriety;
- Arbitrary, grossly unfair, unjust or idiosyncratic conduct;
- Breach of an Investor's legitimate expectations;
- A lack of transparency and candour in an administrative process;
- Acting beyond the scope of lawful authority; and
- Failing to act in good faith.

[291] Rudolf Dolzer and Margrete Stevens, *Bilateral Investment Treaties* (Boston; Martinus Nijhoff Publishers, 1995) at p. 59, quoting F.A. Mann, "British Treaties for the Promotion and Protection of Investments" in *Further Studies in International Law* (1990) to p. 238.

4. BIT Case Law on the Minimum Standard

352. Arbitral tribunals constituted to hear investment disputes under bilateral investment treaties ("BITs") have also considered and pronounced on the minimum standard and the content of the fair and equitable treatment obligation.

(a) The Minimum Standard Applied in Context

353. As a general matter, the level of development of the host State, including the quality, strength and resources available to support a system of "rule of law", plays an important role in the application of the standard to the particular circumstances of a case.[292]

354. In *X v. Central European Republic*, the tribunal took into account the special factual background to the dispute, including whether the investor may "not have taken sufficient account that the country was still in a state of transition, in which the Government and public authorities were labouring to develop a well-functioning market economy."[293]

355. Similarly, in *Generation Ukraine v. Ukraine*, the tribunal stated that:

> [I]t is relevant to consider the vicissitudes of the economy of the state that is host to the investment in determining the Claimant's legitimate expectations, the protection of which is a major concern of the minimum standards of treatment contained in bilateral investment treaties.[294]

356. It follows that for a highly developed legal system with extensive resources and institutional stability, such as Canada, the minimum standard of treatment, including that contained in Article 1105, requires better conduct than what may be required for a less-developed country. This interpretation is consistent with the NAFTA framework, which

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[292] See Nick Gallus, "The Influence of the Host State's Level of Development on International Investment Treaty Standards of Protection" (2005) 6:4 *J. of World Investment & Trade*.

[293] *X v. Central European Republic*, SCC Case 49/2002, Award, 141, reprinted in *Stockholm Arbitration Report* 2004:1 (2004).

[294] *Generation Ukraine v. Ukraine*, ICSID Case No. ARB/00/9, Award, September 16, 2003 at para. 20.37.

promotes fair competition and increased investment opportunities among three highly developed States.

(b) Interpretations of Fair and Equitable Treatment

357. As noted above, it is well-recognized that the fair and equitable treatment standard originates in the obligation of good faith under international law. The standard has, however, acquired more specific meaning through arbitral decisions and treaties under the "common guiding beacon" of good faith.[295]

358. The starting point for consideration of the fair and equitable treatment standard is succinctly summarized by the tribunal in *Azurix*. Having canvassed NAFTA and BIT awards in which the standard was discussed, the tribunal positioned its interpretation of fair and equitable treatment in light of the investment treaty context in which it is most commonly found:

> The question whether fair and equitable treatment is or is not additional to the minimum treatment requirement under international law is a question about the substantive content of fair and equitable treatment and, whichever side of the argument one takes, the answer to the question may in substance be the same.
>
> […]
>
> […] The standards of conduct agreed by the parties to a BIT presuppose a favourable disposition towards foreign investment, in fact, a pro-active behaviour of the State to encourage and protect it. To encourage and protect investment is the purpose of the BIT. It would be incoherent with such purpose and the expectations created by such a document to consider that a party to the BIT has breached the obligation of fair and equitable treatment only when it has acted in bad faith or its conduct can be qualified as outrageous or egregious.[296]

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[295] See *Sempra Energy International v. Argentina*, ICSID Case No. ARB/02/15, Award, September 26, 2007 at para. 297.

[296] *Azurix Corp. v. The Argentine Republic*, ICSID Case No. ARB/01/21, Award, July 14, 2006 at paras. 364, 372. Article II.2(a) of the Argentina-United States BIT provided as follows:

[Citations omitted. Emphasis added]

359. In *Occidental Exploration and Petroleum Company*, the tribunal observed that a stable legal and business framework is an essential element of the fair and equitable treatment obligation, drawing upon recent arbitral awards in which emphasis was placed on the stability and predictability afforded by the host State to the investor's investment:

> Various arbitral tribunals have recently insisted on the need for this stability. The Tribunal in *Metalclad* held that the Respondent "failed to ensure a transparent and predictable framework for Metalclad's business planning and investment. The totality of these circumstances demonstrate a lack of orderly process and timely disposition in relation to an Claimant of a Party acting in the expectation that it would be treated fairly and justly…"
>
> [...]
>
> The Tribunal is of the opinion that in the instant case the Treaty standard is not different from that required under international law concerning both the stability and predictability of the legal and business framework of the investment. To this extent the Treaty standard can be equated with that under international law as evidenced by the opinions of the various tribunals cited above. It is also quite evident that the Respondent's treatment of the investment falls below such standards.
>
> The relevant question for international law in this discussion is not whether there is an obligation to refund VAT, which is the point on which the parties have argued most intensely, but whether the legal and business framework meets requirements of stability and predictability under international law. It was earlier concluded that there is not a VAT refund obligation under international law, except in the specific case of the *Andean Community* law…but <u>there is certainly an obligation not to alter the legal and business environment in which the investment has been made. In this case it is the latter question that triggers a treatment that is not fair and equitable</u>.[297]

> "Investment shall at all times be accorded fair and equitable treatment, shall enjoy full protection and security and shall in no case be accorded treatment less than required by international law."

[297] *Occidental Exploration and Petroleum Company v. The Republic of Ecuador,* at paras. 185, 190 and 191. LCIA Case No. UN3467, Final Award, 1 July 2004, The specific language of the obligation in the U.S./Ecuador BIT at issue in this proceeding was as follows:

[Emphasis added]

360. In addition to a stable framework for investment, the *TecMed* tribunal found a clear connection between the principle of good faith and a State's obligation to provide foreign nationals with a transparent regulatory environment. Its elucidation of that connection was impressive, and therefore deserving of full recital:

> The Arbitral Tribunal considers that [the Treaty's minimum standard provision], in light of the good faith principle established by international law, requires the Contracting Parties to provide to international investments treatment that does not affect the basic expectations that were taken into account by the foreign Claimant to make the investment. The foreign Claimant expects the host State to act in a consistent manner, free from ambiguity and totally transparently in its relations with the foreign Claimant, so that it may know beforehand any and all rules and regulations that will govern its investments, as well as the goals of the relevant policies and administrative practices or directives, to be able to plan its investment and comply with such regulations. Any and all State actions conforming to such criteria should relate not only to the guidelines, directives or requirements issued, or the resolutions approved thereunder, but also to the goals underlying such regulations. The foreign Claimant also expects the host State to act consistently, i.e. without arbitrarily revoking any pre-existing decisions or permits issued by the State that were relied upon by the Claimant to assume its commitments as well as to plan and launch its commercial and business activities. The Claimant also expects the State to use the legal instruments that govern the actions of the Claimant or the investment in conformity with the function usually assigned to such investments, and not to deprive the Claimant of its investment without the required compensation. In fact, failure by the host State to comply with such pattern of conduct with respect to the foreign Claimant or its investments affects the Claimant's ability to measure the treatment and protection awarded by the host State and to determine whether the actions of the host State conform to the fair and equitable treatment principle. Therefore, compliance by the host State with

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> Investment shall at all times be accorded fair and equitable treatment, shall enjoy full protection and security and shall in no case be accorded treatment less favourable than that required by international law.

See also *CMS Gas Transmission Company v. The Argentine Republic*, ICSID Case No. ARB/01/8, Award, May 12, 2005 at para. 274 ("Based on the BIT under consideration, the Tribunal drew from the treaty's objectives to conclude that a "stable legal and business environment is an essential element" of the fair and equitable treatment standard").

> such pattern of conduct is closely related to the above-mentioned principle, to the actual chances of enforcing such principle, and to excluding the possibility that state action be characterized as arbitrary; i.e. as presenting insufficiencies that would be recognized "…by any reasonable and impartial man," or, although not in violation of specific regulations, as being contrary to the law because: …(it) shocks, or at least surprises, a sense of juridical propriety.
>
> The Arbitral Tribunal understands that the scope of the undertaking of fair and equitable treatment under Article 4(1) of the Agreement described above is that resulting from an autonomous interpretation, taking into account the text of Article 4(1) of the Agreement according to its ordinary meaning (Article 31(1) of the Vienna Convention), or from international law and the good faith principle, on the basis of which the scope of the obligation assumed under the Agreement and the actions related to compliance therewith are to be assessed.
>
> If the above were not its intended scope, Article 4(1) of the Agreement would be deprived of any semantic content or practical utility of its own, which would surely be against the intention of the Contracting Parties upon executing and ratifying the Agreement since, by including this provision in the Agreement, the parties intended to strengthen and increase the security and trust of foreign Claimants that invest in the member States, thus maximizing the use of the economic resources of each Contracting Party by facilitating the economic contributions of their economic operators. This is the goal of such undertaking in light of the Agreement's preambular paragraphs which express the will and intention of the member States to "…intensify economic cooperation for the benefit of both countries…" and the resolve of the member States, within such framework, "…to create favourable conditions for investments made by each of the Contracting Parties in the territory of the other…[298]
>
> [Emphasis added]

361. The obligation on a host State to act consistently and transparently in its relations with a foreign investor is now widely recognized among arbitral tribunals as an essential

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[298] *Tecnicas Medioambientales v. Mexico*, ICSID Case No. ARB(AF)/00/2 Award, May 29, 2003, at paras. 154-156. The minimum standard obligation at issue in this case, under the Mexico/Spain BIT, was as follows:

> Each Contracting Party will guarantee in its territory fair and equitable treatment, according to international law, for the investments made by Claimants of the other Contracting Party.

element of fair and equitable treatment.[299] A fundamental aspect of this obligation is the State's continuing respect for the foreign investor's legitimate expectations concerning the prevailing regulatory environment formed upon making its investment. The tribunal in *LG&E* summarized the legitimate expectations of a foreign investor for the purpose of a fair and equitable treatment claim as follows:

> It can be said that the Claimant's fair expectations have the following characteristics: they are based on the conditions offered by the host State at the time of the investment; they may not be established unilaterally by one of the parties; they must exist and be enforceable by law; in the event of infringement by the host State, a duty to compensate the Claimant for damages arises except for those caused in the event of state of necessity; however, the Claimant's fair expectations cannot fail to consider parameters such as business risk or industry's regular patterns.[300]

362. The tribunal in *Sempra Energy International*, building on the reasoning of the *Tecmed* tribunal, observed that the fundamental premise of the fair and equitable treatment standard, whether equated with the customary international law minimum standard or understood to establish an independent obligation under international law, is to ensure the stability of the law and the observance of legal obligations:

> The Respondent has distinguished a number of recent cases in which the principle of fair and equitable treatment has been upheld, particularly the *Tecmed, MTD* and *OEPC* cases. That is correct given that the circumstances of individual cases are almost invariably different. There remains, however, a requirement of good faith that permeates the whole approach to the protection granted under treaties and contracts. Even if the standard were restricted to a question of reasonableness and proportionality not entailing objective liability, as the Respondent argues in the light of *Tecmed*, there are nevertheless expectations arising from

[299] See *LG&E Energy Corp. LG&E Capital Corp. and LG&E International Inc. v. Argentina*, ICSID Case No. ARB/02/1, Decision on Liability, October 3, 2006 at para. 125; *CMS Gas Transmission Company v. The Argentine Republic*, ICSID Case No. ARB/01/8, Award, May 12, 2005 at para. 274; *Occidental Exploration and Petroleum Company v. The Republic of Ecuador,* LCIA Case No. UN3467, Final Award, July 1, 2004 at para. 183; *Metalclad v. Mexico*, ICSID Case No. ARB(AF)/97/1, Award, August 30, 2000, at para 99.

[300] *LG&E Energy Corp. LG&E Capital Corp. and LG&E International Inc. v. Argentina*, ICSID Case No. ARB/02/1, Decision on Liability, October 3, 2006 at para. 130.

> promises that must be respected when relied upon by the beneficiary.
>
> It follows that it would be wrong to believe that fair and equitable treatment is a kind of peripheral requirement. To the contrary, it ensures that even where there is no clear justification for making a finding of expropriation, as in the present case, there is still a standard which services the purpose of justice and can of itself redress damage that is unlawful and that would otherwise pass unattended. Whether this result is achieved by the application of one or several standards is a determination to be made in the light of the facts of each dispute. What counts is that in the end the stability of the law and the observance of legal obligations are assured, thereby safeguarding the very object and purpose of the protection sought by the treaty.[301]
>
> [Emphasis added]

363. In that case, the tribunal determined that the measures in question had substantially changed the legal and business framework under which the investment was decided and implemented, thereby resulting in breach of the treaty:

> The measures in question in this case have beyond any doubt substantially changed the legal landscape and business framework under which the investment was decided and implemented. Where there was business certainty and stability, there is now the opposite. The tariff regime speaks for itself in this respect. A long-term business outlook has been transformed into a day-to-day discussion about what is next to come. The guarantees given are no longer available. The Respondent might be right in distinguishing this case from the situations that recent decisions had in view, but this does not mean that the present conditions are consistent with the meaning of the protection granted under the Treaty.
>
> Even assuming that the Respondent was guided by the best of intentions, what the Tribunal has no reason to doubt, there has here been an objective breach of the fair and equitable treatment due under the Treaty. The Tribunal thus holds that the standard

[301] *Sempra Energy International v. Argentina*, ICSID Case No. ARB/02/15, Award, September 26, 2007 at paras. 299 to 300.

> established by Article II(2)(a) of the Treaty has not been observed, to the detriment of the Claimant's rights.[302]
>
> [Citations omitted. Emphasis added.]

364. These decisions clearly establish that fair and equitable treatment further imposes an obligation to ensure a stable, transparent and predictable environment for investment.

C. Canada's Breaches of Article 1105

365. Canada, through the PMRA, has taken several actions and decisions which fail to meet the minimum standard of treatment contained in Article 1105 based on the above factors. This is supported by the findings and comments of the Review Board. These key findings are referenced below where appropriate.

1. The PMRA's Decisions to Suspend the Crompton Canada's Lindane Product Registrations Were Clearly Improper and Discreditable

(a) The PMRA's decision to require a "voluntary" withdrawal was based on irrelevant considerations

366. The initial decision by the PMRA to require a "voluntary" withdrawal of lindane products for use on canola was triggered by a trade irritant and not for a legitimate safety/pesticide regulation concern. In other words, the PMRA was motivated by economic and trade concerns with the United States and not by safety concerns. The PMRA's decision to require the withdrawal was accordingly based on irrelevant considerations and was beyond the proper scope of the PMRA's statutory mandate.

367. In a 2001 overview document, the PMRA described its mandate and functions as follows:

> The goal of the PMRA is to protect human health and the environment while supporting the competitiveness of agriculture, forestry, other resource sectors and manufacturing. The PMRA is responsible for providing safe access to pest management tools, while minimizing risks to human and environmental health. The

[302] *Ibid.*, at paras. 303 to 304. See also *LG&E Energy Corp, LG&E Capital Corp. and LG&E International Inc. v. Argentina*, ICSID Case No. ARB/02/1, Decision on Liability, October 3, 2006 at paras. 124 to 125.

> Agency is also dedicated to integrating the principles of sustainability into Canada's pest management regulatory regime.[303]

368. As is clear from that description, the PMRA's mandate is to regulate pest management products within the framework of protecting human health and the environment. These science-based considerations are the criteria by which the PMRA is to regulate the industry.

369. Moreover, the Regulations prescribe the manner in which the PMRA's mandate is to be exercised, including the basis upon which regulatory decisions concerning the registration and de-registration of a product are to be made.

370. Under section 20 of the Regulations, registration of a control product may be cancelled or suspended only where the Minister finds, "based on current information available to him, the safety of the control product or its merit or value for its intended purposes is no longer acceptable to him."[304]

371. Section 16 of the Regulations prescribes the procedure for the "voluntary" withdrawal of a regulated product. Section 16 states:

> Where the registrant intends to discontinue the sale of a control product, he shall so inform the Minister and the registration of that control product shall, on such terms and conditions, if any, as the Minister may specify, be continued to allow any stocks of the control product to be substantially exhausted through sales.[305]

372. As the PMRA had no legal basis under the Act or its Regulations to cancel or suspend the registrations of lindane products for canola use, the PMRA forced the Investor and other lindane product registrants in Canada to enter into the Conditional Withdrawal Agreement, which was outside the scope of either section 16 and section 20 of the

[303] Exhibit A5.

[304] Exhibit A2, Regulations, Section 20.

[305] Exhibit A2, Regulations, Section 16.

Regulations. The PMRA did so as a result of the trade commitments Canada had made to the United States under the ROU – commitments based on factors wholly extraneous to the pesticide regulatory regime and the PMRA's jurisdiction under the Act and Regulations.

373. As explained earlier in this Memorial, the U.S. government in its complaints to Canada in 1997-98 was responding to economic concerns raised by U.S. canola farmers due to the efficacy of lindane products used by Canadian farmers which were unavailable to U.S. farmers. The U.S. government raised this as a trade issue with the Canadian Government, and concerns were raised about U.S. measures that could impede or prohibit Canadian canola exports to the U.S. The Canadian Government, in response to fears of U.S. trade action, effectively imposed the withdrawal on registrants. At no time prior to the Conditional Withdrawal Agreement was the issue one of environmental concerns, and certainly not one of occupational exposure concerns.

374. The fact that the withdrawal was based on trade concerns with the United States can be found in the very text of the Conditional Withdrawal Agreement. The fourth condition of the Agreement stated as follows:

> 4. In the event that PMRA determines that lindane is safe to be used on canola as a seed treatment or EPA should issue a canola tolerance or determine that lindane is exempt from requiring a tolerance in canola, Uniroyal shall request from PMRA the reinstatement of products and uses of lindane on canola that were voluntarily withdrawn. PMRA agrees to grant such reinstatement within 30 days after Uniroyal's application for reinstatement and payment of a fee of $154.00, without any other pre-conditions, including the possibility that PMRA has not completed its re-evaluation of lindane prior to EPA issuing a canola tolerance or an exemption from tolerance. […]
>
> [Emphasis added]

375. In other words, Crompton Canada was entitled to recommence production of Lindane Products for use on canola if the EPA issued a tolerance for such use. The PMRA committed itself to granting a re-instatement of products for use of canola

notwithstanding that the PMRA might not have completed its scientific assessment. The PMRA's unequivocal position was that the removal of the trade irritant (by the granting of a U.S. tolerance) would have obviated the need for the withdrawal.

376. The decision to require a "voluntary" withdrawal of Crompton Canada's registrations of Lindane Products for canola use was therefore made on the basis of considerations entirely irrelevant to any analysis that might form the basis for an obligation to withdraw, or the grounds for suspension or cancellation of the registration of a control product under the pesticide regulatory regime. Moreover, it was this decision by the PMRA to require the "voluntary" withdrawal of Crompton Canada's registrations of Lindane Products for canola which set in motion the destruction of the Investor's entire lindane seed treatment business in Canada.

(b) The PMRA's Decision to Suspend Crompton Canada's Lindane Product Registrations was made without Adequate Evidentiary Support

377. Among the commitments contained in the Conditional Withdrawal Agreement, the PMRA committed to the following:

> 2. PMRA and the EPA shall coordinate and collaborate on the timely review and re-evaluation of any new lindane data already submitted and/or to be submitted in accordance with any data call in or regulatory request and provide a scientific assessment of lindane by the end of 2000.

378. It is recalled that the PMRA's scientific assessment was not completed until late 2001 and, notwithstanding any apparent collaboration with the EPA, the PMRA in its Occupational Exposure Assessment reached the opposite conclusions to those reached in 2002 by the EPA. Given the numerous flaws in the Assessment, Crompton Canada requested the establishment of an independent review board to review the PMRA's Special Review process and it's conclusions.

379. Following Crompton Canada's application to the Federal Court of Canada compelling the Minister of Health to strike a review board pursuant to the Act, the Lindane Review Board was established in October 2003 to consider the PMRA's Occupational Exposure

Assessment and the underlying Special Review process. The Review Board completed its work and issued its report in August 2005, nearly five years after the date by which the PMRA had committed to complete its scientific assessment, and found both the process and the Assessment to have been seriously flawed.

380. The Review Board observed that, despite early concerns with regard to the availability of toxicological and other data, the PMRA failed to request information from the registrants:

> PMRA's records indicate that as early as May 1998, prior to the Special Review announcement, Cheryl Chaffey of the PMRA raised concerns about the available reproductive studies of Lindane and suggested, "it may be prudent to request further data or comment from the registrant in light of these findings of reproductive toxicity." Again, in December 1999, the PMRA's records indicate that it was of the view that the available data on metabolism and toxicokinetics in mammals was limited and that it warranted information on absorption, distribution, metabolism and excretion. However, the PMRA did not request this information from registrants prior to or during the course of the Special Review.
>
> Additionally, the PMRA's files disclose a December 6, 1999 internal memorandum directed to Ms. Chaffey requesting detailed information about commercial seed treatment activities with dust formulations, information about product ingredients that may reduce dust generation and information to help determine whether existing liquid seed treatment studies can be used as surrogates to assess commercial activities with dust. However, the PMRA did not request any such information from registrants until November 5, 2001, after it had released its findings on October 30, 2001.[306]

381. The Review Board further found that the PMRA made several unacceptable scientific findings attributable to its reliance on questionable and/or inadequate information. The key findings by the Review Board in this regard may be summarized as follows:

- While the evidence for sensitivity to the young cannot clearly be refuted, the evidence in support is "minimal" and "suggestive" rather than conclusive.[307]

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[306] Exhibit A4, Review Board Report, paras. 66-67.

[307] Exhibit A4, Review Board Report, para. 162.

- The PMRA failed to take adequate account of uncertainty factors in its analysis:

> The Board further concludes that it is PMRA's responsibility to invoke uncertainty factors in accordance with well-established practice both in Canada and internationally, in order to take appropriate account of uncertainty in knowledge as well as severity of endpoints.[308]

- With respect to immunotoxicity endpoint, the PMRA relied on studies published in the open scientific literature, which it would not normally do. Further, the PMRA did not consider the extent to which contaminants could be a major contributing factor in the underlying immunotoxicity**.** The evidence for lindane-related immunotoxicity is not compelling.[309]

- The additional 10x uncertainty factor, over and above the standard default 100x factor, is not justified. The PMRA itself acknowledged that an additional uncertainty factor as low as 3x would be considered adequate by many toxicologists for the specific endpoints at issue.[310]

- The PMRA's conclusion of common toxicological endpoints and aggregated exposure for both inhalation and dermal exposure is not sufficiently supported by the evidence and available data:

> The Board is especially concerned that while PMRA rejected inferences regarding the toxicological outcome of the dermal study presented to its witnesses by Crompton during the hearings because it had not had an opportunity to independently review the entire study, PMRA did not have any such reservation about adopting the conclusions of a [Joint Meeting on Pesticide Residues (JMPR)] temporary advisor in the context of an interim draft report which, in the end, was not endorsed by the JMPR. In light of the foregoing, and the Board's assessment of the positions adopted by both JMPR and EPA on this issue, the Boards finds that a conclusion of common toxicological endpoints and aggregated exposure for both inhalation and dermal exposure, as concluded by PMRA, is not sufficiently supported.[311]

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[308] Exhibit A4, Review Board Report, para. 163.

[309] Exhibit A4, Review Board Report, para. 171.

[310] Exhibit A4, Review Board Report, para. 179.

[311] Exhibit A4, Review Board Report, para. 187.

- The PMRA's resolution of key evidentiary deficiencies may substantially impact its qualitative exposure characterizations and influence the acceptability of occupational exposures, including:

  > The exposure assessment for on-farm seed treatment was limited to the Fenske dust study which is irrelevant to the Lindane Product liquid formulations;
  >
  > The exposure assessment for planting treated seed would have resulted in substantially lower exposure values had the PMRA relied upon the main Canadian study in this area as opposed to European studies;
  >
  > The inclusion of dermal absorption in the calculation of worker exposure values and the incorporation of differences in dermal absorption between humans and laboratory animals may also substantially impact the margin of exposure calculations.[312]

382. In the PMRA's "Information Note – Lindane", dated April 26, 2006, the PMRA acknowledged the deficiencies raised by the Review Board, in particular:

- Interested parties were not given adequate opportunity to offer new or additional data or research to the PMRA that could affect the risk assessment.
- The outcome of the workers' risk assessment for lindane was affected by consideration of outdated labels, limited exposure data and a conservative approach taken by the PMRA with respect to the assessment of the toxicity of lindane.[313]

383. As concluded by the Review Board, the PMRA's failure to adequately and properly support its scientific assessment resulted in a seriously flawed analysis. It was, however, on the basis of this impugned analysis that the PMRA ordered the deregistration of all the Investor's remaining lindane product registrations, without a right of phase-out, and refused the Investor's request for reinstatement of its lindane products for canola use. The result was significant financial loss to the Investor through loss of sales and disposal costs.

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[312] Exhibit A4, para. 206.

[313] Thomson Statement, Exhibit C18.

2. The PMRA Breached the Investor's and Crompton Canada's Legitimate Expectations in regard to the PMRA's Commitments under the Conditional Withdrawal Agreement and the Canadian Regulatory Regime for Seed Treatment Products

384. As noted above, there were four key commitments made by the PMRA which formed the bases upon which Crompton Canada agreed to the conditional withdrawal of its lindane registrations for canola use.

- First, lindane-treated canola seed could continue to be sold by seed treaters and planted by canola growers after July 1, 2001;
- Second, a scientific assessment of lindane would be completed by the end of 2000;
- Third, Crompton Canada's Lindane Products would continue to be registered on all remaining crops listed on those product labels after the removal of canola/rapeseed, and Crompton Canada would be entitled to continue to produce Lindane Products for such uses that remained on the label; and
- Fourth, the registration of lindane replacement products would be expedited.

385. Canada breached all four of these key commitments and, in so doing, substantially changed the legal landscape and business framework applicable to the Investor's investment. This constituted a breach of the Investor's and Crompton Canada's legitimate expectations that Canada would abide by the commitments made to it in the Conditional Withdrawal Agreement and maintain regulatory stability with regard to the canola seed treatment market.

386. In addition to the failure to abide by those commitments, the PMRA acted contrary to its own regulatory framework which requires, among other things: (1) science-based decision-making; (2) a phase-out of existing stock through sales; (3) an opportunity for registrants to meaningfully participate in important regulatory processes; and (4) the registration of products within a reasonable period of time, provided there are no science-based concerns or deficiencies in the submission.

(a) The PMRA Threatened and Misinformed Growers with regard to the July 1, 2001 Deadline for Withdrawal

387. The sixth condition of the Conditional Withdrawal Agreement provided as follows with regard to the deadline for withdrawal of lindane for canola uses:

> 6. All stocks of Uniroyal's product containing lindane for use on canola/rapeseed are allowed to be used up to and including July 1, 2001.

388. Crompton Canada included condition #6 in the Conditional Withdrawal Agreement to ensure that Crompton Canada and Gustafson could continue to sell Lindane Products up to and including July 1, 2001, and to permit purchasers to purchase the products and treat seed with the products until that date. The obvious implication of this clause is that seed treaters could sell treated seed after July 1, 2001 and that such seed could be planted after this date. Any other interpretation would have the result that Crompton Canada could sell its product until July 1, 2001 and seed treaters could treat seed until July 1, 2001, but the seed treater/retailer could not sell treated seed the next day, nor could a farmer plant such treated seed. If that were the case, no purchase would of course occur, so that the sale "deadline" of July 1, 2001 would be effectively moved back to well before the July 1, 2001 date. At no time prior to October 28, 1999 did the PMRA indicate that Crompton Canada's interpretation was incorrect.[314]

389. However, subsequent to the conclusion of the Conditional Withdrawal Agreement, the PMRA unilaterally imposed an additional restriction that seed treated with lindane could not be sold or planted after July 1, 2001. Further, the PMRA advised that such sale of lindane-treated seed or planting of such seed would be subject to enforcement under the legislation, including inspection and the imposition of fines up to $250,000.[315]

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[314] Ingulli Statement, para. 81.

[315] Ingulli Statement, para. 90.

390. As a result, sales of Crompton Canada's Lindane Products declined as seed treaters and farmers became very concerned that they would be subject to fines if they had stocks of lindane-treated seed on hand after July 1, 2001.[316]

391. Crompton Canada's original understanding of the July 1, 2001 deadline was consistent with the understanding of the other registrants, as evidenced in their letters to the PMRA confirming their agreement to the conditional withdrawal. Both Zeneca and Rhône-Poulenc wrote to the PMRA in late 1999 confirming their understanding that lindane products could only be sold until July 1, 2001. The other registrant, IPCO, confirmed to the PMRA its understanding that lindane products could not be used to treat seed after July 1, 2001.[317]

392. In other words, in the agreements of all the registrants to the conditional withdrawal, there was no suggestion of any restriction on the sale of treated seed or the planting of such seed. The Investor and Crompton Canada, along with other lindane product registrants, had a legitimate expectation that sales and use of treated seed would continue after July 1, 2001 until exhausted, based on the conditions agreed to in the Conditional Withdrawal Agreement, and reasonably relied on that expectation to its detriment.

393. This expectation was reinforced by statutory provisions which provided, in the normal course, that registrants be allowed to exhaust all stock of a "voluntarily" withdrawn product through sales.[318] Indeed, the PMRA's standard practice at the time and subsequent to the withdrawal of lindane further illustrates the aberrance of PMRA's

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[316] Ingulli Statement, para. 113.

[317] Ingulli Statement, Exhibits B24 to B26.

[318] Exhibit A2, Regulations, Section 16:

> "Where the registrant intends to discontinue the sale of a control product, he shall so inform the Minister and the registration of that control product shall, on such terms and conditions, if any, as the Minister may specify, be continued to allow any stocks of the control product to be substantially exhausted through sales." [Emphasis added]

conduct in this regard. The following decisions reflect PMRA practice to afford producers, retailers and users of a product being withdrawn a sufficient period of continued sales and use following the date by which production is to cease in order that stocks of the product be used up:

- Personal insect repellents containing DEET (RRD2002-01 – phase out ordered based on human health risk assessment): In the phase out of products containing less than 30% DEET, retail sale of the control product was permitted up to two and one half years following the cessation of sales by the registrants (i.e. registrants could sell the product up to August 31, 2002, whereas retail sales continued until December 31, 2004). Other products containing DEET at higher concentrations were similarly afforded a period of continued retail sales of at least one and one half years following the cessation of sales by registrants.

- Azinphos-methyl (RRD2004-5 – phase out ordered based on occupational risk assessment and environmental concerns): The phase out of all uses of azinphos-methyl, a broad spectrum organophosphate insecticide, originally permitted a one to one and one half year phase out period for continued retail sales and use, respectively, beyond the date for cessation of sales by registrants. Upon receiving further occupational exposure data, the PMRA extended each of the phase out dates in order to permit it to review the data. Although the PMRA concluded that risks to workers continued to be of concern, it extended the phase out period for registrants, retailers and users of azinphos-methyl by an average of six years, stating as following in its July 17, 2007 Re-evaluation Notice (Rev 2007-08):

  > "Since the publication of Re-evaluation Note REV2006-04, the PMRA has acknowledged significant challenges involved in transitioning from azinphos-methyl to safer alternatives. Newer alternatives are more costly and generally require more precise application. Crop experts point out the importance of adopting these innovations gradually so that growers learn appropriate application techniques and gain confidence in the efficacy of the new pesticides.
  >
  > Canadian extension experts and growers believe it will take several years to integrate multiple selective products in a season-long control strategy. The PMRA will, therefore, extend that last date of use for critical uses of products containing azinphos-methyl to 2012, with a condition that the PMRA will monitor compliance with stewardship program requirements."

- Phorate (RRD2004-11 - phase out ordered based on environmental risk assessment): The phase out of phorate, a broad spectrum organophosphate insecticide, originally permitted a one and one half to two year phase out period for continued retail sales and use, respectively, beyond the date for cessation of

> sales by registrants. In March 2008, the PMRA extended the phase out period for registrants, retailers and users of phorate for use on potatoes to control wireworm by six years, reasoning that "[a]dequate alternative management strategies are not yet available". (Re-evaluation Note REV2008-05, "Update on the Use of Phorate on Potatoes", March 26, 2008).[319]

394. The PMRA's conduct following conclusion of the Conditional Withdrawal Agreement in respect of the deadline agreed to for use of Crompton Canada's Lindane Products, including misinforming growers as to the relevance of that deadline for the purchase and use of treated seed, followed up by threats of substantial fines, breached the Investor's legitimate expectation, on which it had reasonably relied, that Crompton Canada's Lindane Products would continue to generate sales from treated seed. As a result, sales of Crompton Canada's Lindane Products for treatment of canola/rapeseed virtually ceased in the spring of 2001.

(b) The PMRA Failed to Timely Issue its Scientific Assessment

395. The second breach was with respect to the scientific assessment. The Investor's and Crompton Canada's understanding and agreement were based on the fact that the assessment would be completed by the end of 2000, as the PMRA had clearly undertaken. Once a proper assessment had been completed, the Investor and Crompton Canada were confident that the Lindane Products would be accepted for use on canola and that production could resume, thereby ensuring that the market for the Lindane Products would continue uninterrupted.

396. Indeed, the second and fourth conditions of the Conditional Withdrawal Agreement provided as follows:

> 2. PMRA and the EPA shall coordinate and collaborate on the timely review and re-evaluation of any new lindane data already

[319] See also Re-evaluation of Terbupos, RRD2004-04, imposing similar phase out periods on the basis of risk of harm to the environment, and Re-evaluation Note REV2008-06 (March 26, 2008) extending those periods for 6 years on the same reasoning. Available at the PMRA website at: http://www.pmra-arla.gc.ca/.

> submitted and/or to be submitted in accordance with any data call in or regulatory request and provide a scientific assessment of lindane by the end of 2000.
>
> […]
>
> 4. In the event that PMRA determines that lindane is safe to be used on canola as a seed treatment or EPA should issue a canola tolerance or determine that lindane is exempt from requiring a tolerance in canola, Uniroyal shall request from PMRA the reinstatement of products and uses of lindane on canola that were voluntarily withdrawn. PMRA agrees to grant such reinstatement within 30 days after Uniroyal's application for reinstatement and payment of a fee of $154.00, without any other pre-condition, including the possibility that PMRA has not completed its re-evaluation of lindane prior to EPA issuing a canola tolerance or an exemption from tolerance. Thereafter, Uniroyal reserves the right to recommence production of its lindane-containing product for use on canola/rapeseed in Canada and/or USA.

397. The PMRA never completed a proper scientific assessment. On December 19, 2001, the PMRA issued a letter confirming the conclusions from its seriously flawed October 26, 2001 Occupational Exposure Assessment, which followed an equally flawed process in which registrants were denied a meaningful opportunity to participate.

398. As discussed in Part Two above, the PMRA acknowledged in a meeting with Crompton Canada that despite its commitment in the Conditional Withdrawal Agreement and statements in the announcement of the Special Review to complete a scientific assessment by the end of 2000, the PMRA had put no resources toward completing the review because the PMRA thought the issue would go away by the July 1, 2001 deadline, and there would be no need to expend resources on such a review.[320]

399. The Investor and Crompton Canada legitimately expected that the PMRA would, in good faith, fulfill its commitment to issue a scientific assessment by 2000, fully expecting a favourable review. Indeed, the PMRA at every instance stated it was collaborating with the EPA (and that such collaboration had been a cause of the delay in finalizing the

[320] See Exhibit B53 to Ingulli Statement.

scientific review), and yet the PMRA reached the opposite conclusions than those reached by the EPA in respect of occupational exposure. The Investor had expected completion of the review by 2000, in order that it could promptly apply for reinstatement of Crompton Canada's Lindane Products for use on canola. The 30-day period for reinstatement agreed to by the PMRA in condition #4 of the Conditional Withdrawal Agreement anticipated the re-instatement of Crompton Canada's lindane products for use on canola well in advance of the 2002 planting season, if not for the 2001 season. The PMRA's failure in this regard contributed to Crompton Canada's loss of sales of its Lindane Products for both canola and non-canola crops in 2002 and beyond.

400. In other words, had the PMRA timely completed a proper scientific assessment of Crompton Canada's Lindane Products, it was a reasonable and legitimate expectation of the Investor that Crompton Canada's products could be reinstated for canola use in time for the 2002 planting season.

(c) The PMRA Arbitrarily Terminated Crompton Canada's Registrations for All Uses

401. As will be described in greater detail below, contrary to the PMRA's commitments, the PMRA terminated the Investor's lindane product registrations for all uses on February 21, 2002, without first conducting a proper scientific assessment. Condition #5 of the Conditional Withdrawal Agreement provided as follows with regard to the production and sale of lindane products for non-canola uses:

> 5. Uniroyal Chemical Co. lindane-based products will continue to be registered on all remaining crops including mustard and cole crops listed on those product labels after the removal of canola/rapeseed. Uniroyal Chemical Co. reserves the right to continue to produce Lindane Products for such uses that remain on the label.

402. On February 11, 2002, the PMRA suspended Crompton Canada's rights under condition #5 to market five of its Lindane Products for use on crops other than canola seed. On February 21, 2002, the PMRA terminated Crompton Canada's three remaining lindane product registrations.

403. As a result of the PMRA's unilateral actions, Crompton Canada could not sell certain of its Lindane Products, as contemplated by the Conditional Withdrawal Agreement, after February 11, 2002, and could not sell any Lindane Product after February 21, 2002.

404. In December 2001, the PMRA offered to either suspend the Investor's lindane product registrations or to phase them out through a "voluntary" discontinuation which would have permitted a gradual phase-out of use by growers on wheat, barley, oats, rye, flax, corn, beans, soybeans and peas through to December 31, 2004. Crompton Canada refused to comply with the imposed "voluntary" deregistration, as there was no legitimate basis for the immediate suspension of the affected registrations.[321]

405. Because Crompton Canada did not agree to "voluntarily" discontinue sales of its Lindane Products, it was not granted the right to a phased-out termination of lindane as provided for in section 16 of the Regulations.

406. The purported basis for the PMRA's actions in this regard was its Occupational Exposure Assessment. However, concerns arising from the Assessment were evidently not so significant as to require the immediate termination of the registrations of other registrants. Rather, counter to the Investor's and Crompton Canada's reasonable and legitimate expectations under the Conditional Withdrawal Agreement and the statutory regime governing the regulation of pesticides, the PMRA terminated its registrations effective immediately while affording its competitors an additional two years for the use of their products.

407. The Investor's and Crompton Canada's expectations in this regard were validated and reinforced by the Lindane Review Board's conclusions concerning the PMRA's Assessment, to the effect that a proper assessment performed on the basis of appropriate scientific materials could have yielded risk exposure data within an acceptable range:

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[321] Ingulli Statement, paras. 128-129 and Exhibit B56.

The Board recognizes that resolution of some of the key issues identified in the Jones Korpalski study will require further dialogue between PMRA and Crompton, and the Board encourages this dialogue to proceed. Moreover, the Board is of the view that PMRA now has the benefit of further generic knowledge on seed treatment facilities and products (which it is entitled to use), and that this knowledge may substantially influence the exposure assessment and acceptability of chemical seed treatments.

The Board also recognizes that the resolution of other key issues in the exposure assessment may substantially impact the quantitative exposure characterizations and influence the acceptability of occupational exposures. For example, the exposure assessment for on-farm seed treatment is limited to the Fenske dust study (1986) which is not relevant to the liquid formulations. The exposure assessment for planting treated seed would have resulted in substantially lower exposure values if it had been based on the one available Canadian study (the Dean (1990) study) instead of the two European Union studies (Findlay and Chester (1995) and Leplay (1995)).

Furthermore, the unit exposure values calculated for planting treated seed could likely be refined through exposure mitigation measures, such as the use of closed-cab tractors and high-capacity air seeders. The incorporation of dermal absorption into the calculation of worker exposure values and the incorporation of differences in dermal absorption between humans and laboratory animals may also substantially impact the margin of exposure calculations. The dust inhalation associated with Lindane as opposed to surrogate products and the impact of polymeric seed coating on dust inhalation is also relevant. Additionally, a more accurate characterization of exposure over a multiple day period as opposed to a single day may also be informative, especially with respect to commercial seed treatment.

The Board notes that the risk assessment generated by PMRA during the Special Review did not include either a quantitative uncertainty analysis or a quantitative sensitivity analysis. These analyses could include the impact of departures from international reviews and differences between the assumptions and/or policy decisions made for Lindane as opposed to other similar products assessed by PMRA. Such analyses can provide useful information to subsequent risk management decisions.

As a result, the Board is satisfied that while PMRA's preliminary evaluation does conclude MOEs that, while well below the target MOE of 1000x established by PMRA, are in the range of several 100x. The Board is also satisfied that any modification in the interpretation of any of the toxicological endpoints included in the

> Special Review, such as aggregate exposure and selection of additional uncertainty factors, taken together with PMRA's preliminary assessment of exposure in the Jones Korpalski study, suggest that target and actual MOEs may begin to approach an acceptable range.[322]

408. The February 11 and February 21, 2002 decisions were taken without proper scientific support, as required by the legislative regime governing registration and deregistration decisions, and in direct violation of the PMRA's commitments under the Conditional Withdrawal Agreement. The PMRA's conduct in this regard was both unfair and inequitable in undermining the Investor's and Crompton Canada's legitimate expectation that Crompton Canada's remaining lindane product registrations would remain intact, or at a minimum, would not be suspended without proper scientific justification. The Review Board's conclusions in this regard are further discussed below in subsection IV.C.3.

(d) The PMRA failed to Expedite Registration of Crompton Canada's Lindane Replacement Product

409. The PMRA also breached its commitment to give expedited review to Crompton Canada's lindane replacement product.

410. In 1999, Crompton Canada had obtained registration of Vitavax rs Fungicide, the lindane-removed version of Vitavax rs Flowable. Also in 1999, Gustafson Partnership had obtained registration of Gaucho 480, a stand-alone insecticide for use on canola.

411. Although seed treaters could use both products together, this was much less efficient than using an all-in-one insecticide/fungicide product, such as Gaucho FS FL. Moreover, the Investor and Crompton Canada had made it clear as part of the Conditional Withdrawal Agreement process that it required an expedited registration of an all-in-one lindane product replacement.

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[322] Exhibit A4, Review Board Report, paras. 205-209.

412. The Gaucho CS FL product for which expedited registration was sought, pursuant to the terms of the Conditional Withdrawal Agreement, was, in effect, the Vitavax rs Flowable Dynaseal product, which contained the insecticide imidacloprid instead of lindane. Notwithstanding its commitment to expedite review of the registrants' lindane-substitute products, the PMRA refused to expedite the review of Gaucho CS FL, claiming it was not "part of the original opportunity".[323]

413. Development of the Gaucho CS FL product had begun in earnest early in 1999, based on dialogue between Crompton Canada, Gustafson and the PMRA regarding plans for the withdrawal of the use of lindane on canola. The product was developed as a direct result of those discussions. Crompton Canada and Gustafson were to develop a formulation, as similar to Vitavax rs Flowable/Dynaseal as possible, in which lindane was replaced by imidacloprid. The objective was to submit the formulation as soon as possible so that it would be reviewed in an expedited fashion by the PMRA in exchange for a voluntary withdrawal of Crompton Canada's Lindane Products for use on canola.[324]

414. The development of the formulation was more difficult than expected, and was not submitted for registration until March 21, 2000, approximately one year after the originally anticipated date.[325]

415. Based on an expedited review commitment made by the PMRA as part of the Conditional Withdrawal Agreement process, approval was anticipated within approximately 3 months. Given that the Gaucho CS FL was simply a new formulation of active ingredients that were each already approved by the PMRA for use on canola as a seed treatment at equivalent usage rates, the registration was classified as a Category B submission. This is a less complicated submission which should take less time to process

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[323] Ingulli Statement, Exhibit B68.

[324] Kibbee Statement, para. 9.

[325] Kibbee Statement, para. 10.

than a submission, for a formulation which contains active ingredients which have themselves not yet been registered.[326]

416. The approval was not obtained within the 3 month time frame anticipated from the expedited review. It was not approved in twelve months, as was referred to in the June 2000 letter from PMRA. It was not approved within the PMRA's performance standard of 462 days, nor was it approved within the average Category B submission time frame of 423 days, nor the average Category B.2.6 submission time frame of 457 days. More than 90% of all Category B.2.6 submissions were approved more quickly than Gaucho CS FL. Indeed, it is possible that Gaucho CS FL was the slowest of all approvals for that type of submission at that time.[327]

417. Gaucho CS FL was finally registered on July 17, 2002. This was 848 days or almost two years and four months after submission. This is twice as long, or 425 days longer, than the average Category B submission approval.[328]

418. The PMRA's treatment of Crompton Canada and its lindane-substitute Gaucho CS FL must be contrasted to that of Syngenta and its products Helix and Helix XTra.

419. Notwithstanding the PMRA's assertions to Crompton Canada that it had "only committed to facilitate access to lindane-free products by fast tracking simple formulation changes," the PMRA stated in a registration note dealing with Helix on February 16, 2000, that "[t]he EPA and the PMRA have been expediting the review of Helix, endeavouring to coordinate a registration decision to facilitate access to a lindane replacement product."[329]

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[326] Kibbee Statement, para. 16.

[327] Kibbee Statement, para. 20.

[328] Kibbee Statement, para. 21.

[329] Ingulli Statement, para. 159; Kibbee Statement, Exhibit D4.

420. Helix, which was a more complex "Category A" submission, was submitted for registration prior to the lindane withdrawal, and without qualifying as a replacement product. Indeed, Novartis, the submitter of Helix, did not have a lindane product registered, but was in effect given the expedited treatment promised by the PMRA to lindane registrants for their lindane replacement products.[330]

421. There were numerous irregularities with the Helix submission, as discussed above in Part Two, Section V.E.3. Notwithstanding that there were several deficiencies with the Helix submission and that it was a Category A submission, Helix was granted registration in a period much shorter than would normally be expected, and in a period much shorter than the period of the Gaucho CS FL submission, notwithstanding that Gaucho CS FL was a Category B submission without any significant deficiencies.

422. As a result of the expedited registration of Helix/Helix XTra in late 2000, this product was available for use in the 2001 and 2002 growing seasons. During this period, Crompton Canada and Gustafson were only able to offer separate insecticide and fungicide products, which could not compete with the all-in-one formulation growers were accustomed to from the lindane products.

423. Because of the PMRA's refusal to expedite Crompton Canada's lindane replacement product, Gaucho CS FL, (in breach of the legitimate expectation it had created in the Conditional Withdrawal Agreement and discussed with the Investor), Crompton Canada was not able to offer a replacement product for sale until the 2003 growing season by which time Helix – in the absence of lindane products - had become the dominant seed treatment product in the market (even though it had – and continues to have – only a temporary registration, as a formal Regulatory Decision Document has never been published on the product). These breaches resulted in significant detriment to the Investor and its Canadian seed treatment for canola business.

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[330] Kibbee Statement, paras. 27-28.

3. The PMRA Denied the Investor Due Process by Suspending Crompton Canada's Lindane Product Registrations Without a Meaningful Opportunity to be Heard

424. The PMRA's decision to suspend Crompton Canada's lindane product registrations on the basis of the Occupational Exposure Assessment was seriously flawed. This decision essentially failed to meet the minimum standard of treatment due to the Investor on all grounds. In particular, the PMRA failed to accord the Investor and/or Crompton Canada a meaningful opportunity to be heard, resulting in an outcome that the Review Board found offensive to fundamental principles of fairness.

425. In its March 1999 Announcement of a Special Review, the PMRA indicated that its primary focus would be to "examine the chemistry of existing lindane products registered in Canada, and the extent to which these products may contribute to levels of various isomers in the environment."[331]

426. At no point over the course of the 30 month period it took the PMRA to complete its Special Review did the PMRA request relevant data from registrants, contrary to long-standing practice in pesticide regulation, and notwithstanding the Investor's and Crompton Canada's offers to provide data.

427. Furthermore, registrants were initially offered only seven days to comment on the Occupational Exposure Assessment once issued, which period was extended upon requests by registrants to two weeks. The comment period was, however, merely a formality, as in the same letter that it extended the "comment period" the PMRA requested detailed information from registrants on the liquidation of products containing lindane. As described in Part Two, Section V.D above, registrants nevertheless provided joint written comments identifying flaws in the risk analysis, including improper assumptions underpinning the PMRA's conclusions.

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[331] Ingulli Statement, Exhibit B50.

428. Furthermore, Crompton Canada offered to work with the PMRA in respect of new mitigation measures. However, as the Review Board observed:

> Crompton states that PMRA rejected this offer by advising that no amount of mitigation could achieve acceptable MOEs [margins of exposure]. In its testimony, PMRA essentially confirmed Crompton's interpretation noting that it, PMRA, did not request any additional data or information on use practices, exposure or anything else because PMRA had determined, in the absence of consultation with Crompton, that adequate mitigation would not be possible to achieve its target MOEs.[332]

429. It is telling that the Review Board prefaced its conclusions as to the soundness of the PMRA's Assessment with the following general observations on fairness of process - or the lack thereof - in the PMRA's Assessment:

> Considerations of fairness in the way PMRA conducted the Special Review arise in response to the question of whether PMRA fairly canvasses and properly assessed the relevant data and research regarding Lindane and its uses in Canada.
>
> […]
>
> Although the Board has no intention of dealing with this matter as a judicial review, it recognizes that the fairness of process followed, and the information considered, can impact the scientific robustness of PMRA's risk analysis and decision-making.[333]

430. The Review Board found the PMRA's Special Review to be fundamentally flawed in both its process and conclusions, making the following key findings in this regard:

- Fairness requires that registrants be afforded a <u>meaningful</u> opportunity to make representations to the PMRA, particularly where the decision is as dramatic as a cancellation of registrations.[334]

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[332] Exhibit A4, Review Board Report, para. 87.

[333] Exhibit A4, Review Board Report, paras. 59 and 63.

[334] Exhibit A4, Review Board Report, paras. 103-106.

- This is particularly so in respect of lindane, which had a long-standing approval for use in Canada.[335]

- The PMRA had an obligation to advise the Investor that its focus was going to be on occupational risk:

> [O]nce PMRA knew its focus in the Special Review was going to be on occupational risk, it should have advised Crompton, knowing that the Special Review announcement made no mention of occupational risk, and knowing that all communications it had with Crompton were primarily in respect of environmental concerns.[336]

- The comment period afforded the Investor was inadequate:

> [T]he Board can see how Crompton may have been taken aback by PMRA's decision and left wholly insufficient time to prepare an adequate response for the reasons indicated above as well as the limited detail and documentation provided by PMRA for its calculations.[337]

This is particularly so given that it took PMRA nearly three years to conduct the Special Review and yet it provided the Investor with only a few weeks to respond.

- There was considerable haste on the part of the PMRA after the risk assessment was released to bring the matter to a close. This haste was "particularly perplexing" given that lindane had been in use for over 40 years.[338]

- Given the timing of the announcement and the limited use season for lindane, other options for effective control could have been invoked in the short-term. This was:

> …a major flaw in the process, leading to an unsatisfactory result. Addressing mitigation, in the Board's opinion, is fundamental in conducting a robust scientific inquiry leading to a regulatory decision. It is clear to the Board that this did not occur in the case of Lindane.[339]

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[335] Exhibit A4, Review Board Report, para. 107.

[336] Exhibit A4, Review Board Report, para. 112.

[337] Exhibit A4, Review Board Report, para. 119.

[338] Exhibit A4, Review Board Report, para. 121.

[339] Exhibit A4, Review Board Report, para. 122.

- The PMRA should have been aware of the current status of industry practices with regard to application of seed protection products and therefore the actual extent of occupational exposure.[340]

- The PMRA's risk mitigation stage was not adequate, the decision was made without consideration of adequate risk mitigation opportunities, and resulted in an outcome that was not fair to affected parties.[341]

431. The PMRA's failure to accord the Investor and Crompton Canada due process in the course of its Special Review resulted in an Assessment of Lindane that is fundamentally flawed, and which nevertheless formed the basis for the PMRA's decision to deregister all of Crompton Canada's Lindane Product registrations in Canada, effectively shutting down the Investor's seed treatment business in Canada.

4. The PMRA Failed to Maintain a Transparent Regulatory Environment

432. Throughout the course of the Investor's and Crompton Canada's dealings with the PMRA, there was a marked absence of transparency in the PMRA's decision-making processes.

433. The PMRA's decision to require the cessation of all sales and use of Crompton Canada's Lindane Products on canola/rapeseed on July 1, 2001, contrary to the registrants' uniform understanding of this date, was made in a totally non-transparent manner, contradicting previous discussions with and representations by the PMRA to registrants.

434. The PMRA's decisions refusing to establish a board of review upon request, as required by Section 23 and 24 of the Regulations, demonstrate a complete lack of transparency in the regulatory process governing PMRA registration, cancellation and suspension decisions and indeed an indifference toward, if not defiance of, its own regulatory regime.

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[340] Exhibit A4, Review Board Report, para. 126.

[341] Exhibit A4, Review Board Report, para. 127.

435. More specifically, where the Minister refuses to amend the registration of a control product or cancels or suspends a registration, section 21 of the Regulations requires the applicant/registrant to be notified in writing. Section 23 of the Regulations provides that an applicant/registrant who receives such a notice can request the Minister for a hearing to review that decision. Section 24 of the Regulations next provides that when the Minister receives a request for a hearing the Minister shall appoint a review board.

436. Crompton Canada incurred the expense of pursuing a Federal Court of Canada proceeding entirely due to Canada's failure to abide by its statutory commitments, and in direct disregard of Crompton Canada's statutory rights. The PMRA's intransigence in this regard is utterly incomprehensible in view of the clear statutory obligations concerning the establishment of Boards of Review.

437. The manner in which the PMRA conducted the Special Review of lindane was also totally non-transparent. Indeed, not only was there an absence of transparency as to the real focus of the PMRA's review and the basis on which it conducted that review, but the PMRA's sole communications with the Investor in this regard had indicated that its concerns were entirely, and misleadingly, different from those it ultimately expressed in its report.

438. Finally, the PMRA's management of registration applications for lindane replacement products, both in light of its commitment to expedite the review of replacement products and the standard timelines for review of similar products in the normal course, was non-transparent and highly suspect. Indeed, several decisions of the PMRA in this regard smack of a concerted effort to avoid transparency in its decision-making. The PMRA's failure to issue a Regulatory Decision Document in respect of Helix or Helix XTra, which would enable public comment on the registration and science and toxicology data in support thereof, almost eight years after issuance of a temporary registration, is a case in point.

439. The PMRA's obfuscations and/or lack of diligence in maintaining transparency in the pesticide regulatory regime over this period, from the emergence of trade concerns regarding lindane use on canola for export to the U.S. through the Review Board process, has cost the Investor the entirety of its lindane seed treatment business in Canada.

5. The PMRA Acted Beyond the Scope of Lawful Authority in Suspending Crompton Canada's Lindane Product Registrations

440. Under section 20 of the Regulations, the Minister may cancel or suspend a registration "when, based on current information available to him, the safety of the control product or its merit or value for its intended purposes is no longer acceptable to him".

441. The decision to impose the conditional withdrawal on Crompton Canada was done on the basis of trade concerns, as described above. The PMRA did not have a legitimate basis under section 20 for the effective cancellation or suspension of the Investor's registrations, either with respect to canola or to non-canola uses.

442. By virtue of the Conditional Withdrawal Agreement – in which the PMRA allowed registrants to sell lindane products for use on canola after December 31, 1999, even though the canola use had been de-registered – the PMRA had agreed not to enforce its legislation and, indeed, to permit registrants, seed treaters and distributors, and farmers to act in contravention of the legislation.

443. The PMRA's position was that Crompton Canada could continue to sell its Lindane Products subject to the Conditional Withdrawal Agreement between January 1, 2000 and July 1, 2001, notwithstanding the fact these products were no longer registered (for canola use), as was required by the Regulations. In other words, the PMRA by committing to the Conditional Withdrawal Agreement, agreed to cease enforcing the law in the period between January 1, 2000 and July 1, 2001.

444. The Investor has a right to expect Canada to its use legal instruments to achieve the States' regulatory objectives and not to act in contravention of its own laws. Failure to do so constitutes a breach of its NAFTA obligations under Article 1105.

6. The PMRA's Conduct vis-à-vis the Investor was Arbitrary, Grossly Unfair, and Unjust

445. All of the above-described actions of the PMRA demonstrate arbitrariness and unfairness towards the Investor and Crompton Canada's Lindane Products.

446. In particular, the following actions were arbitrary, grossly unfair and/or unjust, thereby constituting a breach of Canada's obligations under Article 1105:

- The PMRA's decision to effectively prohibit the retail sale and/or use of treated seed for a period following the July 1, 2001 deadline was arbitrary and grossly unfair to Crompton Canada, who held the lion's share of the lindane seed treatment product for canola/rapeseed at the time. As discussed above, not only was this a breach of the PMRA's commitments under the Conditional Withdrawal Agreement and the registrants' uniform understanding of the withdrawal deadline, it caused widespread confusion in the marketplace leading many seed-treaters and canola growers to abandon sales and use of the lindane products for canola long before they were required to by the actual terms of the Conditional Withdrawal Agreement;

- The PMRA's decision to wait for the July 1, 2001 deadline to pass in lieu of dedicating the necessary resources to properly conduct and issue a scientific assessment of lindane before the end of 2000 was arbitrary and grossly unfair, also demonstrating an absence of good faith in dealing with the Investor;

- The "scientific assessment" that the PMRA ultimately issued in December 2001, as the Review Board observed, lacked fundamentally in fairness of process to such an extent as to impugn and undermine the scientific findings underpinning the assessment resulting in an unjust regulatory decision to deregister all of Crompton Canada's Lindane Products. In the Review Board's words:

> The revocation of a registration is the most severe and restrictive measure a regulator can take, and, in the Board's experience, it is left for the most harmful of products, at least to the extent that PMRA deregisters a product without giving the registrant a reasonable amount of time to address mitigation. In his evidence, John Worgan of PMRA himself admitted that it was unusual for

> PMRA to come to a decision so quickly and without adjusting its findings at all after comment from registrants.
>
> […]
>
> Addressing mitigation […] is fundamental in conducting a robust scientific inquiry leading to a regulatory decision. It is clear to the Board that this did not occur in the case of Lindane.[342]

- The PMRA's termination of Crompton Canada's remaining Lindane Products registrations was grossly unfair in view of its commitments in the Conditional Withdrawal Agreement concerning continued sales and marketing of lindane products for non-canola uses, the phase out period accorded to Crompton Canada's competitors' products, and the fact that the decision to terminate was based on a fundamentally biased, ill-founded occupational health study and this termination that itself was non-compliant with the commitments made by the PMRA; and

- Finally, the PMRA's treatment of Crompton Canada's Lindane Products vis-à-vis replacement products, the review of which the PMRA had committed to expedite, was both arbitrary and grossly unfair in light of the treatment accorded to competitor replacement products such as Helix and Helix XTra.

7. The PMRA Failed to Act in Good Faith in its Dealings with and Treatment of the Investor and Crompton Canada

447. Finally, all of the above-described actions further demonstrate that PMRA failed to conduct itself in good faith vis-à-vis the Investor and Crompton Canada's Lindane Products.

448. As noted above, in order to have breached Canada's obligations under Article 1105 PMRA need not have acted in bad faith, it need only have acted in a manner inconsistent with good faith, such as by failing to deal with the Investor or its investment in a fair, and straight-forward manner, failing to abide by commitments made to the Investor or its investment, upon which they reasonably relied to their detriment, or by treating the Investor in a discriminatory manner.

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[342] Exhibit A4, paras. 120 and 122.

449. Each of the above-described actions demonstrates that the PMRA's conduct fell far short of what is required by the principle of good faith and therefore that Canada has breached its obligations under Article 1105.

V. CANADA HAS BREACHED ITS OBLIGATIONS UNDER NAFTA ARTICLE 1103

A. Overview

450. Notwithstanding the Investor's foregoing arguments that Canada had breached the minimum standard of treatment contained in Article 1105, the Investor submits in the alternative that Canada has breached Article 1103 by failing to accord to the Investor and its lindane seed treatment business more favourable treatment available under third-party treaties. In particular, Canada has failed to accord to the Investor and its lindane seed treatment business more favourable substantive treatment available under fair and equitable treatment provisions in third-party BITs negotiated by Canada.

451. This argument is made in the alternative, because it is the Investor's position that "fair and equitable treatment" under the customary international law minimum standard (as provided for under NAFTA Article 1105) is equivalent to "fair and equitable treatment in accordance with the principles of international law" found in third-party BITs. Given that the latter is not limited to the minimum standard under customary international law, it is referred to in this Memorial as the "independent" or "free-standing" fair and equitable treatment standard. In the event that the Tribunal holds that the standard under Article 1105 is less favourable than the independent standard provided for in third-party BITs to which Canada is party, the Investor submits it is entitled to receive the more favourable treatment by virtue of NAFTA Article 1103.

B. NAFTA Article 1103

452. NAFTA Article 1103 provides as follows:

> 1. Each Party shall accord to Claimants of another Party treatment no less favorable than that it accords, in like circumstances, to Claimants of any other Party or of a non-Party with respect to the

> establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments.
>
> 2. Each Party shall accord to investments of Claimants of another Party treatment no less favorable than that it accords, in like circumstances, to investments of Claimants of any other Party or of a non-Party with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments.

453. Article 1103 imposes an obligation of "non-discrimination" on the NAFTA Parties that is constituted of three elements.

454. In order to satisfy its Article 1103 obligation, Canada is required to accord to U.S. investors and their investments (i) treatment that is no less favourable than it accords (ii) in like circumstances (iii) to investors of any other State with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments. As will be demonstrated below, Canada has failed to satisfy this obligation in the circumstances.

1. The Purpose of the MFN Clause

455. The International Court of Justice has described the purpose of an MFN clause as "establish[ing] and maintain[ing] at all times fundamental equality without discrimination among all of the countries concerned."[343]

456. In the words of one author, an MFN clause thus serves to encourage investment by reassuring Investors that they will not be driven out of business by more favourable conditions for investment granted to a competitor, and enable investors to adapt to changing circumstances by guaranteeing that any more favourable treatment granted to Investors from another country will also inure to the first investor :

[343] See *Rights of Nationals of the United States of America in Morocco* (*France v. United States of America*), 1952 I.C.J. 176, 192 (27 August 1952).

> An MFN clause […] has an important function in stabilizing expectations over time so as to reassure Claimants about making long-term investments. Absent the MFN clause, a Claimant would worry that the host state might grant a competitor more favourable conditions for investment and thereby drive the first Claimant out of business. The MFN clause ensures that any more favourable treatment granted to Claimants from another country will also inure to the first Claimant.[344]

457. MFN clauses are also inherently liberalizing in the trade context, functioning as a "one-way ratchet", and should be applied broadly :

> "Indeed, it has been said in the trade context that "[o]ne of the chief advantages of the unconditional form is that it removes the necessity for repetition of pledges every time conditions are altered by a new commercial treaty". However, this presumed benefit carries with it a cost in that it is a one-way ratchet. A country wishing to shift policy away from Claimant protections in favour of other policy goals would need to renegotiate or renounce every BIT incorporating the provisions it wishes to change. An MFN clause thus creates a structural bias in favour of liberalization.
>
> […]
>
> [T]he case for a broad application of the MFN clause remains undiminished. Unlike a liberal reading of a substantive provision that might impose policy obligations on a host state that it did not contemplate nor accept, a broad application of the MFN clauses requires only that, once the host state has agreed to grant a particular treatment to one state's Claimant, the host state must accord the same treatment to others. While "there is no fixed wording or formula of the clause … its *raison d'être* is always the same: to establish between the contracting parties a treatment equal to that enjoyed by any third nation." It would defeat this purpose to impose restrictions on the scope of the MFN clause where no limitations or exception are apparent from the text, context, or surrounding circumstances. Moreover, the variety of limitations that are routinely written into MFN clauses demonstrate that states are able to craft MFN clauses that are limited in scope if they so choose.[345]

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[344] Scott Vesel, "Clearing a Path through a Tangled Jurisprudence: Most-Favored-Nation Clauses and Dispute Settlement Provisions in Bilateral Investment Treaties" (2007) 32 *Yale J. Int'l L.* 125 at p. 142.

[345] *Ibid*., p. 142-44. See also Richard Snyder, *The Most-Favored Nation Clause: An Analysis with Particular Reference to Recent Treaty practice and Tariffs* (New York: King's Crown Press, 1948) at p. 35.

[Citations omitted. Emphasis added.]

458. Thus, the purpose of an MFN clause, such as NAFTA Article 1103, is to level the playing field between foreign investors by ensuring that the host State does not discriminate against any foreign investor or its investment by providing more favourable treatment to one than it provides to the other.

2. The Scope of the MFN Obligation

(a) Legal Requirements

459. Canada has excluded from the scope of Article 1103 all bilateral or multilateral international agreements in force or signed prior to entry into force of the NAFTA, *i.e.* January 1, 1994, as well as agreements which are signed or which enter into force after the NAFTA involving aviation, fisheries, maritime matters and telecommunications. This means that Canada's MFN obligations apply to general trade and/or investment treaties which were signed or which entered into force after January 1, 1994.

460. As noted above, Article 1103 contains three conjunctive requirements. Canada is required to accord to investors: (i) treatment no less favourable than that accorded (ii) in like circumstances (iii) to investors of any other State with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments. These requirements are outlined below.

461. However, a specific investor or investment which has received more favourable treatment than the Investor need not be identified for the purpose of invoking better protection under a third-party treaty. As observed by Richard Snyder in his treatise on MFN clauses, the benefit of an MFN clause is intended to inure to foreign investors going forward, not just those whose investments are real or anticipated at the time the treaty containing the clause is implemented:

> M. Visser argues with unimpeachable logic […] that most-favored-nation treatment must mean equality of treatment at all times. Otherwise, the clause performs only half of its job. All

> treaties of commerce affect the future; this particular clause should not be taken to apply solely to past and present conditions.[346]

462. So long as better treatment is available to investors and investments of another State, the Investor is entitled to claim the benefit of that better treatment subject to the further conditions discussed below.

Treatment No Less Favourable

463. "Treatment" in this criterion is limited to treatment relative to the activities specified in Article 1103, namely the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments. Although to the investor's knowledge there has been no substantive consideration of this criterion by a NAFTA tribunal, the same term in Article 1102 (National Treatment) has been interpreted as involving:

- Measures that *de jure* appear to favour the national(s) of one foreign State over the nation(s) of another foreign State; and

- Measures that *de facto* create a disproportionate benefit for the national(s) of one foreign state over the national(s) of another foreign State.[347]

In Like Circumstances

464. The term "in like circumstances" has similarly been interpreted by NAFTA tribunals in respect of the parties' national treatment obligations. The term "in like circumstances" refers to the comparator group or investor for the purpose of determining whether there has been discriminatory treatment.

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[346] See Richard Snyder, *The Most-Favored Nation Clause: An analysis with Particular Reference to Recent Treaty practice and Tariffs* (New York: King's Crown Press, 1948) at para. 35.

[347] See *S.D. Myers v. Canada*, NAFTA Partial Award (UNCITRAL), November 13, 2000, at para. 252; See also *Marvin Roy Feldman v. Mexico,* ICSID Case No. ARB(AF)/99/1, Award, December 16, 2002, at para. 181.

465. In *Pope & Talbot*, the tribunal held that this criterion is composed of a two-part test:

- The treatment should be compared with that accorded other foreign investors/investments in the same business or economic sector; and
- Resulting differences in treatment will be presumed violations, unless they have a reasonable nexus to rational government policies that:
  - do not distinguish, *de jure* or *de facto*, between foreign-owned investors/investments; and
  - do not otherwise unduly undermine the investment liberalizing objectives of NAFTA.[348]

(b) Article 1103 is Not Limited by the FTC's Note of Interpretation

466. As noted, MFN clauses function as a "one way ratchet" in favour of liberalization. As a result, it matters not whether a State has negotiated less favourable substantive treatment in a recent treaty if more favourable treatment continues to be available under older existing treaties. This means that a shift in policy away from a more liberal position can not affect an investor's entitlement to claim the benefit of more favourable substantive rights under a third-party treaty where the protections under that treaty remain as they were prior to the host State's shift in policy or subsequent treaty negotiations with other States.[349]

467. Thus, Article 1103 enables an investor of a Party to secure more favourable treatment negotiated since the entry into force of the NAFTA. In the instant case, this includes entitlement to a more favourable standard of fair and equitable treatment contained in Third-party treaties than that provided for in Article 1105 and within the terms of the FTC's Note of Interpretation.

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[348] *Pope & Talbot v. Canada*, NAFTA (UNCITRAL), Interim Award on Merits, April 10, 2001, at para. 78.

[349] See Scott Vesel, "Clearing a Path through a Tangled Jurisprudence: Most-Favored-Nation Clauses and Dispute Settlement Provision in Bilateral Investment Treaties" (2007) 32 *Yale I. Int'l L.* 125 at pp. 142-143.

468. Rudolf Dolzer and Margrete Stevens have observed in respect of State practice whereby fair and equitable treatment is specifically provided for in a BIT that the:

> fact that parties to BITs have considered it necessary to stipulate this [fair and equitable treatment] standard as an express obligation rather than relied on a reference to international law and thereby invoked a relatively vague concept such as minimum standard, is probably evidence of a self-contained standard.[350]

469. Professor Stephen Vasciannie has also concluded that the minimum standard and the fair and equitable treatment standard are likely not identical, but that inclusion of "fair and equitable treatment" in a treaty requires, in all circumstances, treatment that is fair and equitable:

> […] given the substantial volume of State practice incorporating the fair and equitable standard, it is noteworthy that the instances in which States have indicated or implied an equivalence between this standard and the international minimum standard are relatively sparse. Moreover, bearing in mind that the international minimum standard has itself been an issue of controversy between developed and developing States for a considerable period, it is unlikely that a majority of States would have accepted the idea that this standard is fully reflected in the fair and equitable standard without clear discussion. These considerations point ultimately to the conclusion that the two standards in question are not identical: both standards may overlap significantly with respect to the issues such as arbitrary treatment, discrimination and unreasonableness, but the presence of a provision assuring fair and equitable treatment in an investment instrument does not automatically incorporate the international minimum standard for foreign Claimants. Following Mann, where the fair and equitable standard is invoked, the central issue remains whether the actions in question are in all circumstances fair and equitable or unfair and inequitable.[351]

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[350] Rudolf Dolzer and Margrete Stevens, *Bilateral Investment Treaties* (Boston; Martinus Nijhoff Publishers, 1995) at p. 60.

[351] Steven Vasciannie, "The Fair and Equitable Treatment Standard in International Investment Law and Practice" (1997) *British Yearbook of International Law* 99 at p. 144.

470. Thus, to the extent there is a difference in the quality and nature of treatment required by "fair and equitable treatment" under customary international law and international law (e.g. treaties), the Investor is entitled to the better treatment by operation of Article 1103.

471. Finally, consistent with basic principles of treaty interpretation, any limitation imposed on the meaning of "fair and equitable treatment" in NAFTA Article 1105 by the FTC's Note of Interpretation is inapposite to the meaning of "fair and equitable treatment" in Canadian BITs where the plain language of the BIT does not support such an interpretation.

3. NAFTA Case Law on Article 1103

472. The tribunal in *ADF v. United States of America* considered the scope of Article 1103 in the context of an investor's claim that Article 1103 allowed it to enjoy the benefits of provisions in the U.S.-Albania and U.S.-Estonia BITs, which provided to Albanian and Estonian investors a standard of fair and equitable treatment that was not tied to the customary international law minimum standard. The tribunal held that ADF had not established that the provisions of the two BITs created any free-standing rights to fair and equitable treatment.[352] However, ADF's Article 1103 claim was not dismissed on this basis but rather on the ground that the MFN provision did not apply to government procurement.[353]

473. In *Pope & Talbot*, although the investor had not alleged a breach of Article 1103 but rather a breach of Article 1105, the tribunal nevertheless stated in *obiter dicta* that Article 1103 gives investors the benefit of better substantive protection offered in BITs to which Canada is a party:

> In addition to the context, object and purpose of NAFTA, there is a practical reason for adopting the additive interpretation to Article

[352] See *ADF Group Inc. v. United States of America*, Award, ICSID Case No. ARB(AF)/00/1, January 9, 2003.

[353] *Ibid*. at para. 196.

> 1105. As noted, the contrary view of that provision would provide NAFTA investors a more limited right to object to laws, regulation and administration than accorded to host country investors and investments as well as to those from countries that have concluded BITs with a NAFTA party. […] NAFTA investors and investments that would be denied access to the fairness elements untrammelled by the "egregious" conduct threshold that Canada would grant onto Article 1005 would simply turn to Articles 1102 and 1103 for relief.[354]

474. In *UPS*, the tribunal similarly acknowledged in *obiter dicta* that Article 1103 may accord investors a higher level of protection than that available under other provisions in the NAFTA. The tribunal commented that although the FTC's Note of Interpretation concerning the minimum standard of treatment in Article 1105 limits the standard to what is required by customary international law, there is "likely availability to the Claimant of the protection of the most favored nation obligation in article 1103, by reference to other bilateral investment treaties".[355] The tribunal further observed that "the very fact that many of the treaties do expressly create a stand alone obligation of fair and equitable treatment" gives added force to the ordinary meaning of Article 1105(1).[356]

475. These NAFTA cases illustrate that whatever the NAFTA Parties' intentions with regard to the standard of treatment expressed in Article 1105, Article 1103 is not limited by the FTC Note of Interpretation on Article 1105 and must be given its full meaning in accordance with applicable principles of treaty interpretation.

4. BIT Case Law on MFN Clauses

476. BIT case law further clarifies the scope of MFN clauses such as Article 1103 and, in particular, their availability to secure greater substantive protection for Investors under third-party treaties.

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[354] *Pope & Talbot,* NAFTA (UNCITRAL), Interim Award on Merits, April 20, 2001, at para. 117.

[355] See *UPS v. Canada*, NAFTA (UNCITRAL), Decision on Jurisdiction, November 22, 2002 at para. 97.

[356] *Ibid.*

(a) The *ejusdem generis* principle

477. The International Court of Justice has established that the rights of a beneficiary of an MFN clause are defined with respect to the subject matter both of the clause itself and the rights conferred by the host State under the third-party treaty.[357] In the *Ambatielos Case,* the Commission of Arbitration to which the International Court of Justice had referred the case stated:

> [T]he most-favoured-nation clause can only attract matters belonging to the same category of subject as that to which the clause itself relates. […] It is true that the administration of justice', when viewed in isolation is a subject-matter other than 'commerce and navigation', but this is not necessarily so when it is viewed in connection with the protection of the rights of traders. Protection of the rights of traders naturally finds a place among the matters dealt with by Treaties of commerce and navigation. Therefore it cannot be said that the administration of justice, in so far as it is concerned with the protection of these rights, must necessarily be excluded from the field of application of the most-favored-nation clause, when the latter includes 'all matters relating to commerce and navigation'.[358]

478. More recently, in *Maffezini v. Spain*, the investor sought to use the MFN obligation in the Spain-Argentina BIT to take advantage of a more favourable provision in the Spain-Chile BIT. Under the Spain-Argentina BIT, the investor was required to submit the dispute to the domestic courts of the host state during at least the first 18 months of the dispute. The Chile-Spain BIT had no such provision. The tribunal held that so long as the subject matter is covered in the third-party treaty, then that treatment is extended to the investor under the first treaty, subject to public policy considerations which may negate the extension of rights:

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[357] See *Rights of Nationals by the United States of America in Morocco (1952)*, (France v. U.S.A.), ICJ 1952, Vol. I; *Ambatielos Case* (1952, 1953 and 1956), U.N. R.I.A.A., Vol. XII, 1963 (The ICJ found it had jurisdiction in the first proceedings to decide whether the United Kingdom was under an obligation to submit to arbitration, and subsequently referred the cases to a Commission of Arbitration for resolution.)

[358] *Ambatielos Case,* R.I.A.A. XII, pp 83-153 (6 March 1956), at p. 107. The Arbitration Commission ultimately determined that the third party treaties invoked provided for rights no more favourable than those resulting from the basic treaty.

> From the above considerations it can be concluded that if a third-party treaty contains provisions for the settlement of disputes that are more favourable to the protection of the Claimant's rights and interests than those in the basic treaty, such provisions may be extended to the beneficiary of the most favored nation clause as they are fully compatible with the ejusdem generis principle. Of course, the third-party treaty has to relate to the same subject matter as the basic treaty, be it the protection of foreign investments or the promotion of trade, since the dispute settlement provisions will operate in the context of these matters; otherwise there would be a contravention of that principle. This operation of the most favored nation clause does, however, have some important limits arising from public policy considerations that will be discussed further below.[359]

479. Accordingly, so long as the subject matter of the third-party treaty relates to the subject matter of the basic treaty, *i.e.* the protection of foreign investment and/or the promotion of trade, more favourable provisions in the former may be extended to the investor under the MFN clause in the latter to secure the more favourable protection of the investor's rights.

(b) Extension of Substantive *versus* Procedural Rights

480. The *Maffezini* decision has been the subject of some controversy concerning the nature of the rights extended in that case.[360] However, concerns surrounding the extension of

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[359] *Maffezini v. Spain*, Decision on Jurisdiction, ICSID Case No. ARB/97/7, January 25, 2000 at paras. 56 and 62. See also *Siemans AG v. Argentina*, Decision on Jurisdiction, ICSID Case No. ARB/02/8, August 3, 2004 (where Siemans was successful in avoiding the same 18-month waiting period in the domestic courts before pursuing arbitration, as contained in the Germany-Argentina BIT, in favour of the shorter waiting period provided to claimant under the Chile-Argentina BIT).

[360] See e.g. *Salini Construttori SpA and Italstrade SpA v. Jordan*, Decision on Jurisdiction, ICSID Case No. ARB/02/13, November 15, 2004 (The tribunal held that the MFN provision in the Jordan-Italy BIT did not cover dispute settlement clauses, because the MFN clause was not sufficiently broad, there was no proof that this was the intention of the parties, and there was no long-standing practice by either Jordan or Italy to support this interpretation.); *Plama Consortium Limited v. Bulgaria*, Decision on Jurisdiction, ICSID Case No. ARB/03/24, February 8, 2005 ("[A]n MFN provision in a basic treaty does not incorporate by reference dispute settlement provisions in whole or in part set forth in another treaty, unless the MFN provision in the basic treaty leaves no doubt that the contracting Parties intended to incorporate them"); *Tecnicas Medioambientales TecMed S.A. v. United Mexican States*, Award, ICSID Case No. ARB(AF)/00/2, May 29, 2003 (Among its claims of expropriation and a breach of fair and equitable treatment, TecMed sought to invoke the MFN clause in the Spain-Mexico BIT to take advantage of a provision in the Austria-Mexico BIT which allowed for the retroactive application of the BIT to acts that occurred prior to its entry into force. The tribunal refused to apply the *Maffezini* decision to "the time dimension of application of [the Agreement's] substantive provisions" because such provisions were a core matter specifically negotiated by the parties. *Ibid*. at para. 69).

procedural rights, and in particular dispute settlement provisions, may be and frequently are distinguished from the invocation of MFN clauses to secure better *substantive* treatment.

481. In *Occidental Exploration and Petroleum Company v. Ecuador*, the tribunal held that the government, in refusing to continue reimbursing the investor's VAT payments, had treated the Investor less favourably than national companies. In light of this, it did not need to consider the MFN issue. The tribunal nevertheless commented on the relevance of *Maffezini* (and the extension of procedural rights) to the question of the MFN obligation as it relates to substantive treatment :

> This finding makes it unnecessary for the Tribunal to examine whether there were in addition most-favoured-nation-treatment obligations involved. In view of the fact that the parties have discussed in detail the meaning of Maffezini in this context, the Tribunal believes it appropriate to clarify that that case is not really pertinent to the present dispute as it dealt with the most-favoured-nation-treatment only insofar as procedural rights of the claimant there were involved, not substantive treatment as is the case here.[361]

482. In *Asian Agricultural Products Ltd. (AAPL) v. Sri Lanka*, the investor, a British investor whose investment was destroyed in a civil war that broke out in Sri Lanka, invoked the MFN clause in the U.K.-Sri Lanka BIT to take advantage of the full protection and security provision in the Sri-Lanka-Switzerland BIT, which, unlike the U.K.-Sri Lanka BIT, did not contain an exception for civil war and public disturbances.

483. Although the tribunal held that the Sri Lanka-U.K. BIT MFN clause "may be invoked to increase the host State's liability in case a higher standard of international protection becomes granted to investments pertaining to nationals of the Third state",[362] the investor

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[361] *Occidental Exploration and Petroleum Company v. Ecuador*, Award, LCIA Case No. UN3467 July 1, 2004 at para. 178.

[362] *Asian Agricultural Products Limited v. Democratic Socialist Republic of Sri Lanka*, ICSID Case No. ARB/87/3, Award, June 27, 1999, at para. 43.

could not successfully do so in this case because there was no proof that the third-party BIT provided for a "strict liability standard of protection in case of losses suffered due to property destruction.[363] Thus, the investor had not demonstrated any practical difference in treatment between the two BITs.

484. In *MTD v. Chile*, the investors successfully invoked the MFN clause of the Chile-Malaysia BIT in order seek a more robust standard of fair and equitable treatment in the Chile-Croatia and Chile-Denmark BITs. Although the tribunal ultimately held that Chile had not breached the provisions of the Chile-Croatia and Chile-Denmark BITs, it reasoned as follows with regard to the extension of substantive rights under those BITs to the investor :

> The Tribunal considers the meaning of fair and equitable treatment below and refers to that discussion. The Tribunal has concluded that, under the BIT, the fair and equitable standard of treatment has to be interpreted in the manner most conducive to fulfill the objective of the BIT to protect investments and create conditions favourable to investments. The Tribunal considers that to include as part of the protections of the BIT those included in Article 3(1) of the Denmark BIT and Article 3(3) and (4) of the Croatia BIT is in consonance with this purpose. The Tribunal is further convinced of this conclusion by the fact that the exclusions in the MFN clause relate to tax treatment and regional cooperation, matters alien to the BIT but that, because of the general nature of the MFN clause, the Contracting Parties considered it prudent to exclude. A *contrario sensu*, other matters that can be construed to be part of the fair and equitable treatment of Claimants would be covered by the clause.[364]

485. Both procedural and substantive rights were considered by the tribunal in *Telenor Mobile Communications AS v. Hungary*. Telenor argued that its investment had been expropriated by the Hungarian government, and that it had been treated unfairly and inequitably in violation of Article III of the Hungary-Norway BIT. Under the Hungary-Norway BIT, however, the fair and equitable treatment obligation was expressly

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[363] *Ibid*. at para. 54.

[364] *MTD Equity Sdn. Bhd. And MTD Chile S.A. v. Chile*, ICSID Case No. ARB/01/7, Award, May 25, 2004, at para. 104.

inarbitrable. Telenor sought to use the MFN clause of the BIT to allow it to take advantage of provisions in other Hungarian BITs which did allow for the fair and equitable treatment clause to be the subject of arbitration. The tribunal held that only the investor's substantive rights were protected by the MFN clause:

> In the first place, Article 31 of the 1969 Vienna Convention on Treaties requires a treaty to be interpreted "in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purposes." In the absence of language or context to suggest the contrary, the ordinary meaning of "investments shall be accorded treatment no less favourable than that accorded to investments made by Claimants of any third State" is that the Claimant's substantive rights in respect of the investments are to be treated no less favourably than under a BIT between the host State and a third State, and there is no warrant for construing the above phrase as importing procedural rights as well. It is one thing to stipulate that the Claimant is to have the benefit of MFN investment treatment but quite another to use an MFN clause in a BIT to bypass a limitation in the very same BIT when the parties have not chosen language in the MFN clause showing an intention to do this, as has been done in some BITs.[365]
>
> [Emphasis added]

486. The above cases establish the following principles to guide the application of Article 1103:

- MFN clauses, including Article 1103, must be interpreted liberally in order to ensure that their underlying purpose to secure equality of treatment as between foreign investors and their investments is achieved;
- According to the *ejusdem generis* principle, an MFN clause can attract the more favourable treatment available in other treaties only in regard to the same "subject matter"; and

[365] *Telenor Mobile Communications AS v. Hungary*, ICSID Case No. ARB/04/15, Award, June 22, 2006 at para 92.

- An investor's substantive rights in respect of it's investments under a basic treaty are to be treated no less favourably than under a BIT between the host State and a third State.[366]

C. Canada's Breaches of Article 1103

1. More Favourable Treatment is Available under Third-Party Treaties

487. More favourable substantive treatment is available to the Investor and its Canadian seed treatment investment under the fair and equitable treatment provisions of third-party treaties negotiated by Canada, dealing with the same subject matter, which are not limited or defined by the minimum standard of treatment in customary international law.

488. "Fair and equitable treatment" most commonly finds expression in Canadian BITs as follows:

> Each Contracting Party shall accord investments or return of Claimants of the other Contracting Party:
>
> (a) fair and equitable treatment in accordance with principles of international law; and
>
> (b) full protection and security.

489. Canada is party to no less than 16 BITs signed and entered into force after January 1, 1994, which provide for fair and equitable treatment in accordance with "international law" or the "principles of international law".[367] Basic principles of treaty interpretation

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[366] See also Organisation for Economic Cooperation and Development, Working Paper on International Investment, "Most-Favoured-Nation Treatment in International Investment Law", No. 2004/2, September 2004.

[367] Agreement between the Government of Canada and the Government of Barbados for the Reciprocal Promotion and Protection of Investments, done at Bridgetown, 29 May 1999; Agreement between the Government of Canada and the Government of the Republic of Ecuador for the Promotion and Reciprocal Protection of Investments, done at Quito, 29 April 1996; Agreement between the Government of Canada and the Government of the Republic of Venezuela for the Promotion and Protection of Investments, done at Caracas, 1 of July 1996; Agreement between the Government of Canada and the Government of the Arab Republic of Egypt for the Promotion and Protection of Investments, done at Cairo, 13 November 1996; Agreement between the Government of Canada and the Government of the Kingdom of Thailand for the Promotion and Protection of Investments, done at Bangkok, 17 January 1997; Agreement between the Government of Canada and the Government of the Eastern Republic of Uruguay for the Promotion and Protection of Investments, done at Ottawa, 29 of October 1997; Agreement between the Government of Canada and the Government of the Republic of Costa Rica for the Promotion and Protection of Investments, done at San José, 18 March 1998; Agreement between the Government of the Republic of Croatia and the Government of Canada for the Promotion and Protection of Investments, 1997; Agreement between the

require that these provisions be interpreted on the basis of their plain meaning and in light of the objects and purposes of the treaties in which they appear, i.e. treaties designed to promote and protect foreign investment in order to stimulate business initiatives and the development of economic cooperation between the two treaty parties. Thus, the Canada-Panama BIT provides in its preamble as follows:

> […]
>
> DESIRING to increase the favourable conditions for the reciprocal investment of capital by nationals of both Contracting Parties; TAKING into consideration the importance of establishing a predictable environment for the development of investments;
>
> […]
>
> [Emphasis added]

490. These treaties stand in contrast to the NAFTA and to a limited number of bilateral treaties in which fair and equitable treatment is specifically tied to the minimum standard of treatment provided for in customary international law.[368]

Government of Canada and the Government of the Republic of the Philippines for the Promotion and Reciprocal Protection of Investments, done at Manila, 9 November 1995; Agreement between the Government of Canada and the Government of the Republic of Romania for the Promotion and Reciprocal Protection of Investments, done at Bucharest, 17 April 1996; Agreement between the Government of Canada and the Government of the Republic of Panama for the Promotion and Protection of Investments, done at Guatemala, 12 September 1996; Agreement between the Government of Canada and the Government of the Republic of Trinidad and Tobago for the Reciprocal Promotion and Protection of Investments, done at Toronto, 11 of September 1995; Agreement between the Government of Canada and the Government of the Republic of Latvia for the Promotion and Protection of Investments, done at Ottawa, 26 April 1995; Agreement between the Government of Canada and the Government of Ukraine for the Promotion and Protection of Investments, done at Ottawa, 24 October 1994; Agreement between the Government of Canada and the Government of the Lebanese Republic for the Promotion and Protection of Investments, done at Ottawa, 11 April 1997; Agreement between the Government of Canada and the Government of the Republic of Armenia for the Promotion and Protection of Investments, done at Ottawa, 8 May 1997. Available online http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/fipa-apie/fipa_list.aspx?lang=en.

[368] See e.g. *Agreement between Canada and the Republic of Peru for the Promotion and Protection of Investments*, June 20, 1997, Article 5 of which provides, in pertinent part, as follows:

> 1. Each Party shall accord to covered investments treatment in accordance with the customary international law minimum standard of treatment of aliens, including fair and equitable treatment and full protection and security.

491. Notwithstanding the Investor's main contention that all of the conduct discussed above in sections IV.B.3 and 4 informs both the meaning and breadth of the fair and equitable treatment obligation within the minimum standard, to the extent the tribunal finds otherwise, any conduct identified in BIT case law on the basis of substantially similar treaty provisions as the Canadian BIT provisions highlighted above should apply to give meaning to these latter provisions. Thus, the conclusions of the tribunals in *Occidental Exploration and Petroleum Company, Azurix* and *Tecmed,* to name but a few, assist in identifying those substantive rights to which the Investor is entitled, untrammelled by limitations imposed in customary international law, by virtue of NAFTA Article 1103.

492. Accordingly, these BITs each offer more favourable substantive protection through a standard of fair and equitable treatment untied to the customary international law minimum standard.[369]

2. Canada Failed to Accord the Investor the More Favourable Standard of Fair and Equitable Treatment Available in Canadian BITs

493. To the extent the customary international law minimum standard imposes a lower burden or states, the free-standing fair and equitable treatment obligation contained in BITs including Canadian BITs, is not so restricted.

494. For the reasons discussed in Section IV.C above, Canada failed to treat the Investor and its lindane seed treatment business fairly and equitably by the more favourable standard of fair and equitable treatment contained in the afore-mentioned BITs, which benchmark the standard of treatment to be accorded investors to what is required under international

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> 2. The concepts "fair and equitable treatment" and "full protection and security" in paragraph 1 do not require treatment in addition to or beyond that which is required by the customary international law minimum standard of treatment of aliens.

[369] As noted earlier, it is the Investor's principal submission that the fair and equitable treatment standard in Article 1105 is, in content, the same standard as the "free-standing" fair and equitable treatment standard found in the various third-party treaties negotiated by Canada. However, if the tribunal is of the view that the fair and equitable treatment standard expressed in Canada's BITs offers more favourable substantive protection than Article 1105, then the Investor submits that it is entitled to treatment in accordance with that more favourable standard, by virtue of Article 1103.

law, as opposed to the narrower customary international law minimum standard. As such, Canada has breached its MFN obligations under Article 1103.

VI. CANADA HAS BREACHED ITS OBLIGATIONS UNDER ARTICLE 1110

A. Overview

495. Canada unlawfully expropriated the Investor's investment by implementing regulatory measures which had the effect of depriving the Investor of the whole of the reasonably to be expected economic benefit of its lindane seed treatment investment in Canada, without payment of any compensation and otherwise in non-compliance with its commitments under the NAFTA.

B. NAFTA Article 1110

496. Article 1110(1) of NAFTA states:

> No Party may directly or indirectly nationalize or expropriate an investment of a Claimant of another Party in its territory or take a measure tantamount to nationalization or expropriation of such an investment […] except
>
> (a) for a public purpose;
>
> (b) on a non-discriminatory basis;
>
> (c) in accordance with due process of law and Article 1105(1); and
>
> (d) on payment of compensation […].

497. A "measure" is defined in NAFTA Article 201(1) as "any law, regulation, procedure, requirement or practice".

498. The measures taken by the PMRA in its course of conduct between 1998 and continuing today fail to meet any of these conjunctive requirements.

1. Scope of Article 1110

(a) Expropriation May be Direct or Indirect

499. It is widely recognized that expropriation may be either direct or indirect. In its report on the *Taking of Property*, the U.N Conference on Trade and Development explained as follows:

> Certain governmental measures may not involve an actual physical taking of property, but may still result in the effective loss of management, use or control, or a significant depreciation of the value, of the assets of a foreign Claimant.
>
> […]
>
> Creeping expropriation. This may be defined as the slow and incremental encroachment on one or more of the ownership rights of a foreign Claimant that diminishes the value of its investment. The legal title to the property remains vested in the foreign Claimant by the Claimant's rights of use of the property are diminished as a result of the interference by the State […].[370]

500. NAFTA tribunals have also recognized that expropriation may potentially arise under a broad range of government actions, including State regulatory measures. In *Metalclad*, the tribunal stated:

> 103. Expropriation under NAFTA includes not only open, deliberate and acknowledged takings of property, such as outright seizure or formal or obligatory transfer of title in favour of the host State, but also covert or incidental interference with the use of property which has the effect of depriving the owner, in whole or in significant part, of the use of reasonably to be expected economic benefit of property even if not necessarily to the obvious benefit of the host state.[371]
>
> [Emphasis added]

501. In *Pope & Talbot*, the tribunal further reasoned as follows:

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[370] United Nations Conference on Trade And Development, *Taking of Property*, (2000) Document No. UNCTAD/ITE/IIT/15 at 2.

[371] *Metalclad Corp.* v. *United Mexican States*, ICSID Case No. ARB(AF)/97/1, Award, September 2, 2000 at para. 103.

> 99. While the exercise of police powers must be analyzed with special care […] [r]egulations can indeed be exercised in such a way that would constitute creeping expropriation […]. Indeed, much creeping expropriation could be conducted by regulation, and a blanket exception for regulatory measures would create a gaping loophole in international protections against expropriation. For these reasons, the Tribunal rejects the argument of Canada that the Export Control Regime, as a regulatory measure, is beyond the coverage of Article 1110.[372]

502. Other international tribunals have held that expropriation occurs where government actions unduly interfere with an alien's use or enjoyment of prosperity.[373]

2. The Threshold for an Indirect Expropriation is "Substantial Deprivation"

503. The threshold for finding an indirect expropriation is described by the tribunal in *Pope & Talbot*. In its Interim Award, the tribunal stated as follows:

> While it may sometimes be uncertain whether a particular interference with business activities amounts to an expropriation, the test is whether that interference is sufficiently restrictive to support a conclusion that the property has been "taken" from the owner. Thus, the *Harvard Draft* defines the standard as requiring interference that would "justify an inference that the owner […] will not be able to use, enjoy, or dispose of the property […] The *Restatement,* in addressing the question whether regulation may be considered expropriation, speaks of "action that is confiscatory, or that prevents, unreasonably interferes with, or unduly delays, effective enjoyment of an alien's property." Indeed, at the hearing, the Claimant's Counsel conceded, correctly, that under international law, expropriation requires a "substantial deprivation.[374]

504. These factors have been followed by both NAFTA and BIT tribunals. In *CME Czech Republic B.V. (The Netherlands) v. Czech Republic*, the tribunal found that the Czech

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[372] *Pope & Talbot* v *Canada*, NAFTA (UNCITRAL) Interim Award, June 26, 2000 at para 99. See also *S.D. Myers Inc. v. Canada*, NAFTA (UNCITRAL) Partial Award, November 13, 2000 at para. 280.

[373] See e.g. *Tippetts, Abbell, McCarthy, Stratton v. TAMS-AFFA*, 6 Iran-U.S. CTR 219, 225 Award of June 22, 1984; *Starrett Housing Corp. v Iran,* 4 Iran-U.S. CTR 122, 159, 172 Award of December 19, 1983.

[374] *Ibid.,* para. 102.

government's actions amounted to an indirect expropriation of CME's investment because they "effectively neutralized" the investment:

> The expropriation claim is sustained despite the fact that the Media Council did not expropriate CME by express measures of expropriation. De facto expropriations or indirect expropriations, i.e. measures that do not involve an overt taking but that effectively neutralize the benefit of the property of the foreign owner, are subject to expropriation claims. This is undisputed under international law.[375]
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> [Emphasis added. Citations omitted.]

505. Similarly, the tribunal in *CMS Gas Transmission Company v. Argentina* observed that the essential question in indirect expropriation cases is whether the benefit of a foreign investor's property has been "effectively neutralized":

> The essential question is therefore to establish whether the enjoyment of the property has been effectively neutralized. The standard that a number of tribunals have applied in recent cases where indirect expropriation has been contended is that of substantial deprivation. In the Metalclad case the tribunal held that this kind of expropriation relates to incidental interference with the use of property which has "the effect of depriving the owner, in whole or in significant part, of the use or reasonable-to-be expected economic benefit of property even if not necessarily to the obvious benefit of the host State." Similarly, the Iran - United States Claims Tribunal has held that deprivation must affect "fundamental rights of ownership," a criteria reaffirmed in the CME v. Czech Republic case. The test of interference with present uses and prevention of the realization of a reasonable return on investments has also been discussed by the Respondent in this context.
>
> Substantial deprivation was addressed in detail by the tribunal in the Pope & Talbot case. The Government of Argentina has convincingly argued that the list of issues to be taken into account for reaching a determination on substantial deprivation, as discussed in that case, is not present in the instant dispute. In fact, the Respondent has explained, the Claimant is in control of the investment; the Government does not manage the day-to-day

[375] *CME Czech Republic B.V. (The Netherlands) v. Czech Republic*, Partial Award, UNCITRAL, September 13, 2001 at para. 604.

> operations of the company; and the Claimant has full ownership and control of the investment.[376]

506. In considering the economic impact of a regulatory measure or measures for the purpose of determining a breach of an expropriation provision, the tribunal in *LG&E* underscored the importance of the duration of the measure or measures and the investor's reasonably held expectations with regard to the investment.[377] In regard to this latter criterion, the tribunal relied upon the decision in *Revere Copper & Brass Inc. v. OPIC*, in which the tribunal held that the government was bound by assurances intended to induce investment:

> We regard these principles as particularly applicable where the question is, as here, whether actions taken by a government contrary to and damaging to the economic interests of aliens are in conflict with undertakings and assurances given in good faith to such aliens as an inducement to their making the investments affected by the action.[378]

507. In *Tecmed*, the investor's "reasonably held expectations" were not only relevant to the tribunal's analysis but, ultimately, determinative of its finding that the investor's investment had been fully and irrevocably destroyed by the government measures in question :

> There is no doubt that, even if Cytrar did not have an indefinite permit but a permit renewable every year, the Claimant's expectation was that of a long–term investment relying on the recovery of its investment and the estimated return through the operation of the Landfill during its entire useful life.
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> […]

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[376] *CMS Gas Transmission Company v. Argentina*, ICSID Case No. ARB/01/8 Award, May 12, 2005 at paras. 262-263.

[377] *LG&E Energy Corp., LG&E Capital Corp., LG&E International Inc. v. Argentina*, ICSID Case No. ARB/02/1 Decision on Liability, October 3, 2006 at paras. 190 ("In evaluating the degree of the measure's interference with the Claimant's right of ownership, one must analyze the measure's economic impact — its interference with the Claimant's *reasonable expectations — and the measure's duration".)*

[378] *Revere Copper & Brass Inc. v. OPIC,* 17 ILM 1321 (1978) at p. 1331.

> In view of the above, it is clear the Cytrar would not have an operation level to reach a break-even point and obtain the expected rate of return in a short time. INE could not be unaware of this and of the need to act in line with such expectations to avoid rendering unfeasible any private investment of the scale required to confine hazardous waste in the United Mexican States under acceptable technical operating conditions. Both the authorization to operate as a landfill, dated May 1994, and the subsequent permits granted by INE, including the Permit, were based on the Environmental Impact Declaration of 1994, which projected a useful life of ten years for the Landfill. This shows that even before the Claimant made its investment, it was widely known that the Claimant expected its investments in the Landfill to last for a long term and that it took this into account to estimate the time and business required to recover such investment and obtain the expected return upon making its tender offer for the acquisition of the assets related to the Landfill. To evaluate if the actions attributable to the Respondent - as well as the Resolution - violate the Agreement, such expectations should be considered legitimate and should be evaluated in light of the Agreement and of international law.[379]
>
> [Emphasis added]

508. In considering whether an expropriation has occurred, a tribunal must therefore consider not only to the objective impact of the measure or measures in question on the economic benefit to the investor's investment, but also to the relative impact of the measure or measure on the investor's reasonably held expectations.

3. The Intent Behind a Measure is Irrelevant

509. Although the *Tecmed* tribunal recognized that regulatory measures may be both expropriatory yet non-compensable, it reasoned that this is only legitimate where the government's measures are proportional to the public interest being protected, and considering the relative impact on the investor. The tribunal held that, without evidence of a serious emergency, public hardship or wide-ranging consequences, the socio-political difficulties were not sufficient under either international law or the BIT to justify depriving a foreign investor of its investment:

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[379] *Tecnicas Medioambientales TecMed S.A. v. United Mexican States*, ICSID Case No. ARB(AF)/00/2, Award, May 29, 2003, at paras. 149-50.

> In this case, there are no similar or comparable circumstances of emergency, no serious social situation, nor any urgency related to such situations, in addition to the fact that the Mexican courts have not identified any crisis. The actions undertaken by the authorities to face these socio–political difficulties, where these difficulties do not have serious emergency or public hardship connotations, or wide–ranging and serious consequences, may not be considered from the standpoint of the Agreement or international law to be sufficient justification to deprive the foreign Claimant of its investment with no compensation, particularly if it has not been proved that Cytrar or Tecmed's behavior has been the determinant of the political pressure or the demonstrations that led to such deprivation, which underlie the Resolution and conclusively conditioned it.
>
> […]
>
> While the Resolution is based on some of these violations to deny the renewal of the Permit, apparently through a literal and strict interpretation of the conditions under which the Permit was granted, it would be excessively formalistic, in light of the above considerations, the Agreement and international law, to understand that the Resolution is proportional to such violations when such infringements do not pose a present or imminent risk to the ecological balance or to people's health, and the Resolution, without providing for the payment of compensation as required by Article 5 of the Agreement, leads to the neutralization of the investment's economic and business value and the Claimant's return on investment and profitability expectations upon making the investment.[380]

510. To the extent government intention is taken into account, it is secondary to the actual effect of the measure on the investor in an expropriation analysis. In the *Tippetts* case, for example, the Iran-U.S. Claims tribunal placed little significance on the intention of the government:

> The intent of the government is less important than the effects of the measures on the owner, and the form of the measures of control or interference is less important than the reality of their impact.[381]

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[380] *Ibid*., at paras. 147 and 149.

[381] *Tippetts, Abbett, McCarthy, Stratton v. TAMS-AFFA Consulting Engineers of Iran*, 6 Iran-U.S. CTR 219 Award of June 1984 at p. 225-226.

511. This passage was cited with approval by the Iran-U.S. Claims Tribunal in *Phillips Petroleum v. Iran*. In this case, Phillips Petroleum brought a claim against the government of Iran for essentially repudiating an agreement between the National Iranian Oil Company and the Consortium to which Phillips Petroleum was a party. The repudiation eliminated Phillips Petroleum's right to lift oil independently, and to produce at rates agreed upon prior to the revolution. With respect to the relationship between government motivation and expropriation, the tribunal stated:

> […] Therefore, the Tribunal need not determine the intent of the Government of Iran; however, where the effects of actions are consistent with a policy to nationalize a whole industry and to that end expropriate particular alien property interests, and are not merely the incidental consequences of an action or policy designed for an unrelated purpose, the conclusion that a taking has occurred is all the more evident.
>
> Although a government's liability to compensate for expropriation of alien property does not depend on proof that the expropriation was intentional, there seems little doubt in this Case that the new Islamic Republic intended to bring the JSA to an end and to place NIOC fully in charge of all oil production and sales…[…][382]

512. A similar approach was taken by the tribunal in *Biloune v. Ghana Investment Centre*, where several discreet actions by the government effectively caused the Claimant to discontinue his project. Although the government claimed that it had not intended to affect the investment, the tribunal commented as follows:

> The motivations for the actions and omissions of Ghanaian governmental authorities are not clear. But the Tribunal need not establish those motivations to come to a conclusion in the case. What is clear is that the conjunction of the stop work order, the demolition, the summons, the arrest, the detention, the requirement of filing assets declaration forms, and the deportation of Mr. Biloune without possibility of re-entry had the effect of causing the irreparable cessation of work on the project. Given the central role of Mr Biloune in promoting, financing and managing MDCL, his expulsion from the country effectively prevented MDCL from further pursuing the project. In the view of the Tribunal, such

[382] *Phillips Petroleum v. Iran*, 21, Iran-U.S. CTR 79, Award of June 29, 1989, at paras. 97-98.

> prevention of MDCL from pursuing its approved project would constitute constructive expropriation of MDCL's contractual rights in the project and, accordingly, the expropriation of the value of Mr Biloune's interest in MDCL, unless the Respondents can establish by persuasive evidence sufficient justification for these events.[383]

513. The case of *Vivendi Universal SA v. Argentina* further supports the proposition that it is the effect of a measure, not the government's intent, which is the critical factor in an expropriation analysis. In this case, the dispute arose out of a concession agreement between Vivendi and the authorities of the province of Tucuman for the privatization of water and sewage services. Vivendi claimed that the provincial authorities breached the concession agreement by unilaterally modifying tariffs, using the media to generate public hostility, and using their regulatory power to require re-negotiation of the Concession Agreement. The tribunal rejected Argentina's argument that state action must be presumed to be legitimate, absent bad faith:

> Turning to Respondent's proposition that an act of state must be presumed to be regulatory, absent proof of bad faith, this is incorrect. There is extensive authority for the proposition that the state's intent, or its subjective motives are at most a secondary consideration. While intent will weigh in favour of showing a measure to be expropriatory, it is not a requirement, because the effect of the measure on the Claimant, not the state's intent, is the critical factor. As Professor Christie explained in his famous article in the British Yearbook of International Law more than 40 years ago, a state may expropriate property where it interferes with it even though the state expressly disclaims such intention. Indeed international tribunals, jurists and scholars have consistently appreciated that states may accomplish expropriations in ways other than by formal decree; often in ways that may seek to cloak expropriative conduct with a veneer of legitimacy.[384]

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[383] *Biloune v. Ghana Investment Centre*, Awards of October 27, 1989 and June 30, 1990, at para. 26, in A.J. vanden Berg (ed.), Yrbk. Comm. Arb. Vol. XIX (1994), pp. 11-32.

[384] *Compania de Aguas del Aconquija SA and Vivendi Universal SA v. Argentina*, ICSID Case. No. ARB/97/3 Award, August 20, 2007 at para. 7.5.20.

514. In *Azurix*, a case also involving operation of a water and sewerage concession in Argentina, the tribunal stated that the real question is quite simply whether a government's actions should give rise to compensation:

> For the Tribunal, the issue is not so much whether the measure concerned is legitimate and serves a public purpose, but whether it is a measure that, being legitimate and serving a public purpose, should give rise to a compensation claim. In the exercise of their public policy function, governments take all sorts of measures that may affect the economic value of investments without such measures giving rise to a need to compensate. The tribunal in S.D. Myers found the purpose of a regulatory measure a helpful criterion to distinguish measures for which a State would not be liable: "Parties [to the Bilateral Treaty] are not liable for economic injury that is the consequence of bona fide regulation within the accepted police powers of the State." This Tribunal finds the criterion insufficient and shares the concern expressed by Judge R. Higgins, who questioned whether the difference between expropriation and regulation based on public purpose was intellectually viable:
>
> > "Is not the State in both cases (that is, either by a taking for a public purpose, or by regulating) purporting to act in the common good? And in each case has the owner of the property not suffered loss? Under international law standards, a regulation that amounted (by virtue of its scope and effect) to a taking, would need to be 'for a public purpose' (in the sense of in general, rather than for a private interest). And just compensation would be due. At the same time, interferences with property for economic and financial regulatory purposes are tolerated to a significant extent.[385]

515. Thus, the *Azurix* tribunal preferred the proportionality approach in *TecMed*, finding it to provide "useful guidance for purposes of determining whether regulatory actions would be expropriatory and give rise to compensation.[386]

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[385] *Azurix Corp. v. Argentina*, ICSID Case No. ARB/01/12Award, July 14, 2006 at para. 310. The quote from Justice Higgins is attributed to "The Taking of Property by the State: Recent Developments in International Law", *Recueil des Cours*, vol. III (1982), p. 331.

[386] *Ibid*., at para. 312.

4. Expropriated Property May be Tangible or Intangible

516. NAFTA tribunals have also recognized market share as a property interest that can be wrongfully expropriated. In *S.D. Myers*, the tribunal recognized that market share constitutes an investment for the purpose of a NAFTA claim:

> The tribunal recognizes that there are a number of other bases on which SDMI could contend that it has standing to maintain its claim including that […] its market share in Canada constituted an investment.[387]

517. NAFTA tribunals have similarly considered market access as a property interest that may be subject to illegal expropriation:

> [T]he Tribunal concludes that the Investment's access to the U.S. market is a property interest subject to protection under Article 1110.
>
> [...]
>
> While Canada suggests that the ability to sell softwood lumber from British Columbia to the U.S. is an abstraction, it is, in fact, a very important part of the business of the Investment. Interference with that business would necessarily have an adverse effect on the property that the Claimant has acquired in Canada, which, of course, constitutes the Investment […] The Tribunal concludes that the Claimant properly asserts that Canada has taken measures affecting its investment, as that term is defined in Article 1139 and used in Article 1110.[388]

C. Canada's Breaches of Article 1110

518. The measures taken by the PMRA to suspend the registrations of Crompton's Lindane Products constitute expropriation or measures tantamount to expropriation. Crompton's Lindane Products business represented a significant proportion of its investment, including its market share, in Canada.

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[387] *S.D. Myers Inc.* v *Canada*, NAFTA (UNCITRAL) Partial Award, November 13, 2000 at para. 232.

[388] *Pope & Talbot*, NAFTA (UNCITRAL), Interim Award June 26, 2000, at paras. 96, 98. See also *Methanex Corp. v United States*, NAFTA (UNCITRAL), Final Award, August 3, 2005, Part IV, ch. D, para.17.

1. Suspension of Crompton's Lindane Product Registrations Constituted Expropriation or Measures Tantamount to Expropriation

519. The Investor and its Canadian investment sustained significant damages directly by reason of the PMRA's measures. Those measures have substantially deprived and continue to substantially deprive the Investor of customers, revenue, goodwill and market share.

520. The measures taken by the PMRA to coerce a "voluntary" withdrawal by the Investor from its Lindane Products business, even without their discriminatory aspects (as will be set out below), and the PMRA's breaches of its agreement to permit the marketing of existing stocks after the July 1, 2001 deadline for sales to end, constituted expropriation of recognized and protected investments of the Investor in Canada. The measures clearly interfered with the substantial proportion of the Investor's business in Canada. Indeed, the Investor was substantially deprived of its lindane products for canola investment as of July 1, 2001 and of its entire lindane products seed treatment business in Canada as of February 21, 2002.

2. The Measures Were Not Taken for a Public Purpose Contrary to Article 1110(1)(a)

521. Article 1110 prohibits expropriation, or measures tantamount to expropriation except, among other requirements, if taken for a "public purpose". In requiring Crompton Canada to remove its Lindane Products from the Canadian market for their chief purpose, and suspending Crompton Canada s registrations and thus its legal authorization to sell the products in Canada for their chief purpose, the PMRA had no new, pertinent or reasonable scientific rationale. The only ostensibly science-based "reason" for requiring the termination of Crompton Canada's lindane business in Canada was a study carried out ten (10) years earlier and did not reflect current practice in the seed treatment industry to protect workers. The PMRA knew the study was obsolete and should have requested a new one. Helix was approved based on a current study and would not have been registered if the old study was used**.**

522. Under section 20 of the Act, the Minister may only cancel or suspend a controlled product where, based on "current information", the "safety of the control product or its merit or value for its intended purposes is no longer acceptable." To cancel or suspend a product registration on any other basis was and is an unlawful excess of jurisdiction.

523. In fact, the actual basis propelling the PMRA to implement the measures was to protect the U.S. market share of Canadian canola growers from possible adverse trade action against growers' exports to the U.S. The protection from foreign threats of the property interests in exports of one class of Canadian producers is not a valid "public purpose" as that term has been defined in the NAFTA or customary international law.

524. Thus, the effect of the PMRA's measures was to forestall a possible threat to one group of producers in Canada (canola growers and exporters) by sacrificing, through expropriation or measures tantamount to expropriation, the substantial part of the Investor's investment in its lindane business.

525. Furthermore, the PMRA's subsequent deregistration of all of Crompton Canada's Lindane Product registrations in February 2002 is tainted by the original improper purpose motivating the PMRA's negotiation of the Conditional Withdrawal Agreement and conduct of the Special Review process and the Occupational Exposure Assessment. The deficiencies in the Special Review process and the Assessment, and in particular the PMRA's failure to accord the Investor due process or abide by fundamental principles of fairness, further demonstrates that the Assessment, which purportedly formed the basis for deregistration of the remainder of the Investor's lindane registrations, was not carried out for a "public purpose".

526. Accordingly, the first requirement for legal expropriation was not met.

3. Expropriation of the Crompton Canada's Lindane Products Business Violated Due Process and Constituted a Breach of International Law

527. Article 1110(1)(c) requires that expropriation, or measures tantamount thereto, be carried out in accordance with due process of law and Article 1105(1). This provision in turn states:

> Each Party shall accord to investments of Claimants of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security.[389]

528. Thus, the PMRA's measures are subject to scrutiny under international law standards of due process and denial of justice, and NAFTA Article 1110(1) is breached where investors are denied fair and equitable treatment. The Investor was denied fair and equitable treatment in the insertion by the PMRA of the additional restriction that all distribution and use of its lindane products (as well as their sale), had to end on July 1, 2001, contrary to its "voluntary" withdrawal agreement.

529. The Investor was also denied fair and equitable treatment in the PMRA's breach of its Agreement with Crompton Canada to conduct a scientific assessment of lindane by the end of 2000, yet holding the Investor to its voluntary undertakings that were made in reliance on the PMRA's undertakings concerning the assessment.

530. The Investor was further denied fair and equitable treatment when the PMRA arbitrarily suspended its lindane product registrations on February 11, 2002 and February 21, 2002 for all of Crompton Canada's Lindane Product uses, on the basis of a highly-flawed occupational exposure study and the highly-flawed process culminating in that study. Accordingly, for these reasons and those further articulated in Section IV. above, the expropriation or measures tantamount to expropriation were contrary to NAFTA Article 1110 on the basis that they constituted a denial of due process and a breach of Article 1105(1).

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[389] NAFTA, Articles 1110(1)(c), 1105(1).

4. No Compensation Was Paid to the Investor in Respect of the Expropriation or Measures Tantamount to Expropriation

531. No funding, payment or compensation was paid by Canada or any of its departments, agencies or corporations at any time in connection with the termination of the Investor's lindane business in Canada.

532. Canada has met none of the cognitive requirements to carryout a lawful expropriation under Article 1110. Accordingly, Canada has breached its NAFTA-Article 1110 obligations to the Investors, causing loss or injury for which the Investor is entitled compensation.

VII. DAMAGES, INTEREST AND COSTS

A. Overview

533. Canada's violations of Articles 1103, 1105 and/or 1110 have injured the Investor by destroying the full value of its lindane seed treatment business in Canada. The Investor is therefore entitled to full compensation under NAFTA for the losses it has sustained by reason of those breaches.

B. The Measure of Compensation for Breach of NAFTA

1. Remedies Available under NAFTA

534. Article 1135 of the NAFTA limits the kinds of awards that a tribunal may issue to remedy a breach of a substantive obligation. Specifically, Article 1135 provides as follows:

> 1. Where a Tribunal makes a final award against a Party, the Tribunal may award, separately or in combination, only:
>
> (a) monetary damages and any applicable interest;
>
> (b) restitution of property, in which case the award shall provide that the disputing Party may pay monetary damages and any applicable interest in lieu of restitution.

> A tribunal may also award costs in accordance with the applicable arbitration rules.
>
> 2. Subject to paragraph 1, where a claim is made under Article 1117(1):
>
> > (a) an award of restitution of property shall provide that restitution be made to the enterprise;
> >
> > (b) an award of monetary damages and any applicable interest shall provide that the sum be paid to the enterprise; and
> >
> > (c) the award shall provide that it is made without prejudice to any right that any person may have in the relief under applicable domestic law.
>
> 3. A Tribunal may not order a Party to pay punitive damages.

535. Notwithstanding the above provision, the NAFTA does not provide a complete guide to a tribunal for assessing compensation for an investor that has suffered loss or harm arising from a breach of a Chapter 11 obligation. Only the expropriation provisions in Article 1110 set out how compensation is to be calculated in the event of a breach of that obligation. Breaches of other Chapter 11 obligations require that recourse be had to standards of compensation established under international law.

2. Measure of Compensation for Canada's Breach of Article 1110

536. Article 1110(2) through (6) set forth the principles in accordance with which compensation must be paid in situations where an expropriation has occurred. These paragraphs require the following:

- Compensation shall be "equivalent to the fair market value of the expropriated investment immediately before the expropriation took place";
- Compensation shall be paid without delay and shall be fully realizable;
- Compensation shall include interest "at a commercially reasonable rate" for the G7 currency in which it is paid, from the date of expropriation until the date of actual payment; and
- Compensation shall be freely transferable.

537. Article 1110 reflects the measure of compensation most commonly ordered at international law.[390] "Fair market value" was defined by the Iran-U.S. Claims Tribunal in *Starrett Housing* as:

> The price that a willing buyer would pay to a willing seller in circumstances in which each had good information, each desired to maximize his financial gain, and neither was under duress or threat.[391]

538. Similarly, in *INA Corporation v. Iran*, the tribunal stated that "[f]air market value may be stated as the amount which a willing buyer would have paid a willing seller for the shares of a going concern".[392]

539. The fair market value of expropriated property may include both tangible and intangible property. Through the expropriation, an investor is deemed to be selling its right to all economic benefits attached to the expropriated property. Where the property is a going concern as at the date of expropriation, the economic benefits expropriated are appropriately measured as the cash flow that would have been received by the investor but for the expropriation, less any economic benefits received from the expropriated property subsequent to the expropriation.

540. In the present circumstances, the Investor has not received any economic benefits from the property subsequent to the expropriation, *i.e.* it has received no compensation from Canada, nor has it been able to meaningfully mitigate its losses. The Investor's valuation of its damages is further set forth below.

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[390] See *Amoco International Finance Corporation v. The Islamic Republic of Iran*, 15 Iran-U.S. C.T.R. 189 at p. 255 ("Market value, apparently, is the most commendable standard, since it is also most objective and the most easily ascertainable when a market exists for identical or similar assets.").

[391] *Starrett Housing Corporation v. The Islamic Republic of Iran,* 16 Iran-U.S. C.T.R. 112 at para. 18 (Award of August 14, 1987).

[392] *INA Corporation v. Iran*, 8 Iran-U.S. C.T.R. 373, (August 13, 1985), at p. 380.

3. Measure of Compensation for Canada's Breaches of Articles 1103 and 1105

541. The Investor is entitled to compensation for the injury and loss resulting from Canada's failure to accord its lindane business treatment no less favourable than the treatment accorded to investors of other States and/or to uphold the minimum standard of treatment guaranteed by Article 1105, irrespective of any finding of expropriation. The ultimate injury to the Investor of these violations is the same - the total loss of its lindane seed treatment business in Canada.

542. In the absence of specific textual guidance as to the measure of compensation applicable to non-expropriatory breaches of the NAFTA or case law on this point, the tribunal may have recourse to international law for assistance in determining the applicable standard of compensation.

543. The standard of compensation under customary international law requires that a party be compensated for its entire loss flowing from a breach of an international legal obligation. In *Chorzow Factory*, the Permanent Court of International Justice stated that any award must make the Claimant whole as if it had suffered no loss:

> The essential principle contained in the actual notion of an illegal act […] is that reparation must, as far as possible, wipe-out all the consequences of the illegal act and re-establish the situation which would, in all probability, have existed if that act had not been committed. Restitution in kind, or, if this is not possible, payment of a sum corresponding to the value which a restitution in kind would bear; the award, if need be, of damages for loss sustained which would not be covered by restitution in kind or payment in place of it – such are the principles which should serve to determine the amount of compensation for an act contrary to international law.[393]

544. The International Law Commission's Draft Articles on State Responsibility further set forth the basic principles of reparation for unlawful conduct of a State, whether expropriation or otherwise. Article 31 thus provides as follows:

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[393] *Chorzow Factory (Germany v. Poland)*, (1928), 17 P.C.I.J., Ser. A No. 17, 3 at 29 ("*Chorzow Factory*").

> 1. The responsible State is under an obligation to make full reparation for the injury caused by the internationally wrongful act.
>
> 2. Injury includes any damage, whether material or moral, caused by the internationally wrongful act of a State.[394]

545. The NAFTA sets out a *lex specialis* upon which the lawfulness of a government measure can be assessed. If a measure is found to violate a NAFTA obligation, then it constitutes an unlawful act and, consistent with the principle set out in *Chorzow Factory* and the Draft Articles, full reparation must be made, i.e. payment of compensation in an amount that will wipe out the consequences of the illegal measure.

546. In *Metalclad*, the tribunal determined that the same standard of compensation applicable to breach of Article 1110 should apply to breach of Article 1105 because both breaches involved the complete loss of the investment:

> In this instance, the damages arising under NAFTA, Article 1105 and the compensation due under NAFTA, Article 1110 would be the same since both situations involve the complete frustration of the operation of the landfill and negate the possibility of any meaningful return on Metalcald's investment. In other words, Metalclad has completely lost its investment.[395]

547. In *CMS Gas Transmission*, the tribunal found a violation of the fair and equitable treatment standard of the U.S.-Argentina BIT which, like NAFTA, did not specify a measure of damages for breach of this obligation. Upon canvassing relevant authorities, the tribunal concluded that compensation should be based on the property's "fair market value", quoting from the following definition:

> The price expressed in terms of cash equivalents, at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arm's length in an open and unrestricted market, when neither is

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[394] Draft Articles on Responsibility of States for Internationally Wrongful Acts, adopted by the International Law Commission at its 53rd Session (November 2001).

[395] *Metalclad v. Mexico*, ICSID Case No. ARB(AF)/97/1, Award, August 30, 2000, at para. 13.

> under compulsion to buy and sell and when both have reasonable knowledge of relevant facts.[396]

548. This is effectively the same standard as that codified in Article 1110 and should apply equally to Canada's breaches of Articles 1103 and 1105.

C. Valuation of Damages

549. For the actual valuation of the Investor's damages, the Investor submits the expert opinion of Messrs. Manuel A. Abdala, Pablo Spiller and Andres Chambouleyron of LECG, LLC (the "Experts"). In their report, which accompanies this Memorial, the Experts provide an assessment of damages arising from Canada's breaches of its obligations under the NAFTA based on the standard of compensation applicable to this case (the "LECG Report"). The Experts estimate that the Investor is entitled to at least U.S. $80.2 million.

1. Fair Market Value of Investor's Investments

(a) Valuation Methods

550. The Experts have selected the discounted cash flow (the "DCF") method to compute the fair market valuation of the Investor's investments. The DCF method values assets by the stream of cash flow they generate into the future. The Experts also considered the following alternative methods:

- The Stock Market Valuation method, which uses the value of a company's stock to measure the company's equity value; and
- The Book Value Method, which uses the book value of the company before and after a particular event to assess the impact of that event.

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[396] *CMS Gas Transmission Company v. Argentine Republic,* ICSID Case No. ARB/01/8, Award, May 12, 2005, at para. 402, citing the International Glossary of Business Valuation Terms, American Society of Appraisers. See also *BG Group Plc. v. Argentina*, UNCITRAL, Final Award, December 24, 2007 at paras. 419-429.

551. The Experts rejected both the Stock Market Valuation method and the Book Value method as inappropriate to the circumstances of this case. With regard to the Stock Market Valuation method, the Experts stated as follows:

> Even though Chemtura had a publicly traded stock by the time Canada took the measures, and still does today, the quotation of this stock reflects Investor's expectations at each moment of how Chemtura's overall value will evolve over time. Given that Chemtura is a corporation with various businesses in several countries, it would be literally impossible to disentangle the impact of Canada's measures on the value of the specific lindane business line from the impact of any macroeconomic, regulatory or market condition changes taking place in any of the countries Chemtura has a business in.
>
> In sum and even though the stock market valuation is a valid tool for assessing damages to corporations with liquidly traded stocks as Chemtura's, it is not the appropriate tool for the case at hand, as it does not allow us to separate and identify value or changes in value in the relevant business segment.[397]
>
> [Footnotes omitted]

552. Similarly, the Experts rejected the Book Value approach for the following reasons:

> […] This approach has the advantage of being objective, based on accounting principles and proven figures. Book valuations might not be accurate if, for example, there are intangible assets not being registered in the books. In that situation, the book value would be recorded at a lower value than appropriate. The BV approach has the disadvantage that the value of the assets in the books may, at a given point in time, not adequately reflect the fair market valuation given by the expected stream of future cash flows that the asset may generate.
>
> There are various reasons why the BV approach is inapplicable to the case at hand. First, given that prior to the measures Crompton's lindane products represented a small share of its overall business, movements in the overall value of the firm around the date of measures are the result not just of the measures, but also of other unrelated business shocks. Second, because the BV approach is not forward looking as it fails to capture the increase in production, and thus in profits, that Crompton would

[397] LECG Report, paras. 54-55.

> have experienced in the absence of the measures, given the variations that took place in both canola and other cereals' planted acreage. Third, since prior to the measures Crompton's main economic asset was an intangible – its registration of lindane products - for the BV approach to be of use, the economic value of these registrations should have been included as an intangible. Crompton's financial statements, however, included no intangibles. Thus, elimination of the registrations could not imply a write-off as the value of that intangible was never included in the company's books.
>
> In sum and even though the BV method could be a useful reference for valuation, it is not an appropriate tool for the case at hand, as it does not allow us to properly identify changes in value in the relevant business segment.[398]
>
> [Footnotes omitted]

553. The Experts therefore explain their choice of the DCF method as follows:

> The Discounted Cash Flow Model (DCF) method is the main tool used internationally to value companies and it is well suited to calculate damages in companies with a history of profitability as it reflects a company's ability to generate cash flows in the future. Crompton's lindane canola business was, until 2001, a well-established line of business, with a solid history of profitability and with a very stable and predictable market demand.
>
> For the case at hand, the DCF approach has an intrinsic advantage over other methods for the case at hand in that it allows separation of decreases in profits because of Canada's measures from others due to specific business or market conditions, such as changes in demand for the relevant crops, reductions in seeded acreages, or any other factors that are unrelated to the measures complained of.
>
> For the case at hand, the DCF method measures the value of a business by adding the stream of free cash flows that the company expects this business to generate in the future, discounted at a rate that reflects the company's cost of raising capital. The term "free" cash flow means a flow of cash that is generated by the company, and that is available to be distributed between the two groups of stakeholders that put capital at risk in the company, shareholders and lenders. The free cash flow in any given year is the residual cash earned by the company after meeting all its operating and

[398] LECG Report, paras. 56-58.

> investment expenses and taxes, but prior to debt and other financial payments.
>
> Since prior to the measures, Crompton's lindane product net sales represented around 17.6% of its overall Canadian business, rather than assessing the impact of the measures on Crompton as a whole, we focus on the impact of the measures on Crompton's lindane seed treatment business for both canola and non-canola uses. In this respect, revenues, variable costs and incremental income taxes attributed to the lindane business would have been different had Canada not implemented the measures.[399]
>
> [Footnotes omitted.]

554. Under the DCF approach, damages are measured as the difference in present value of simplified cash flows under a scenario free of Canada's measures (the "But For" scenario) and the same stream of profits under a scenario with Canada's measures (the "Actual" scenario). The Experts explain their methodology as follows:

> We define the scenario under Canada's measure as the Actual scenario. In this scenario, Crompton's lindane seed treatment business for canola has basically disappeared by July 1st, 2001 and for non-canola in February 2002. In turn, Gustafson Partnership's sales of lindane products for canola have been, to a lesser extent, replaced with sales of non-lindane products such as Gaucho CS and Prosper.
>
> We define the But-For scenario as the one in which PMRA completes its review on lindane by late 2000, reinstates canola on the labels of Crompton's lindane for canola products and does not force the de-registration of all its other non-canola lindane products. In addition, and partially as a consequence of PMRA's But-For actions, Chemtura obtains tolerance limits for lindane on canola in the U.S. by early 2003 and a full registration during 2007.
>
> To develop the But-For scenario we follow specific instructions provided by Counsel to Claimant concerning the evolution of the regulatory environment affecting lindane for products in the U.S. In particular, we have been instructed as to the following (see Exhibit 4):

[399] LECG Report, paras. 59-62.

a) Absent Canada's measures, the PMRA would have completed its scientific review by late 2000 and Crompton could have thereafter exercised the option to reintroduce lindane products in the Canadian market.

b) Absent Canada's measures, Chemtura would have not voluntarily discontinued its efforts to pursue registration for indane products for canola use in the U.S. Chemtura did not pursue its application for registration and tolerance of lindane for canola and reregistration of other lindane uses in the U.S. because of PMRA's decision to terminate lindane use on canola seed altogether in early 2001 and on all other crops in 2002. In the absence of Canada's measures, Chemtura would have successfully obtained a tolerance for lindane for canola products from the U.S. EPA by early 2003 and a full registration or continued tolerance by 2007. This, in turn, would have allowed Crompton to resume sales of lindane products to Canadian canola growers in time for the 2003 seeding season.

c) PMRA's completion of a fair and unbiased review of lindane by late 2000 would have also allowed Crompton to continue its manufacturing and sale of lindane products for non-canola crops in 2002 as these crops involved no trade dispute with the U.S.

d) EPA's July 2006 Addendum to its 2002 Re-Registration Eligibility Decision followed a voluntary withdrawal from the U.S. registration process by lindane product registrants. Chemtura's withdrawal was occasioned by the termination of the lindane market in Canada and the relative cost of continuing to comply with information requests within the registration process. But for this termination, Chemtura would have pursued registration and/or tolerance, which should have resulted in the issuance of lindane product registrations or lindane tolerances in 2007.

e) Damages to Chemtura should be assessed until the end of 2022. This date is determined by EPA's typical reregistration cycle of 15 years after the anticipated registration date and/or issuance of tolerance date of 2007.

Thus, given these instructions, and our discussion in Secton III.2.3 above, we assume that even though Canada's measures start in late 2000, damages to Claimant started to materialize by the end of February 2002 from Crompton's non-canola lindane business and in January 2003 for Crompton's canola lindane business.

Given the (almost) two-year interval between the ban and the reinstatement of canola in the labels of Crompton's lindane

> products, canola growers would have temporarily and partially abandoned their purchases of lindane products for the 2001 and 2002 seeding seasons in favour of lindane replacements. We also assume that, given the historically proven competitive advantage of lindane products for canola use, canola growers would have switched back to pre 2001 use levels of lindane products once the U.S. EPA had granted Chemtura a registration and/or a conditional tolerance in early 2003.[400]
>
> [Footnotes omitted.]

(b) The DCF Method is Supported in International Law

555. The NAFTA provides no guidance as to methodology to be used in valuing damages owed to an investor under Chapter 11. The Experts' choice of the DCF method to value the Investor's investment is, however, supported in international investment dispute practice. Following the rulings of the Iran-U.S. Claims Tribunal,[401] both ICSID[402] and NAFTA tribunals have generally recognized that, where the expropriated assets are a going concern or rights in a going concern, the DCF method is the appropriate method of valuation.

556. In an article on the valuation of damages in ICSID cases, Paul Friedland and Eleanor Wong provide a helpful description of the DCF method:

> The DCF method values an income-producing asset by estimating the cash flow which the asset would be expected to generate over the course of its life, and then discounting that cash flow by a factor which reflects the time value of money and the risk associated with such cash flow. It involves first calculating the cash receipts expected in each future year, then subtracting that year's expected cash expenditure. The result is the net cash flow for the year. Because cash to be received in the future is worth less

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[400] LECG Report, paras. 67-81.

[401] See *Phillips Petroleum v. The Islamic Republic of Iran*, 21 Iran-U.S. C.T.R. 79, June 29, 1989, at para. 112. See also *Amoco International Finance Corporation v. The Islamic Republic of Iran*, 15 Iran-U.S. C.T.R. 189 (Concurring Opinion), 14 July 1987; *Starrett Housing Corporation and the Government of the Islamic Republic of Iran*, 16 Iran-U.S. C.T.R. 112, Award 14 August 1987.

[402] Paul D. Friedland and Eleanor Wong, "Measuring Damages for the Deprivation of Income-Producing Assets: ICSID Case Studies" (1991) *ICSID Review* 400 at p. 426.

> than the same amount of cash received today, the net cash flow for each future year is then discounted to determine its value on the valuation date, which is usually referred to as its "present value" as of that date. This discounting is accomplished through the application of a discount rate which reflects the time value of money, expected inflation and any risk attached to the cash flows. The discount rate is usually measured by examining the rate of return available in the market on alternative investments having risk comparable to that of the asset or enterprise being valued. The sum of the present values of the net cash flows for each of the future year is the value of the asset or enterprise as determined by the DCF method.[403]

557. Following a review of ICSID case law, the same authors observed that the DCF method is consistent with the conservative judicial approach to valuation:

> Because of this conservative approach, the DCF Method as applied by an adjudicative tribunal may yield different results than those arrived at by a risk-taking Claimant using the very same method. Judicial conservatism, as demonstrated in the above-practice, refutes the arguments of those who oppose the DCF Method on the grounds that it yields speculatively inflated awards or that it leads to a 'risk-taking' assessment of an asset's value incompatible with the judicial function. Furthermore, once one accepts that the value of an asset lies in its ability to generate cash in the future, it becomes evident that any valuation contains inherent elements of uncertainty and the DCF Method has the advantage that it confronts such uncertainty directly.[404]

558. NAFTA tribunals have also considered the proper basis for valuing an investor's losses under the NAFTA, similarly concluding that the DCF method is appropriate where the asset being valued is a going-concern. In *Metalclad*, the tribunal awarded damages for breach of fair and equitable treatment and expropriation as a result of the government of Mexico's interference with the development and operation of the investor's hazardous waste landfill. Although the tribunal ultimately measured damages on the basis of the investor's actual investment because the landfill was never operative, it observed that:

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[403] *Ibid.*, at p. 407.

[404] *Ibid*., at p. 430.

> [n]ormally, the fair market value of a going concern which has a history of profitable operation may be based on an estimate of future profits subject to a discounted cash flow analysis.[405]

559. The DCF valuation approach is also consistent with the *World Bank Guidelines on the Treatment of Foreign Direct Investment* (1992). The World Bank Guidelines define DCF value as follows:

> The cash receipts realistically expected on the enterprise in each future year of its economic life as reasonably projected minus the year's expected cash expenditure, after discounting this net cash flow for each year by a factor which reflects the time value of money, expected inflation, and the risk associated with such cash flow under realistic circumstances. Such discount rate may be measured by examining the rate of return available in the same market on alternative investments of comparable risk on the basis of their present value; [...][406]

560. The *World Bank Guidelines* reflect generally accepted international standards for the promotion of foreign direct investment, an objective clearly contemplated in Article 102 of the NAFTA.

2. Quantum

561. Using the DCF method, the Experts have calculated that the fair market value of damage to the Investor for both canola and non-canola from Crompton is U.S. $[***] and the fair market value of damage from Gustafson is U.S. $[***]. Thus, the total damage to the Investor is U.S. $80.2 million.[407] This damage calculation is further explained by the Experts as follows:

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[405] *Metalclad v. Mexico*, ICSID Case No. ARB(AF)/99/1 Award, August 30, 2000 at para. 119. See also *Feldman v. Mexico*, ICSID Case No. ARB(AF)/99/1, December 16, 2002 at 82, n. 41 (The tribunal stated in *obiter* that the DCF method is inappropriate where there is no evidence the expropriated asset could not be considered a going concern. Implicit in this statement is an acknowledgement that where the asset in question was a going concern prior to expropriation, the DCF method is an appropriate method for valuing the asset.).

[406] Available at http://ita.law.uvic.ca/documents/WorldBank.pdf.

[407] LECG Report, para. 71.

> Using a simplified DCF approach, we have computed damages to Chemtura from Crompton's canola business for the 2001-2022 period and from their non-canola business for the 2002-2022 period and have expressed damages at the June 30, 2008 valuation date.
>
> We have also computed damages to Chemtura from its stake in Gustafson Partnership. We compute damages to Gustafson Partnership for a more limited time period, 2001-2008. This is because by 2008 Gustafson Partnership's sales of lindane replacements in the Actual scenario generate profits similar to its But-For profits from sales of lindane products, and thus damages to Gustafson Partnership converge to zero towards 2008. This is because although Gustafson Partnership's market share of the canola seed treatment market is substantially higher in the But-For than in the Actual scenario, its But-For canola products are substantially less expensive than its lindane replacement products. As a consequence, Gustafson Partnership obtains per unit of sale higher profits in the Actual than in the But-For scenario, and by 2008 a higher per unit profit in the Actual scenario compensates for its lower market share.[408]

562. The Experts further provide several alternative damage calculations to illustrate how their damage assessment might change when the value of certain assumptions is modified.

Alternative #1

563. In the first alternative scenario, the Experts adjust the weighted average cost of capital ("WACC") by 1.5%, thereby increasing and decreasing the implicit risk on future simplified cash flows. The result in this scenario is a range of damage to the Investor from Crompton for canola of U.S. **$[***]** and from Gustafson for canola of U.S. **$[***]**.[409]

Alternative #2

564. In the second alternative scenario, damages for Crompton and Gustafson's canola business are estimated considering an annual decline in market share of 0%, 2.5% (base case) and 5% from 2009 onwards, taking as a starting point Crompton's 1991-2000

[408] LECG Report, paras. 75-76.

[409] LECG Report, para. 79.

average market share of **[***]**%. It is noted that when market share is kept constant at **[***]**%, damages increase by **[***]**%, while damages decrease by **[***]**% when market share is reduced annually by 5%.[410] On this scenario, the Experts calculate that the fair market value of damage to the Investor from Crompton ranges between U.S. $**[***]** and the fair market value of damage from Gustafson is U.S. $**[***]**.[411]

Alternative #3

565. Finally, in the third alternative scenario, damages are estimated using three different projections of canola production growth: (1) Canola Council's 2006 projections of canola production for 2007-2015; (2) the base case which follows the historical (1998-2008) linear trend; and (3) the lower bound that subtracts from the base case the same difference between this one and the Canola Council projection.[412] Each projection is linearly extended to 2022. On this scenario, the Experts calculate that the fair market value of damage to the Investor from Crompton is a range of US. $**[***]** and from Gustafson is US $**[***]**.

566. Thus, the potential range of damage for which the Investor is entitled compensation is illustrated below:

DAMAGE FROM CROMPTON	**BASE CASE (US.$) (2001-2022) (canola & non-canola)**	**ALTERNATIVE SCENARIO #1 (U.S.$) (2001-2022) (canola only)**	**ALTERNATIVE SCENARIO #2 (U.S.$) (2001-2022) (canola only)**	**ALTERNATIVE SCENARIO #3 (U.S.$) (2002-2022) (canola only)**
($Million US$ as of June 30, 2008)				
(+) Total But-For Net Sales	**[***]**	**[***]**	**[***]**	**[***]**

[410] LECG Report, para. 80.

[411] LECG Report, para. 72.

[412] LECG Report, para. 81.

DAMAGE FROM CROMPTON	**BASE CASE (US.$) (2001-2022) (canola & non-canola)**	**ALTERNATIVE SCENARIO #1 (U.S.$) (2001-2022) (canola only)**	**ALTERNATIVE SCENARIO #2 (U.S.$) (2001-2022) (canola only)**	**ALTERNATIVE SCENARIO #3 (U.S.$) (2002-2022) (canola only)**
(-) Total But-For Variable Costs	**[***]**	**[***]**	**[***]**	**[***]**
(-) Total But-For Income Tax	**[***]**	**[***]**	**[***]**	**[***]**
Total But-For Cash Flows	**[***]**	**[***]**	**[***]**	**[***]**
(-) Actual Cash Flows	**[***]**	**[***]**	**[***]**	**[***]**
Damage from Crompton	**[***]**	**[***]**	**[***]**	**[***]**
DAMAGE FROM GUSTAFSON				
(-) Total Gustafson But-For Net Sales	**[***]**	**[***]**	**[***]**	**[***]**
(-) Total Gustafson But-For Variable Costs	**[***]**	**[***]**	**[***]**	**[***]**
(-) Total Gustafson But-For Income Tax	**[***]**	**[***]**	**[***]**	**[***]**
Total Gustafson But-For Cash Flows	**[***]**	**[***]**	**[***]**	**[***]**
(-) Actual Gustafson Cash Flows	**[***]**	**[***]**	**[***]**	**[***]**
Damages to Gustafson	**[***]**	**[***]**	**[***]**	**[***]**
Crompton's Shares in		**[***]**	**[***]**	**[***]**

DAMAGE FROM CROMPTON	BASE CASE (US.$) (2001-2022) (canola & non-canola)	ALTERNATIVE SCENARIO #1 (U.S.$) (2001-2022) (canola only)	ALTERNATIVE SCENARIO #2 (U.S.$) (2001-2022) (canola only)	ALTERNATIVE SCENARIO #3 (U.S.$) (2002-2022) (canola only)
Gustafson	[***]			
Damage to Crompton from Gustafson	[***]	[***]	[***]	[***]
Damage to Crompton and Gustafson from non-canola	[***]	[***]	[***]	[***]
Total Damage to Chemtura as of June 30, 2008	**80.2**	**78-83**	**74-87.8**	**76.9-83.5**

3. Additional Damages to Crompton Canada by virtue of Canada's NAFTA Breaches

567. The PMRA's actions also caused Crompton Canada to commence several proceedings before the Federal Court of Canada in order to protect its lindane business and to attempt to remediate the actions taken by the PMRA. Further, Crompton Canada was forced to spend a considerable amount in the Lindane Review Board process, which resulted in a finding by the Review Board that the PMRA had acted improperly.

568. All of these costs are directly attributable to the conduct of the PMRA described herein, which conduct resulted in Canada being in breach of its NAFTA Chapter 11 obligations, and have not been reimbursed to the Investor in any other proceedings.

569. The total cost of these proceedings was approximately US[***].

D. Interest

570. Article 1135(1) of the NAFTA provides that the tribunal may, as part of a final order, award interest. Furthermore, Article 1110(4) establishes, with regard to compensation for

an expropriation, that interest is to be paid at a commercially reasonable rate from the date of the expropriation to the date of payment.

571. NAFTA Article 1110 provides that compensation shall be equivalent to the fair market value of the investment "immediately before the expropriation took place". Similarly, international law generally requires that compensation "wipe out" the consequences of an unlawful expropriation, as though the expropriation had not occurred.

572. Accordingly, the Investor is entitled to pre-award compound[413] interest on the amount awarded from the date of expropriation[414] at a rate deemed appropriate by the Tribunal following a full hearing of the case.

E. Costs

573. Article 1135(1) of the NAFTA provides that a tribunal may "award costs in accordance with the applicable arbitration rules". Article 40 of the UNCITRAL Rules, which govern this proceeding, permits this Tribunal to award costs of the parties, including legal fees, where it is reasonable to do so.

PART FOUR - RELIEF SOUGHT

574. The Investor claims:

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[413] The granting of compound interest is widely recognized in NAFTA and ICSID case law as the standard in expropriation cases. As noted by the tribunal in *Middle East Cement Shipping & Handling Co. S.A. v. Arab Republic of Egypt* ICSID Case No. ARB/99/6, April 12, 2002 at para. 174: "[C]ompound (as opposed to simple) interest is at present deemed appropriate as the standard of international law in […] expropriation cases." See also *BG v Argentina*, UNCITRAL, Award, December 24, 2007, at para. 455, n. 362; John Gotanda, "Compound interest in international disputes," (Wtr 2003) 34:2 *L.& Policy in Int'l Bus*. 393.

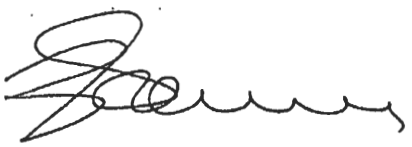
[414] See Max Sorenson, *Manual of Public International Law* (New York: St. Martin's Press, 1968) at 570 (stating that that interest "must be regarded as a proper element of compensation since full indemnity includes the loss of the use of that sum during the period in which it was denied."); See also *Metalclad v. Mexico*, ICSID Case No. ARB(AF)/97/1, Award, August 30, 2000, para. 128; *Asian Agricultural Products v Sri Lanka*, ICSID Case No. ARB/87/3, Award, June 27, 1999 at para. 114; See also *Starrett Housing v Iran*, 16 Iran-U.S. C.T.R. 112 (August 14, 1987) at para. 367; *Tippetts, Abbott, McCarthy, Stratton v. Iran*, 6 Iran-U.S. C.T.R. 219 (June 29, 1984) at p. 17; *INA Corp. v Iran*, 8 Iran-U.S. C.T.R. 373 (August 13, 1985) at p. 16.

(a) Damages for breach of Articles 1105, 1103 and/or 1110 in the amount of U.S.$83,139,672;

(b) Its costs of this arbitration including, without limitation, expert and attorney fees and disbursements plus any Canadian Goods and Services Tax payable thereon; and

(c) Interest on the sums claimed in subparagraphs (a) and (b) until paid.

DATED at Ottawa, Ontario (Canada) this 2nd day of June 2008.



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Counsel for the Investor, Chemtura Corporation (Formerly Crompton Corp.)

ANNEX A

Terms

Term	Description
Act	***Pest Control Products Act*. The Act was repealed and replaced by new legislation which came into force in 2006. However, the events that gave rise to this claim occurred prior to the entry into force of the new Act, and therefore references to the Act are to the Act as it existed in the period under scrutiny.**
Active Ingredient	**This is the chemical compound responsible for the biological control (e.g. insecticide) and is generally provided in a purified form and referred to as Technical Grade. The technical material is not used as such for seed treatment but rather is formulated into commercial products for application in the field.**
Assessment	**See Occupational Exposure Assessment.**
Canadian Canola Growers Association (CCGA)	**A national organization representing the interests of provincial grower associations on national and international issues that affect canola growers.**
Canadian Seed Trade Association (CSTA)	**A national association of seed companies involved in the production and marketing of seeds. These companies include commercial seed treatment companies that would treat canola seed, and would have treated canola seed with Crompton Canada's Lindane Products during the relevant period.**
Canola Council of Canada	**A non-profit association representing stakeholders in the canola sector, including canola growers, crop input suppliers, grain handling companies, exporters, processors, food and feed manufacturers, and governments.**
Canola/Rapeseed	**The difference between canola and rapeseed is that canola is rapeseed modified by the reduction of erucic acid and glucosinolates,**

Term	Description
	which allows the oil produced from canola to be consumed by humans.
Carbathiin/Carboxin	This is a fungicide used on, among other crops, canola. This active ingredient is known as carbathiin in Canada and carboxin in the United States.
CIEL	Centre Internationale d'Études du Lindane, a research-based task force studying lindane.
Cole crops	A general term used to describe several cool weather vegetables in the mustard family, including broccoli, Brussels sprouts, cabbage, cauliflower, and kale, among others.
Conditional Withdrawal Agreement	Agreement between Crompton Canada and the PMRA, finalized on October 28, 1999, by which Crompton Canada agreed to withdraw the registration of its lindane products for use on canola/rapeseed, subject to several conditions.
Crompton Canada	Crompton Co./Cie.; Canadian company which at all relevant times manufactured and sold lindane-based crop protection products (among other products); 100%-owned subsidiary of Crompton. Crompton Canada is now Chemtura Canada Co./Cie.
Crompton	Crompton Corporation, the U.S. Claimant/Claimant, the parent of Crompton Canada; Crompton is now Chemtura Corporation.
Franklin, Dr. Claire	Executive Director of the PMRA at the relevant time.
EPA	U.S. Environmental Protection Agency, responsible for the registration of pest control products in the United States
Gaucho	"Gaucho" is the trade name of a family of products containing the insecticide imidacloprid (and in some cases containing

Term	Description
	other active ingredients). Gaucho was registered by the U.S. EPA for use on canola on November 18, 1994. This registration was held by Gustafson, Incorporated, which until November 1998 was a wholly-owned U.S. subsidiary of Crompton. In the mid to late 1990s, Gaucho was the only significant seed treatment flea beetle control product registered in the U.S. In some correspondence "Gaucho" is used as a short-hand to refer to the active ingredient imidacloprid.
Gaucho CS FL	An all-in-one fungicide-insecticide, containing the active ingredients imidacloprid, thiram and carbathiin. This product was formulated to replace Crompton's Lindane Products. It was ultimately registered by the PMRA on July 17, 2002. This registration was held by Gustafson Partnership, a Canadian partnership which was, from November 1998 until March 2004, 50% owned by Crompton Canada. Note that in some correspondence, the term "Gaucho CS" is used; in these instances, this was a short-hand reference to Gaucho CS FL. In other instances, this product was also referred to as "Gaucho CS Flowable".
Gaucho 75W ST	A powder-form insecticide consisting of 75% imidacloprid. This was a Gustafson product first registered for export use on canola by the PMRA in 1996 and for domestic use in October 1999.
Gaucho 480	A liquid form insecticide, consisting of 480g/L imidacloprid. This was a Gustafson product, first registered for use on canola by the PMRA in October 1999.
Gustafson Partnership	A Canadian seed treatment sales/distribution company which sold, among other products, Crompton's Lindane Products. From November 1998 to March 31, 2004, Gustafson

Term	Description
	Partnership was 50% owned by Crompton Canada. As of March 31, 2004, Crompton Canada sold its 50% interest to Bayer Canada. Prior to November 1998, the business and assets of Gustafson Partnership were wholly owned by Crompton Canada.
Ingulli, Alfred	Executive Vice-President, Crop Protection Division of Crompton at the relevant times.
Inquinosa Internacional, S.A	Manufacturer of lindane technical.
Interprovincial Cooperative Limited (IPCO)	One of four Canadian registrants of lindane-containing products for use on canola at the time of the Conditional Withdrawal Agreement. This company's product was comprised of benomyl, thiram and lindane, and registered in Canada under the name Benolin-R.
Kibbee, John	Regional Technical Manager for Seed Treatments of Crompton Canada; formerly with Gustafson Partnership.
Lindane	Lindane is an insecticide used to control, primarily, flea beetle and wireworm. It is a 99.5% pure gamma isomer of hexachlorocyclohexane.
Lindane Products	Eight lindane-based crop protection products produced and sold by Crompton Canada.
Lindane Review Board	See Review Board.
MOE- Margin of Exposure	The mathematical expression that describes the relationship between the No Observed Adverse Effect Level from the most sensitive and appropriate toxicology study and the human occupational exposure level expected during use of the product.
Novartis Crop Protection Inc.	Manufacturer and distributor of crop protection products. Novartis submitted the application for registration of Helix with the

Term	Description
	PMRA. On November 13, 2000, Novartis and AstraZeneca merged under the new name Syngenta.
Occupational Exposure Assessment	**The Assessment was the outcome of the PMRA's Special Review. The process leading to the Occupational Exposure Assessment, and the methodology and conclusions therein, were found to be flawed by the Lindane Review Board.**
Pettigrew, Ross	**Enforcement/Compliance Officer with the PMRA at the relevant times.**
PMRA	**Pest Management Regulatory Agency, an agency within the jurisdiction of Health Canada responsible for the regulation of pest control products in Canada.**
RED	**Reregistration Eligibility Decision. The EPA commenced a process to re-assess the safety of pest control products registered prior to 1984. At the conclusion of this re-assessment, the EPA issues an RED.**
Review Board	**The Lindane Board of Review, established by the Minister of Health pursuant to the *Pest Control Products Act* on October 22, 2003, to review the PMRA's decisions of February 11, 2002 and February 21, 2002 to deregister Crompton's Lindane Products.**
Rhône-Poulenc Canada	**Canadian subsidiary of Rhône-Poulenc. One of four Canadian registrants of lindane-containing products for use on canola at the time of the Conditional Withdrawal Agreement. Its lindane formulation was made from iprodiane and lindane, and registered in Canada under the names Rovral ST, Rovral CST, Foundation and Foundation CST. In December 1999, Aventis CropScience was formed by the merger of Hoechst AG and Rhône-Poulenc. Aventis CropScience later merged with Bayer to form Bayer**

Term	Description
	CropScience.
Seed treatment products	The end-use products (powders or liquids) sold in the marketplace are mixtures of several components including the active ingredients at a defined concentration. Such products are designed and manufactured with specific physical properties that facilitate their application to seed in the field.
Sexsmith, Wendy	Chief Registrar of the PMRA as of February 16, 2000; prior to that date, Director of the Alternative Strategies and Regulatory Affairs Division of the PMRA; in both capacities, Ms. Sexsmith represented the Executive Director of the PMRA at meetings and drafted most if not all the letters sent by the Executive Director in that matter.
Special Review	On March 15, 1999, the PMRA commenced a scientific assessment of lindane, which was to have been completed by the end of 2000 and which the PMRA was to have been coordinating with the EPA. The PMRA ultimately released the results of this assessment in October 2001.
Syngenta Crop Protection	Manufacturer and distributor of crop protection products, formed by the merger of Novartis and AstraZeneca on November 13, 2000. Syngenta holds the Canadian registrations for Helix and Helix XTra.
Technology Sciences Group Inc. ("TSG")	TSG is a consulting firm which provides a wide range of scientific expertise including toxicology, ecotoxicology, environmental fate, efficacy, chemistry, and exposure and risk assessment, and was retained to assist Crompton with its dealings with the EPA and the PMRA.
Thomson, Paul	Director, New Business Development and Technology of Crompton; formerly with Crompton Canada.

Term	Description
Trace Chemicals	**A business unit of Bayer, acquired by Crompton in March 2006. Trace formulated and sold a variety of seed treatment products, including certain products which met the same market need as certain of Crompton's lindane-containing products.**
Treated seed	**Seed treatment products are applied directly to seed either by the farmer (referred to as on-farm application) or by seed companies or distributors (referred to as commercial application). On-farm applications are generally performed just prior to planting whereas commercial applications are made prior to the planting season allowing seed companies and distributors to sell treated seed in the marketplace.**
Uniroyal Chemical Co./Cie	**Prior to January 24, 2001, the name of Crompton Canada was Uniroyal Chemical Co./Cie.**
Vitavax rs Fungicide	**This was the version of Crompton Canada's Vitavax rs Flowable with the lindane removed. This product contained the two fungicides thiram and carbathiin, and contained no insecticide. This product was created by Crompton Canada in response to the Conditional Withdrawal Agreement in order to provide Canadian growers with a fungicide product for canola. This was registered by the PMRA on May 3, 1999, and the registration was held by Crompton Canada.**
Vitavax rs Flowable	**Crompton's most commercially important lindane-containing product sold in Canada.**
Zeneca Agro.	**Canadian subsidiary of Zeneca. Manufacturer and distributor of crop protection products. One of four Canadian registrants of lindane-containing products for use on canola at the time of the Conditional Withdrawal Agreement. Its products were made from thiabendazole, thiram and lindane, and were**

Term	Description
	registered under the names Premiere Plus Flowable, Premier Flowable, and Premier No-Dye Flowable. Following a merger in 1999, Zeneca became AstraZeneca and then on November 13, 2000, AstraZeneca merged with Novartis to become Syngenta.

ANNEX B

Timeline of Key events

Date	Event
1938	Lindane is registered as a broad-spectrum insecticide in Canada.
1979	Crompton Canada sells its first lindane product in Canada
March 1998	EPA advises that importation of canola seed treated with lindane is prohibited.
1998	The United States Government complains about imports of lindane-treated canola seed for planting from Canada. This was in response to trade complaints from U.S. States (primarily North Dakota) that growers were at a competitive disadvantage compared to Canadian growers who had access to cheaper and more effective seed treatments containing lindane.
November 18, 1998	Novartis (which later became Syngenta) submits application for registration of Helix/Helix XTra.
November 26, 1998	PMRA and Canadian Canola Growers Association ("CCGA") reach an agreement on the terms of a "voluntary" withdrawal of canola/rapeseed claims from lindane labels by December 31, 1999 and for discontinuance of lindane use on canola/rapeseed after July 1, 2001.
December 2, 1998	United States and Canada enter into a Record of Understanding (ROU) regarding "areas of agricultural trade", which includes the discontinuance of lindane for use on canola/rapeseed in Canada.
December 17, 1998	Crompton Canada writes to the PMRA to indicate that it would be prepared to agree to a withdrawal, but only subject to certain conditions, and not in accordance with the terms "agreed to" between the PMRA and the CCGA.
March 15, 1999	PMRA announces a Special Review of pesticide control products containing lindane, focusing on environmental issues.

Date	Event
October 28, 1999	Crompton Canada and the PMRA enter into a conditional withdrawal agreement (Conditional Withdrawal Agreement).
December 31, 1999	Crompton Canada ceases manufacture of lindane products for canola use in Canada and canola use is removed from its labels.
March 2000	Gustafson submits application for registration of Gaucho CS FL to PMRA.
November 2000	PMRA begins commenting publicly that lindane-treated seed may not be sold or planted after the July, 1, 2001 deadline and threatens purchasers, including farmers, with substantial fines.
Spring 2001	Seed treaters and canola growers begin reacting to uncertainty in the market about the stop-use deadline and Crompton Canada's sales of lindane products decline.
April 4, 2001	Crompton Canada commences an application to the Federal Court of Canada (T-585-01) in respect of the Minister of Health's acts and refusals to act in respect of the conditions of the Conditional Withdrawal Agreement in respect of voluntary discontinuance of the sale of lindane for use on canola/rapeseed.
May 8, 2001	Crompton Canada files request for reinstatement of the registrations for each of its Lindane Products for use on canola, based on the PMRA's breaches of the Conditional Withdrawal Agreement.
May 29, 2001	PMRA denies Crompton Canada's reinstatement applications.
June 21, 2001	Crompton Canada commences an application to the Federal Court of Canada (T-1091-01) in respect of the Minister of Health's decision dated May 29, 2001 denying the request by Applicant, Crompton Co./Cie to reinstate canola/rapeseed uses on certain pest control product registrations.
July 1, 2001	Deadline for all registrants to cease selling lindane products for use on canola.

Date	Event
October 30, 2001	PMRA completes its Special Review, nearly one year later than it agreed to in the Conditional Withdrawal Agreement.
November 5, 2001	PMRA provides to registrants of end-use products the results of its findings from the Special Review process.
December 3, 2001	After certain minimal extensions of time, this was the deadline for registrants to provide comments and data in response to the November 5, 2001 Special Review findings. Registrants are also required to provide detailed information regarding liquidation of lindane products.
December 19, 2001	PMRA advises Crompton Canada that the registrations for its lindane products for all uses will be terminated.
February 11, 2002	PMRA terminates the registrations of five of Crompton Canada's lindane products for all uses; PMRA also (again) refuses Crompton Canada's request to amend its registrations to re-instate canola use.
February 18, 2002	Crompton Canada writes to Minister of Health requesting the establishment of a Review Board to review the PMRA's decision to refuse to amend the registrations and of the decision to terminate registrations of its lindane products.
February 21, 2002	PMRA terminates the registrations of Crompton Canada's three remaining lindane products for all uses.
March 14, 2002	Crompton Canada again requests the establishment of a Review Board.
March 14, 2002	Crompton Canada commences an application to the Federal Court of Canada (T-466-02) in respect of the decision dated February 11, 2002 by the PMRA to suspend Crompton Canada's registrations of non-canola use seed treatment products.
March 14, 2002	Crompton Canada commences an application to the Federal Court of Canada (T-477-02) in respect of the decision dated February 11, 2002 by the PMRA refusing to amend Crompton Canada's registrations to re-instate canola use for its seed treatment products.
March 27, 2002	Crompton Canada commences an application to the Federal Court of Canada (T-532-02) in respect of a decision by the

Date	Event
	PMRA, to suspend Crompton Canada's registrations for cereal crop use.
April 5, 2002	PMRA issues a Re-evaluation Note confirming that only Crompton Canada's products are subject to immediate suspension, as other companies accepted the PMRA's proposed "voluntary" discontinuance program.
June 12, 2002	Crompton Canada commences an application to the Federal Court of Canada (T-899-02) in respect of the Minister of Health improperly delegating responsibility for the statutory review of Crompton's three requests for review under section 23 of the *Pest Control Products Regulations* to the PMRA, and requesting that the Minister of Health appoint an impartial review board as required by section 23 of the Regulations.
July 31, 2002	EPA issues its Reregistration Eligibility Decision (RED) for lindane, which found no unacceptable safety concerns and permitted the current registered uses to be maintained.
September 8, 2003	PMRA refuses to renew the registration of Lindane Technical.
September 29, 2003	Crompton Canada for a fourth time requests a Review Board
October 16, 2003	Crompton Canada commences an application to the Federal Court of Canada (T-1914-03) in respect of a decision by the PMRA to refuse to renew the registration for Lindane Technical.
October 22, 2003	Letter from Minister of Health to Crompton Canada advising that the Lindane Board of Review has been established.
May 2004	The Lindane Board of Review commences its work, more than 2 years after the date of Crompton Canada's first request.
August 17, 2005	The Lindane Board of Review publishes its Report, finding serious deficiencies in the PMRA's decisions and processes leading to the termination of Crompton Canada's Lindane business in Canada.

Date	Event
July 2006	Following the agreement of the registrants to "voluntarily" cancel the remaining registrations for lindane, the EPA issues its Addendum to the 2002 RED, indicating that the remaining registrations for lindane will be cancelled.
April 30, 2008	PMRA sends its draft Re-evaluation on lindane to Crompton Canada

ANNEX C

LINDANE REVIEW BOARD

KEY FINDINGS REGARDING PROCEDURAL FAIRNESS

103. While it is appropriate for PMRA officials to manage the Special Review process in a way that allows it to come to an informed and expeditious conclusion, and in accordance with the requirements of the Regulations in the opinion of the Board, registrants should be permitted the opportunity to make representations to those officials before a decision is issued that adversely affects their products, particularly where the decision is, as it was in this case, as dramatic as a cancellation of registrations.

106. Although the PMRA maintains that Crompton was given an adequate opportunity to provide input regarding the conclusions reached in the Special Review regarding the registration of Lindane products, the Board is of the view that to give life to s. 19 of the *Regulations* in a manner consistent with the principles articulated in *Baker*, a meaningful opportunity for input should have been given to Crompton, particularly when PMRA officials began forming the view that the registrations should be cancelled and after the risk assessment was completed but before the Minister's decisions were finalized.

107. The Board does not intend to prescribe the manner and degree to which PMRA should engage registrants in the Special Review process as that will depend on the circumstances and needs of each particular case. However, where cancellation of registrations for a product such as Lindane, which has had a long-standing approval for use in Canada is being considered, affected parties should be alerted to the conclusions being formulated and be provided with a meaningful opportunity to comment on those concerns.

108. With the foregoing in mind, the Board notes that it was not PMRA, but rather [Centre Internationale d'Études du Lindane] CIEL that brought the issue of occupational risk to the parties' attention. Moreover, the Board does not believe that occupational risk was discussed to any significant extent, and further, was not presented as a fundamental aspect of PMRA's Special Review until the risk assessment was completed in October 2001.

112. Nevertheless, the Board is of the view that once PMRA knew its focus in the Special Review was going to be on occupational risk, it should have advised Crompton, knowing that the Special Review announcement made no mention of occupational risk, and

knowing that all communications it had with Crompton were primarily in respect of environmental concerns.

113. Although the process may be different in respect of new evaluations as compared to re-evaluations (including Special Reviews), the Board feels that PMRA does have an obligation to advise the registrant of the focus of its inquiry and review. Proceeding in this manner could have led to a more robust scientific inquiry and assessment.

119. On the other hand, the Board can see how Crompton may have been taken aback by PMRA's decision and left with wholly insufficient time to prepare an adequate response for the reasons indicated above as well as the limited detail and documentation provided by PMRA for its calculations. In this regard, the Board is mindful of the fact that it took PMRA nearly three years to conduct the Lindane Special Review, but provided just a few weeks for Crompton to respond.

120. The Board finds that the comment period afforded to Crompton once PMRA completed its risk assessment was inadequate. The revocation of a registration is the most severe and restrictive measure a regulator can take, and, in the Board's experience, it is left for the most harmful of products, at least to the extent that PMRA deregisters a product without giving the registrant a reasonable amount of time to address mitigation. In his evidence, John Worgan of PMRA himself admitted that it was unusual for PMRA to come to a decision so quickly and without adjusting its findings at all after comment from registrants.

121. In the Board's view, there seemed to be considerable haste on the part of PMRA after the risk assessment was released in October 2001 to bring the matter to a close. This haste was particularly perplexing given that Lindane had been in use for over 40 years. To the extent that mitigation could be adequately addressed, the Board believes that Crompton ought to have been provided more time to address concerns arising out of the risk assessment.

122. The Board appreciates that at least some of the concerns raised by PMRA in its review, most notably issues related to sensitivity of the young, might give rise to concerns of an imminent nature. Notwithstanding that, the Board is of the view that given the timing of the announcement of the outcome of the Special Review by PMRA, and the limited use season for Lindane, other options for effective control could have been invoked in the short term. This, in the Board's opinion was a major flaw in the process, leading to an unsatisfactory result. Addressing mitigation, in the Board's opinion, is fundamental in conducting a

robust scientific inquiry leading to a regulatory decision. It is clear to the Board that this did not occur in the case of Lindane.

126. In the Board's opinion, PMRA was or should have been aware of the current status of industry practices. The Board is surprised that PMRA did not discuss current practices or the existence of outdated label language in the re-evaluation.

127. To that end, the Board concludes that the risk mitigation stage that should have followed PMRA's risk assessment was not adequate and that PMRA did not consider, nor did it give an adequate opportunity to interested parties to propose, risk mitigation opportunities that were not only available at the time, but were, in some cases, already operational.

128. The Board has noted elsewhere in this report that the decision-making process followed by PMRA should have included two sequential and interrelated steps; the risk assessment of existing approved uses and the risk mitigation process intended to identify opportunities for risk reduction. The Board considers this latter phase – the risk mitigation process – to be critical in the overall regulatory process. Taking into account all of the foregoing, the Board finds that the first stage – the risk assessment process – carried out by PMRA was adequate (notwithstanding certain limitations, previously addressed in this Report) and consistent with existing regulations as they applied to Lindane registrations of the time. However, the second stage – the overall decision of the Minister to, effectively, cancel all Lindane registrations – was made without adequate consideration of risk mitigation opportunities and resulted in an outcome that the Board does not consider to have been fair to all potentially affected parties.

ANNEX D

LINDANE REVIEW BOARD

KEY FINDINGS REGARDING SCIENTIFIC ISSUES

162. In the end, the Board concludes that the two competing hypotheses, which have been invoked by PMRA and Crompton to explain the apparent increased toxicity in the young, cannot be definitively resolved on the basis of the available knowledge. While the evidence of sensitivity of the young cannot be clearly refuted, the evidence in support of it is minimal. The Board therefore recommends that PMRA consider the use of an adjustment factor other than the maximum default.

163. The Board further concludes that it is PMRA's responsibility to invoke uncertainty factors in accordance with well-established practice both in Canada and internationally, in order to take appropriate account of uncertainty in knowledge as well as severity of endpoint.

164. Having said this, the Board notes that clear no effect levels were derived for critical outcomes, and that the traditional paradigm for uncertainty (10x10) already takes into account both inter- and intra-animal variability, and that additional uncertainty factors are generally reserved for endpoints that are not adequately addressed, either in terms of severity, or nature of the endpoint, by the traditional default paradigm described above.

170. The Board also notes that concern related to immunotoxicity endpoint was initially raised by an evaluator with PMRA who noted that the potential immunotoxicity endpoint was identified from studies published in the open scientific literature. In reviewing the concerns and observations of this evaluator, the Board notes that PMRA typically would not accept summary reports characteristic of the published literature in general, as evidence to dismiss a presumption of an effect and that only comprehensive study reports that include individual animal data would typically be considered acceptable for PMRA's purposes.

171. Moreover, the Board particularly notes that PMRA's review of the toxicological endpoint of concern was associated with handling of Lindane of either unknown or poor purity and that contaminants could be a major contributing factor in the underlying immunotoxicity. Interestingly, the PMRA reviewer primarily responsible for the evaluation of the immunotoxicity endpoint had observed that the issue of purity in and of itself was sufficient to render the results of the published reports to be of

dubious value. The Board appreciates that, despite the fact that neither JMPR or EPA considered Lindane to raise concerns of increased immunotoxic potential, PMRA came to a different conclusion. The Board discusses below, the weight that, in its view, ought to be given to this concern.

172. The Board is aware that regulatory agencies attempt to use all of the appropriate toxicology and exposure data available when conducting risk assessments. While they typically rely on results from standardized studies conducted under good-laboratory-practices, they must, at times, rely on information obtained from the open literature. The Board is of the opinion that when the validity of the studies it is relying on are in question, PMRA ought to clearly document its concerns in an appraisal of the assessment itself. In the case of Lindane, PMRA relied on non-standardized studies with unclear methods and procedures and still found evidence only consistent with, rather than actually documenting, endocrine effect.

179. In the context of PMRA's evidence regarding the process it invoked in the selection of the additional uncertainty factor utilized in the case of Lindane, the Board notes that PMRA re-affirmed its selection of an additional 10x uncertainty, over and above the standard default of 100x, to account for its interpretation of sensitivity in the young, immunotoxicity and endrocrine effects. However, PMRA also acknowledged in testimony at the hearing, that an additional uncertainty factor as low as 3x would be considered adequate by many toxicologists for the specific endpoints at issue and would not be inconsistent with internationally accepted evaluation criteria.

180. While the Board understands that PMRA's hazard and risk assessment that resulted in the cancellation did not include evaluation of carcinogenicity issues, the Board does consider it unfortunate that the re-evaluation of Lindane, a process that consumed almost two and half years, is not considered by PMRA to be complete and would need to be re-visited if registration of any kind were again to be considered.

185. The Board is concerned that PMRA was prepared to make a determination as to the appropriateness of aggregation of exposure, knowing the impact of this decision on the overall risk assessment, on the basis of a draft interim JMPR report, but was, seemingly, not motivated to verify whether this endpoint had survived the review and debate by the full JMPR committee.

186. Given the importance of the issue of aggregation to the overall risk assessment and because PMRA did not request or review the original dermal toxicity study in order to arrive at an independent conclusion rather than simply adopting, as their own,

the conclusions of the temporary advisor who prepared the initial draft review of the study on behalf of JMPR, the Board attaches less weight to that assessment.

187. The Board is especially concerned that while PMRA rejected inferences regarding the toxicological outcome of the dermal study presented to its witnesses by Crompton during the hearings because it had not had an opportunity to independently review the entire study, PMRA did not have any such reservation about adopting the conclusions of a JMPR temporary advisor in the context of an interim draft report which, in the end was not endorsed by the JMPR. In light of the foregoing, and the Board's assessment of the positions adopted by both JMPR and EPA on this issue, the Board finds that a conclusion of common toxicological endpoints and aggregated exposure for both inhalation and dermal exposure, as concluded by PMRA, is not sufficiently supported.

217. The Board has carefully considered the matter of increased toxicity in the young and the possible relationship of the observation of increased exposure and/or increased sensitivity. While, in the Board's opinion, the evidence for sensitivity of the young cannot be clearly refuted, the evidence is suggestive as opposed to conclusive. The Board recommends that this be taken into account when considering the need for an additional uncertainty factor.

219. While Crompton disputed these findings, PMRA considered Crompton's response to be inadequate to resolve its concerns. PMRA considered the additional studies insufficient in that they did not fully address the full suite of possible immunotoxicological outcomes. In its defence, Crompton points out that the full JMPR committee subsequently withdrew their immunotoxicity concern. Furthermore, Crompton argued that conclusions of immunotoxicity in the open scientific literature were based on studies of either poor or unknown Lindane quality, and further, that the purity (or lack thereof) of technical Lindane is a major determinant of its potential immunotoxicity. In the Board's opinion, the evidence for Lindane related immunotoxicity is not compelling. This should be taken into account when considering the need for additional uncertainty factors.

220. The Board is aware that regulatory agencies attempt to use all of the appropriate toxicology and exposure data available when conducting risk assessments. While they typically rely on results from standardized studies conducted under good-laboratory-practices, they must, at times, rely on information obtained from the open literature. The Board is of the opinion that when the validity of the studies it is relying on are in question, PMRA ought to clearly document its concerns in an appraisal of the assessment

itself. In the case of Lindane, PMRA relied on non-standardized studies with unclear methods and procedures and still found evidence only consistent with, rather the documenting, endocrine effect. The Board is of the view that using a maximum adjustment factor, despite the lack of severity or validity, is excessive.

222. The Board is of the view that the additional 10x uncertainty factor is not justified. It therefore recommends that PMRA consider an adjustment factor other than the additional 10x maximum default. In this regard, the Board notes that clear no effect levels were derived for critical outcomes, and that the traditional paradigm for uncertainty (10x10) already takes into account both inter- and intra-species variability, and that additional uncertainty factors are generally reserved for endpoints that are not adequately addressed, either in terms of severity or nature of the endpoint, by the traditional default paradigm described above.

223. After considering the evidence and arguments submitted regarding toxicological endpoints and aggregation of dermal and inhalation exposure, the Board finds that a conclusion of common toxicological endpoints and aggregated exposure for both inhalation and dermal exposure, as concluded by PMRA, is not sufficiently supported by the evidence and available data.

ANNEX E

PROCEDURAL HISTORY OF THE DISPUTE

1. On November 6, 2001, Crompton Corp., the Investor in this Claim, served upon the Government of Canada ("Canada") a Notice of Intent to Submit a Claim to Arbitration ("Notice of Intent"), in accordance with Article 1119 of the North American Free Trade Agreement ("NAFTA"). This Notice advised Canada of Crompton's intention to submit claims to arbitration under Articles 1102, 1105, 1106 and 1110 of NAFTA.

2. On April 4, 2002, a second Notice of Intent was served upon Canada advising it of the Investor's intention to submit additional claims to arbitration under Articles 1103 and 1104 of NAFTA.

3. On September 19, 2002, a third Notice of Intent was served upon Canada advising it of the Investor's intention to submit further and additional claims to arbitration under Article 1116 and/or Article 1117 of NAFTA.

4. All three Notices of Intent were served at least 90 days prior to the submission of the Claim in compliance with NAFTA Article 1119.

5. In respect of the first two Notices of Intent, on October 17, 2002, the Investor submitted its Notice of Arbitration, consistent with Article 3 of the United Nations Commission on International Trade Law ("UNCITRAL") Arbitration Rules, initiating recourse to arbitration under the UNCITRAL Arbitration Rules.

6. Crompton submitted a second Notice of Arbitration on February 10, 2005, relating to its third Notice of Intent, advising Canada that it would be seeking that the two arbitrations be consolidated.

7. Consistent with NAFTA Articles 1116(2) and 1117(2), and within the meaning of timely submission to arbitration in Article 1137, this matter was submitted to arbitration within three (3) years from the date on which Crompton first acquired, or should have first acquired, knowledge of the breach and knowledge that Crompton

had incurred loss or damage, and within three (3) years from the date on which the enterprise first acquired, or should have first acquired, knowledge of the breach and knowledge that the enterprise has incurred loss or damage. More than six (6) months had elapsed since the events giving rise to this matter, in accordance with NAFTA Article 1120.

8. Crompton and Canada have attempted to settle the claim through consultation and negotiation in accordance with NAFTA Article 1118. Consultations were held between the parties on March 20, 2002 and again on June 7, 2005 in Ottawa.

9. With the submission of this Claim to arbitration on October 17, 2002, and on February 9, 2005, Crompton and Crompton Canada also filed their waivers, and Crompton has filed its consent, as required by Article 1121(1).